The Mission of AOMA is to transform lives and communities through education, patient care, leadership and research in Oriental and other integrative medicines.
5 THE HIPAA PRIVACY RULE ................................................................. 46

5.1 What Is the HIPAA Privacy Rule? .................................................. 46
5.2 How Does HIPAA Affect the Use of Health Information for Research? .................................................. 46
5.3 Is an Authorization Required to Obtain PHI for Research? ...................... 47
5.4 How Will the HIPAA Privacy Rule be Implemented at AOMA? ................. 48
5.5 What Do I Do Once I Obtain a Patient’s Informed Consent or an IRB Waiver of Authorization? 49
5.6 HIPAA Authorization Inquiries .......................................................... 49

6 INTRODUCTION TO INFORMED CONSENT ........................................... 50

6.1 Principle of Informed Consent ......................................................... 50
6.2 Minimal Risk ................................................................................. 51
6.3 Exempt Research ......................................................................... 51
6.4 The Informed Consent Process ....................................................... 52
6.5 Documentation of Informed Consent ............................................. 52
6.6 General Requirements on Informed Consent Form ................................ 53
6.7 Elements of Informed Consent ....................................................... 55
6.8 Storage of Informed Consent Forms ................................................. 66
6.9 Alterations and Waiver of Informed Consent ..................................... 66
6.10 Consent/Assent Procedures for Research Subjects Who Are Children ...... 67
6.11 Research Subject Information and Consent Form (Template) ................. 70

7 APPENDICES ....................................................................................... 77

7.1 Recommended Terms for Use in Consent Forms .................................. 77

8 FORMS .............................................................................................. 83

8.1 HIPAA Authorization Form ............................................................ 83
8.2 IRB Research Application Submission Form ....................................... 83
8.3 Waiver of Authorization or Altered Authorization ................................ 90
8.4 Exemption Determination Application ............................................. 105
8.5 Notification of Research Project Termination ..................................... 110
8.6 Request for Amendment or Withdrawal of Proposal .............................. 121
1.1 Institutional Review Board

**Scope:** Faculty, Staff, Research Participants

**Policy:** Any research to be conducted involving human subjects, whether for pilot study, educational, institutional or formal research purposes, will only be undertaken after such research has been reviewed and approved or exempted by the Institutional Review Board.

**Reference:** Institutional Review

**Revised:** October 2007

1.2 Investigator-initiated Research at AOMA

Investigator-initiated research involving the basic sciences or human subjects is a valuable component to the academic and research initiatives of AOMA Graduate School of Integrative Medicine (AOMA). This research is unique in that the faculty researcher may serve not only as the principal investigator but also the sponsor, and the faculty researcher may include students as co-investigators. Thus, the faculty researcher can expect a higher level of preparation, consideration, and responsibilities. In addition, AOMA must also assume a higher level of responsibility and risk as the institution housing such research. Researchers should also expect to meet additional institutional requirements based on the nature of the research.

1.3 Institutional Research

**Scope:** Faculty, Staff, Students, Research Participants

**Policy:**

AOMA sets standards for the conduct of research, which mandate well-conceived and well-conducted research. The Policy for Institutional Research provides detailed information to support institutional initiatives for guaranteeing compliance with federal regulations governing the conduct of research and the protection of human subjects in research.

**Scientific Review Committee**

Any research to be conducted whether for pilot study, educational, institutional or formal research purposes, will only be undertaken after such research has been reviewed and approved by the Scientific Review Committee (SRC).

The SRC assists and guides investigators through a review process in advance of, and in support of Institutional Review Board (IRB) application. The SRC is a subcommittee of the Faculty Senate and consists of AOMA faculty members from various academic departments (i.e., Biomedicine, Acupuncture, and Herbal Medicine). SRC review is a requirement of the Department of Health and Human Services (DHHS) for all clinical interventional and non-interventional studies. The primary focus of scientific review is on the scientific merit, feasibility, and utilization of AOMA resources.

All investigator-initiated protocols must be submitted to the SRC. Research protocols will be pre-reviewed prior to full scientific review by the SRC; the purpose of the pre-review is to ensure that protocols contain all the required elements and they are organized in a consistent
manner in the appropriate format, following the follow the Research Protocol Guidelines. The purpose of the SRC full review is to provide peer review of research studies and provide researchers an early assessment of their research to identify additional regulatory and institutional requirements and allow researchers to plan for these additional requirements and reduce the delays in initiating such research. The SRC will forward research protocols that involve human subjects or human subject data to the IRB, for IRB review.

Institutional Review Board

Any research to be conducted involving human subjects, whether for pilot study, educational, institutional or formal research purposes, will be undertaken only after such research has been reviewed and approved or exempted by the Institutional Review Board (IRB). The researcher must follow the IRB procedures in submitting the required documentation to the IRB for review. The IRB will conduct continuing review of research being undertaken with human subjects, by faculty, staff, and students, at intervals appropriate to the degree of risk, but not less than once per year for the life of the project.

The IRB is responsible for determining and assuring under the auspices of faculty, staff, and students that the welfare and rights of human subjects are adequately protected and informed consent given, if necessary; human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research; the necessity and importance of the research outweighs the risks to the subjects; and the researcher(s) is/are qualified to conduct research involving human subjects. IRB review is a requirement of the Department of Health and Human Services (DHHS) for all clinical interventional and non-interventional studies.

Humans, whose physiologic or behavioral characteristics, or whose understanding of their lived experiences, and responses, are the object of study are referred to as subjects; however, this policy in no way intends to demean the humanity and individualism of such persons. Recognizing that regulations and policies and procedures are no guarantee of ethical conduct, it is the responsibility of individual researchers to make ethical considerations central in the conduct of research and to have a clear understanding of their duties to human subjects.

SRC and IRB Review Process

• All investigator-initiated studies must comply with AOMA’s Research Protocol Guidelines prior to either SRC or IRB submissions.
  o All research is required to undergo SRC review.
  o All human subjects’ research is required to undergo SRC and IRB review.
• The completed Research Protocol should be submitted to the SRC for pre-review, to determine if the protocol is complete and follows the Research Protocol Guidelines.
• If needed, the SRC pre-review will provide comments and recommendations to the researcher. Once the SRC pre-review comments and recommendation are met, the protocol may be submitted to the SRC for full review.
Towards the IRB via the Scientific Review Committee (SRC)

- The protocol will be circulated to SRC members for their review. A summary of comments and recommendations will be provided back to the researcher, which must be addressed before obtaining SRC approval.
- Once SRC approval is obtained, an IRB application may be submitted to the AOMA IRB. As soon as the IRB application is submitted, the researcher may begin the registration of their research study on ClinicalTrials.Gov.
- The IRB will review the IRB Application, Informed Consent Document, and Research Protocol. The IRB will make comments and recommendations to the researcher.
- Once the researcher addresses the IRB’s comments and recommendations, the IRB will make a decision: 1) Approve; 2) Pending; 3) Disapprove; 4) Conditional Approval. Upon IRB Approval, an IRB Number will be assigned to the project. The investigator will be informed that their study is approved and will be provided a version of their IRB Materials designating said approval, including: 1) IRB Stamp; 2) IRB Number; 3) IRB Signature; 4) Date of Approval, and 5) Date of Expiration.

Reference: Institutional Review
Revised: October 2007, revised April 2

1.4 Introduction to Institutional Review Board (IRB)

AOMA sets standards for the conduct of research which mandate well-conceived and well-conducted research. To assist in maintaining those standards, an Institutional Review Board (IRB) has been established, and this Policy and Procedure Manual for Research with Human Subjects has been prepared for distribution to the AOMA Community. The manual provides
detailed information to support institutional initiatives for guaranteeing compliance with federal regulations governing the protection of human subjects and to guide principal investigators in procedures relevant to the development of research protocols that include human subjects.

The IRB is responsible for determining and assuring under the auspices of AOMA faculty, staff, and students that the welfare and rights of human subjects are adequately protected and informed consent given, if necessary; human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research; the necessity and importance of the research outweighs the risks to the subjects; and the researcher(s) is/are qualified to conduct research involving human subjects.

The IRB will conduct continuing review of research being undertaken with human subjects by faculty, staff, and students in accordance with the policies and procedures outlined in this manual at intervals appropriate to the degree of risk, but not less than once per year for the life of the project. See the section on Continuation/Renewal under International Review Board Types of Review.

Throughout this manual, humans whose physiologic or behavioral characteristics, or whose understanding of their lived experiences, and responses are the object of study are referred to as subjects; however, AOMA in no way intends to demean the humanity and individualism of such persons. Recognizing that regulations and policies and procedures are no guarantee of ethical conduct, it is the responsibility of individual researchers to make ethical considerations central in the conduct of research and to have a clear understanding of their duties to human subjects.

Additional information provided in the manual includes: 1) a definition of research involving human subjects, which must have IRB review and approval and that which is exempt; 2) types of IRB review and resulting actions; 3) policies governing cooperative research; and 4) extensive guidelines for conducting research involving special populations, such as pregnant women and fetuses, prisoners, and children. Guidance also is provided for preparing all documentation, including: 1) the application form; 2) research protocol; 3) informed consent form, along with samples of each, and 4) the procedures to be followed in submitting such documentation to the IRB for review.
2 Protection of Human Research Participants (PHRP)

Human subjects are essential to the conduct of research intended to improve human health. As such, the relationship between investigators and human subjects is critical and should be based on honesty, trust, and respect.

2.1 Federal Regulations for PHRP


These federal regulations require that any institution requesting and receiving funds from a federal department or agency for research involving human subjects must assure that such research is reviewed and approved by the University's Institutional Review Board. The University's administration has made the decision that all research with human subjects, whether funded or unfunded, or subject to Federal regulation or not, will be reviewed and approved in accordance with the guidelines set forth in this manual.

2.2 Federalwide Assurance for PHRP (FWA)

Institutions that engage in research funded by the Department of Health and Human Services (DHHS) must file a Federalwide Assurance (FWA) of compliance with the agency's regulations governing the protection of human subjects.

This Federalwide Assurance (FWA) covers all of an institution's U.S. federally supported human subject research. Awardee institutions are automatically considered to be "engaged" in human subject research whenever they receive a direct HHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award. The awardee is also responsible for ensuring that all collaborating institutions engaged in the research hold an approved Assurance prior to their initiation of the research. The FWA will eliminate the need for other types of Assurance documents (e.g., SPA, CPA). OHRP (Office of Human Research Protections) is responsible for the FWA and Institutional Review Board (IRB) Registration system.

The FWA is a written agreement, which includes the following: A statement of ethical principles and institutional policies governing research involving human subjects IRB, institution, and investigator compliance with 45 CFR Part 46 Certification of IRB approval and institutional endorsement, and a list of IRB members and their qualifications.

The AOMA IRB meets the HHS IRB Requirements:

- IRB Identification No.: IRB00009461
- Exp. Date: 08/16/2016
2.3 Principles and Guidelines for PHRP (Protecting Human Research Participants)

While respecting the right of faculty to academic freedom in research, AOMA is firmly committed to adhering to the basic ethical principles underlying the acceptable conduct of research involving human subjects, as set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. These three principles – 1) respect for persons, 2) beneficence, and 3) justice – are particularly relevant to the protection of human subjects in biomedical and behavioral research, and are the accepted requirements for the ethical conduct of such research.

2.3.1 Respect for Persons
Respect for persons involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

2.3.2 Beneficence
Beneficence entails an obligation to protect persons from harm by maximizing anticipated results and minimizing possible risks of harm.

2.3.3 Justice
Justice requires that the benefits and burdens of research be distributed fairly. Moreover, the principle of respect for persons underlies the need to obtain informed consent; the principle of beneficence underlies the need to minimize risks; and the principle of justice requires that subjects be fairly treated.

2.4 Glossary of Terms

Assent: A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Assurance: A formal, written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

Authorized Institutional Official: An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Contract: An agreement; as used here, an agreement that a specific research activity will be performed at the request, and under the direction, of the agency providing the funds.
AOMA IRB

Research performed under contract is more closely controlled by the agency than research performed under a grant.

**DHHS:** Department of Health and Human Services

**Expedited Review:** Review of proposed research by the IRB Chair or, or Chair’s designee, or group of voting members rather than the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

**Full Board Review:** Review of proposed research at a convened meeting at which one-third of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

**Grant:** Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

**Human Subjects:** Individuals whose physiologic or behavioral characteristics, or whose understanding of their lived experiences and responses, are the object of study of a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

**Informed Consent:** A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution, or agents thereof from liability for negligence.

**Institutional Review Board (IRB):** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

**Minimal Risk:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination.

**Office for Human Research Protections (OHRP):** The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects. OHRP provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research. OHRP helps ensure this by providing clarification
AOMA IRB

and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research

Principal Investigator (PI): The scientist or scholar with responsibility for the design and conduct of a research project. An AOMA faculty research advisor will act as the principal investigator (PI) on student-initiated research projects.

Protocol: The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. (See Minimal Risk)
3 AOMA Institutional Review Board (IRB)

3.1 Mission of IRB

The mission of the AOMA Institutional Review Board (IRB) is to Protect the Rights and Welfare of the Human Research Subject. The IRB is responsible for ensuring that all approved research complies with the letter and spirit of human subject protection regulations as well as the three principles previously defined in the Belmont Report: respect for persons, beneficence, and justice. To accomplish our mission, we strive to:

- Ensure that the risks of scientific advancement shall never outweigh the value of human life.
- Follow our traditions while embracing new technologies and practices.
- Maintain appropriate ethical conduct and regulatory compliance.
- Honor and respect all persons.
- Engage in a continuing quest for excellence.
- Maintain an ‘open book’ policy regarding all studies under consideration.
- Fulfill timely disposition of all studies under consideration.

3.2 Roles and Responsibilities of IRB

Any research that involves human subjects conducted by AOMA faculty, staff, or students, whether funded or unfunded, shall be under the jurisdiction of the IRB. The IRB is responsible for determining and assuring that 1) the welfare and rights of human subjects are adequately protected and informed consent given, if necessary; 2) human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research; 3) the necessity and importance of the research outweighs the risks to the subjects; and 4) the researcher(s) is/are qualified to conduct research involving human subjects.

For all funded research involving human subjects, the Office of the President will be responsible for coordinating the submission of required documentation to the IRB for review. In the case of unfunded research involving human subjects, faculty, staff, and students proposing research involving human subjects will submit all documentation to the designated IRB Chair, or Chair’s designee, who will be responsible for reviewing the research and determining if it warrants review by the IRB. If so, the documentation will be forwarded to the Office of the President for coordination of the IRB review.

Finally, the Office of the President will provide staff support to the IRB in all phases of its work, track and monitor submissions, and maintain records related to all research involving human subjects.

- AOMA IRB was established in 2007 to provide institutional assurance that all research activities involving human participants were being conducted under recognized ethical principles, in compliance with US federal regulations, US Department of Health and Human Services (DHHS), State of Texas.
- IRB has the responsibility for identifying and reviewing all human research activities conducted by or involving AOMA employees to ensure that the research is justifiable and that all human participants are protected from unnecessary harms and risks.
AOMA IRB

- The AOMA-IRB operates under general provisions of the Code of Federal Regulations and holds a DHHS Federalwide Assurance (FWA #00005114, IRB Charter) through the Office for Human Research Protections (OHRP).
- The AOMA-IRB consists of volunteer scientific and nonscientific experts, including AOMA employees and Austin community members.
- IRB has the authority to approve, to require modification of, and to disapprove proposed human subjects research.
- The IRB also has the authority to require progress reports from investigators, to oversee the conduct of a study, and to suspend or revoke its approval of ongoing research. Failure to comply with IRB requirements is considered serious misconduct and may be subject to sanctions, including possible termination of approved research.

3.3 Membership of IRB

IRB is composed of at least five members, and up to seven, from diverse backgrounds who have the professional competence necessary to completely and adequately review human subjects research activities commonly conducted by AOMA. Consideration is also given to how the member’s background will contribute to the diversity of the Board. To promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, prospective Board members must also be sensitive to such issues as community attitudes.

To such end, the IRB Committee shall consist of members with varying professional, racial, ethnic, cultural, and gender differences, who are knowledgeable about professional regulations and conduct and are sensitive to community attitudes. All voting members shall be AOMA employees who are full-time faculty members and who have experience in higher education or are appointed members of the community. At the discretion of the President an, full-time administrators may be selected to serve. At least one voting member of the Committee shall be a non-scientist and one shall be a member of the community.

Members of the IRB Committee will be appointed by President to staggered three-year terms, and will be notified of their appointment in writing by the IRB Chair. Terms are renewable at the discretion of the IRB Chair and with the concurrence of the member. Members do not receive financial compensation. The Chair, and/or others the Chair deems appropriate, will be responsible for training new appointees to the IRB.

Furthermore, if the IRB reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons) the IRB may temporarily appoint one, or more, individuals with specific knowledge and experience in working with these subjects for the project’s review. Such individuals may not vote with the IRB in these instances.

Attendance Expectations
- IRB will meet 4 times a year, and the annual calendar of meeting dates will be sent in advance to the members.
- IRB members are responsible for attending all scheduled IRB meetings, reviewing all assigned materials, and participating in IRB discussions.
AOMA IRB

- Members are asked to notify the IRB Office of their impending absence at least two weeks prior to the scheduled IRB meeting. More than two absences during a 12-month period may result in removal from the Board.

Conflicts of Interest
No member of the IRB may participate in an initial or continuing review of any project in which the member has a conflict of interest, except to provide information to the IRB. In the event that an IRB member has a conflict of interest with any protocol submitted for review, that member must disclose this conflict to the IRB Chair prior to the Board’s review of the protocol. They may respond to questions from Board members. However, they must remove themselves from the room prior to the Board’s deliberation and vote on the protocol. The official minutes will reflect that the member removed him/herself from the IRB meeting during the final discussion and vote on the protocol. An alternate IRB member may be appointed, as needed, to replace the member with the conflict of interest.

Participation in the Expedited Review Process
All Board members are asked to participate in the expedited review process. Based on experience and background, the IRB Office will select one or two Board members to review protocols qualifying for expedited review.

During the review process each reviewer is asked to contact the investigator or the IRB Office, as needed, and write a final report with his/her decision to approve the protocol or to refer it to full Board for review. Reviewers are asked to complete an initial review of the protocol within 5 working days and to communicate those results to the IRB Office.

Removal from the Board
The IRB Chair must present recommendations for removal, along with a written justification, to the President for consideration and final decision (except in cases of absenteeism).

3.4 Training of IRB
All new IRB members receive an orientation from the IRB Office before starting their active service. This orientation includes an overview of the Federal regulations (45 CFR 46, 21 CFR 50 and 21 CFR 56) established to protect human research subjects, the Belmont Report, and other documents/materials pertaining to the protection of human research subjects at AOMA. Copies of these materials will be made available to new Board members at their orientation. A senior IRB member will mentor new members during their first year on the Board. Selection and teaming of new members with mentors will be by mutual agreement. Members are required to obtain PHRP training certificate by going online: https://phrp.nihtraining.com/users/login.php The IRB Office will provide continuing education and support to all IRB members.

IRB member training objectives include:
- Describe the history and importance of human subjects protections
- Identify research activities that involve human subjects
AOMA IRB

- Discover the risks a research project might pose to participants
- Understand how to minimize the risks posed by a research project
- Describe additional protections needed for vulnerable populations
- Understand additional issues that should be considered for international research
- Describe appropriate procedures for recruiting research participants and obtaining informed consent
- Identify the different committees that monitor human subjects’ protections
- Understand the importance of study design in the protection of research participants

Members must make a commitment to participate not only in initial training, but also to participate in ongoing training and to conduct training for other faculty within AOMA, as appropriate. The Office of the President will be responsible for assisting with the development and implementation of all IRB training, as appropriate.

3.5 Changes in Policies and Procedures of IRB

Any policies and procedures governing the IRB may be changed at a regularly convened IRB meeting by a vote of the majority of the IRB members present, based on a quorum of five (5) members present. Any changes made will be to facilitate the effective and efficient operation of the IRB and in no way shall be in conflict with the rules and regulations set forth in federal statutes and regulations relating to the protection of human subjects. Any changes in policy and procedures shall be distributed to all members and shall be included as (an) amendment(s) to this manual. The Office the President will assist in making changes to these policies and procedures and will be responsible for completing and distributing any amendments to this manual. The IRB, in consultation with the Office of the President will review at twelve (12) month intervals the federal guidelines governing research with human subjects, and update, as necessary.

3.6 Authorities of IRB

Any research that involves human subjects conducted by AOMA faculty, staff, or students, whether funded or unfunded, shall be under the jurisdiction of the IRB. Principal investigators who propose human subject research that is not specifically exempted must follow the guidelines for preparing and submitting proposals to the IRB. The Chair is authorized to consult, as necessary, with the Office of the President.

3.7 Functions and Operations Meetings of IRB

Meetings of the IRB shall typically be convened by the Chair, or the Chair's designee, at a minimum of once a quarter. For regular meetings, members shall receive at least seven (7) days' notice. If there is no IRB business for the quarter, the Chair, or other designee, may cancel the meeting and notify all members of such action. Emergency meetings may be convened, as appropriate, and require at least 48 hours' notice. 2/3rd of the members of the IRB, one of whom must be a non-scientist, must be present in order to constitute a quorum and for the meeting to be official. The Chair will vote only in the event of a tie.
3.8 Review and Approval of Research by IRB

In order to approve research covered by the policy contained in this manual, the IRB will determine that all of the following requirements are satisfied:

- Risks to subjects are minimal
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is reasonable
- The study design elements, such as protocol, budget, resources and personnel, are complete and adequate to ensure successful conduct of the research study
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative
- Informed consent will be appropriately documented
- When appropriate, the research protocol makes adequate provision for monitoring the data collected to ensure the safety of subjects
- When appropriate, adequate provisions exist to protect the privacy of subjects and to maintain the confidentiality of data
- Additional safeguards have been included in the study to protect the rights and welfare of vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged individuals.

3.9 Research Covered by and Exempt from IRB Review

To comply with the federal guidelines covering the protection of research subjects, and to ensure appropriate ethical management of research programs conducted by AOMA faculty, staff, and students, all funded and unfunded research proposals involving any risk to human subjects falls within the jurisdiction of the IRB. The center representative will be responsible for determining whether the research should be reviewed or is exempt. If additional information/clarification is necessary, the IRB Chair or the Office of the President should be contacted.

3.9.1 Research Covered by IRB Review

Research which has potential risk to subjects includes, but is not limited to, the following:

- Research which involves the administration of herbs or other substances to subjects
- Research involving pregnant women and/or fetuses in utero
- Research involving subjects with life-threatening physical conditions
- Research involving physically intrusive procedures
- Research which previous experience (by the particular investigator or other investigators) has shown to create a potential of risk to subjects
- Research which potentially could put the subject at risk for legal or civil liability or invade a subject's privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use).
3.9.2 Research Exempt from IRB Review

Research which is regarded as not having potential risk to subjects includes the following:

- Research in which the risks of harm reasonably anticipated are not greater than those ordinarily encountered in daily life or during the performance of routine procedures in education and/or in the practice of psychology and medicine
- Research on the effectiveness of educational, classroom, and/or instructional strategies, provided that these strategies are familiar, and nonintrusive in their implementation
- Research using educational tests (cognitive, diagnostic, aptitude, achievement) if subjects’ identities are thoroughly protected
- Research using survey procedures or interview procedures where subjects’ identities are thoroughly protected and their answers do not subject them to criminal and civil liability
- Research involving the collection or study of existing data, documents, records, specimens, or other products, if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or indirectly.

In the event research is undertaken without the intention of involving human subjects, and subsequently the researcher wishes to involve human subjects in the research, the research must be reviewed by the IRB in accordance with the policies and procedures outlined in this manual. A certification official notification by an institution to the Department of Health and Human Services (DHHS) that all research involving human subjects has been reviewed by the IRB will be submitted to the appropriate funding department/agency for final approval. (See Certification under Certifications and Records.)

3.10 Recent IRB Questions and Issues

3.10.1 Archival Research/Chart Reviews

**Issue:** Can research based on reviews of existing patient records be considered exempt from IRB review? **Response:** Determining whether review of existing records is exempt hinges on the issue of linkage. To qualify for an IRB exemption, the review must establish no linkage (by name or code) between the data and the individual. A one-time review of records with no opportunity or means to return to individual charts could be exempt. If linkage is maintained, archival research/chart reviews is not considered exempt.

Under “Research Exempt from Review,” the IRB Policy and Procedures Manual states:

"Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or indirectly."

Review of patient records can only be considered exempt if the subjects cannot be linked to the information collected. This means that an investigator must not maintain any form of
linkage in order to go back and review the record at a later time. If linkage between the data and the subject must be maintained, the protocol should be submitted for review. If linkage between the data and the subject do not exist, the protocol should be submitted for a waiver.

Retrospective studies of clinical records, including Case Reports and Case Series, of patient(s) are often presented at conferences or published in journals. Case Reports and Case Series based on therapeutic or medical practice involving patient(s) are not designed as experimental research studies, and, as long as patient confidentiality is protected, such studies are exempt from full IRB review. An IRB Waiver Form must be completed and submitted to the IRB Chair, or the Chair’s designee, for review and approval, before research involving Case Reports and/or Case Series may proceed.

3.10.2 Research Involving Single Subjects (N of 1)

Whereas, research studies involving a single human subject are no different than studies involving multiple subjects and, as a result, fall under the purview of full IRB review. Examples of such studies include human behavior studies in which a subject becomes his/her own control by multiple baseline design or clinical trials in which a number of single-subject studies are compared to one another.
3.11 Preparing and Submitting Application for IRB Review

Any research that involves human subjects conducted by AOMA faculty, staff, or students, whether funded or unfunded, which falls into one of the categories of potential risk and/or is not determined to be exempt by the IRB Chair, or the Chair’s designee, must be reviewed by the IRB.

3.11.1 Funded Research

For all funded research involving human subjects, the IRB Chair will be responsible for coordinating the submission of required documentation to the IRB for review at its next scheduled meeting. The investigator initiating the research is responsible for completing 1) the IRB Application Form, including obtaining appropriate signatures, 2) the Protocol, and 3) submitting 5 copies of the IRB Application Form and 5 copies of the Protocol, including all consent forms and research instruments to be used in the study (questionnaires, interviews, surveys, etc.) to the IRB Chair on the last working/business day of the month prior to the next scheduled IRB meeting. Upon receipt of all required paperwork, the IRB Chair will log the IRB submission, assign a protocol number, review it for completeness, and forward all copies to the IRB members. Insufficient information may delay processing and IRB approval.

The IRB Chair or the Chair’s designee, in consultation with the Office of the President, will determine if the research can be reviewed through expedited review.

Once IRB approval is granted, the Office of the President will notify the principal investigator and the appropriate agency. The principal investigator will have 60 days after submission of the grant proposal to a federal funding agency to obtain IRB approval.

3.11.2 Unfunded Research

The investigator initiating the research is responsible for completing 1) the IRB Application Form, including obtaining appropriate signatures, 2) the Protocol, and 3) submitting 5 copies of the IRB Application Form and 5 copies of the Protocol, including all consent forms and research instruments to be used in the study (questionnaires, interviews, surveys, etc.) to the IRB Chair on the last working/business day of the month prior to the next scheduled IRB meeting. Upon receipt of all required paperwork, the IRB Chair will log the IRB submission, assign a protocol number, review it for completeness, and forward all copies to the IRB members. Insufficient information may delay processing and IRB approval.

Upon receipt of all required paperwork, the IRB Chair will log the IRB submission, assign a protocol number, review it for completeness, and forward all copies to the IRB members. Insufficient information may delay processing and IRB approval.

The IRB Chair, or the Chair’s designee, in consultation with the Office of the President, will determine if the research can be reviewed through expedited review.
After IRB approval is given, the Office of the President will notify the principal investigator. The IRB will conduct continuing review of all research, funded or unfunded, in accordance with the policies and procedures outlined in this manual at intervals appropriate to the degree of risk, but not less than once per year for the life of the project.

3.12 Research Protocol for IRB Review

For all research involving human subjects, the initiating investigator will be responsible for completing the IRB Application Form and the Research Protocol.

The Research Protocol is the formal design or plan for the proposed experiment or research activity. Specifically, the Research Protocol is the plan submitted to the SRC and IRB for review and subsequently, to an agency for research support. The Research Protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data. The following format should be used in developing the research protocol, including a Title Page and Abstract.

1.0 INTRODUCTION, BACKGROUND, AND HYPOTHESES
2.0 OBJECTIVES AND SPECIFIC AIMS
3.0 STUDY DESIGN
4.0 DRUG/DEVICE INFORMATION
5.0 SELECTION AND WITHDRAWAL OF SUBJECTS
6.0 STRATIFICATION/DESCRIPTION FACTORS/RANDOMIZATION SCHEME
7.0 INTERVENTION AND TOXICITY MANAGEMENT PLAN
8.0 ASSESSMENT OF EFFICACY AND SAFETY
9.0 CLINICAL AND LABORATORY EVALUATIONS AND STUDY CALENDAR
10.0 CRITERIA FOR EVALUATION AND ENDPOINT DEFINITIONS
11.0 SPECIAL INSTRUCTIONS:
12.0 DATA COLLECTION AND MONITORING
13.0 STATISTICAL ANALYSIS PLAN
14.0 REGISTRATION GUIDELINES
15.0 BIOHAZARD CONTAINMENT
16.0 ETHICAL AND REGULATORY CONSIDERATIONS
17.0 REFERENCES
18.0 APPENDICES

3.13 Research Investigator's Assurance

AOMA Institutional Review Board
Research Investigator Assurance Form

As Investigator of this study, I assure the IRB that, as required by federal regulations:
• Proposed changes in approved studies will be presented to the IRB for review and approval prior to initiation except where necessary to eliminate apparent immediate hazards to the subjects.
The IRB, appropriate institutional officials, the Office for Protection from Research Risks (OPRR) and the FDA, if applicable, will be promptly informed of any unanticipated problems involving risks to subjects or others and research-related injuries.

The informed consent of the subject will be obtained by the investigator in the manner and format approved by the IRB prior to the initiation of the studies.

The study will be resubmitted to the IRB for continuing review at the interval determined by the IRB to be appropriate to the risk, but not less than once a year.

All protocols involving human subjects or specimens obtained from human subjects, whether performed at AOMA or elsewhere, in the grant(s) listed under Funded Research above, have been described in this application or have already been approved by the IRB.

3.14 Certification of IRB Review (for Funded Projects Only)

Certification of IRB review refers to the official notification by AOMA to the DHHS that the research activity or project involving human subjects has been reviewed by the IRB. Certification of initial IRB review is incorporated into the text of the IRB Application Form, which is then forwarded to the Office of the President.

3.15 Suspension or Termination of Research

The IRB shall have authority to suspend or terminate research that is not being conducted in accordance with the IRB’s requirements, other institutional and federal requirements, or has been associated with any serious harm to subjects. Concerns regarding the conduct of research must be reported immediately to the IRB Chair, or the Chair’s designee, by any individual having such knowledge. Any suspension or termination of research must include a statement of the IRB’s action, and the IRB Chair must report its decision promptly to the principal investigator, the Office of the President, and the funding agency, in the case of a sponsored project.

3.15.1 Notification of Research Project Termination Form

AOMA Institutional Review Board
Notification of Research Project Termination Form

RPN NO: 

PRINCIPAL INVESTIGATOR: 

TITLE: 

DATE OF TERMINATION: 

NUMBER OF SUBJECTS ENROLLED/STUDIED:

a) Since date of last annual renewal:
   Males: 
   Females: 

b) For the total Study:
   Males: 
   Females: 

ANY UNTOWARD REACTIONS, SIDE EFFECTS, OR ADVERSE EVENTS: _____YES_____NO
IF YES, describe in detail below:

SUMMARY OF CONCLUSIONS OF THE STUDY:

_________________________________________  ______________________
Signature of Principal Investigator                Date

3.16 Cooperative Research

Cooperative research projects are those that involve more than one institution and can be
designed to be both multi-site and multi-protocol in nature. In the conduct of such projects,
each participating institution is responsible for safeguarding the rights and welfare of human
subjects and for complying with all regulations.
AOMA IRB

Institutional Approval: In cases where the research project will be housed and conducted at another institution with participation by AOMA faculty, staff, or research participants, it is required that documentation of the primary institution's IRB approval and a copy of the research protocol and consent forms be obtained and made part of the AOMA IRB records. The proposed research project must then go through an additional review by and receive approval from AOMA’s IRB. All cooperative research projects involving AOMA faculty, staff, or research participants, whether conducted at AOMA or off-site, must have AOMA IRB approval.

Assurances: It is the responsibility of the lead institution to file the required assurances and certifications with the Office for Human Research Protections (OHRP).

3.17 IRB Records

It will be the responsibility of the Chair, or the Chair's designee, to prepare and/or maintain adequate documentation of IRB activities regarding research involving human subjects, including the following:

- Copies of all research protocols reviewed and actions taken, scientific evaluations, if any, that accompany the protocol, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of issues of dispute and their resolution.

Records of continuing review of research activities:

1) Copies of all correspondence between the IRB and investigators.
2) A list of all IRB members, including their name, race, ethnicity, and gender; earned degrees; affiliation; indications of experience, such as board certifications, licenses, etc.
3) Written procedures governing the IRB.
4) Copies of all documentation regarding research reviewed by the IRB also will be maintained in the Office of the President. All records shall be retained for at least three (3) years. Records relating to funded research conducted shall be retained for at least three years after completion.

3.18 Institutional Review Board Types of IRB Actions

The IRB shall review and have the authority to approve, tentatively approve pending receipt of additional information, or disapprove the subject research, according to the following:

3.18.1 Approve
The protocol is approved as submitted.

3.18.2 Pending
A protocol is considered pending when the problems identified in the protocol are not serious and generally fall into two categories: 1) the investigator needs to clarify an aspect of the study...
or provide additional information, or 2) minor changes need to be made in the informed consent document. In these cases, approval can be given after the investigator rewrites the informed consent and/or submits to the Chair a written response to the IRB’s questions and concerns. The Chair will then poll IRB members to receive final approval.

3.18.3 Disapprove
The IRB will disapprove the proposed research if it places the subjects at risks which far outweigh the benefit or value of the knowledge to be gained, or it raises such serious ethical questions as to be unacceptable. In the event disapproval is foreseen, the investigator will be invited to attend the meeting of the IRB to discuss the protocol. A research activity may be disapproved only after a full IRB review has been conducted.

In each of the above cases, the IRB shall notify the principal investigator of the results of its action in writing. The continuing review of research shall be conducted according to the procedures outlined in Continuation/Renewal.

3.19 Institutional Review Board Types of Review

3.19.1 Full Review
A full review of proposed research shall take place at convened meetings at which one-third of the IRB, one of whom must be non-scientist, must be present. In order to approve research, the IRB shall determine that all criteria for approval are satisfied. In order for the research to be approved, it shall receive the approval of a majority of the members present at the meeting. Most research follows the full review and approval process.

3.19.2 Continuation/Renewal
Continuing review of research must be conducted at intervals appropriate to the degree of risk, but not less than once per year. The IRB cannot approve a research project for more than 12 months. All reviews for continuation will be conducted by expedited review, if no changes have been made to the research protocol and no adverse or unexpected reactions or side effects have occurred or are expected. (However, the full IRB will be given the opportunity to review the continuation/renewal report.) In all other instances, continuing review will be conducted by the full IRB.

3.19.3 Revision
If the investigator, during the course of conducting the research, revises the research protocol (e.g., makes changes to the informed consent form, survey instruments used, or number and nature of subjects), the principal investigator will notify the IRB Chair immediately, and in the case of funded research, the Office of Grants and Contracts. The Chair will determine the need for additional review, the type of review (full or expedited) and notify the IRB members.

3.19.4 Financial Interest Disclosure
AOMA IRB

The principal investigator of the study must advise the Chairman of the Institutional Review Board if there are any personal financial interests that could bear upon his/her objectivity as principal investigator.

3.19.5 Industry-sponsored Research

The General Clinical Research Centers (GCRC) Branch of the National Institutes of Health requires that the hospital’s GCRC Advisory Executive Subcommittee determine whether industry-sponsored research is investigator-initiated or industry-initiated. Industry-initiated research must be paid for in full by the industry, including the full per diem cost for each inpatient day or outpatient visit. Any costs presented in a budget to the industry as being for hospitalization or patient care must be credited to the Hospital. GCRC funds can only be used for investigator-initiated research.

When completing the GCRC Advisory Committee Form, describe how the arrangement for funding developed, and address the following questions: What role, if any, did the profit-making organization play in the design of the protocol? If you designed the protocol, did the profit-making organization make any alterations in the design of the protocol? If so, please specify. If the company designed the protocol initially, did you make any alterations in the design of the protocol? If so, please specify. Is the same study being conducted at other sites under the sponsorship of the same profit-making organization? Is publication of the results contingent upon the approval of the sponsor? (Use additional pages, if needed.)

Attach the completed form and approved budget sheets to your other IRB Submission forms and send to the President’s Office at AOMA.

3.20 General Requirements of Informed Consent

The process of obtaining informed consent shall contain the following elements:

1. It should be obtained from the subject or the subject’s legally authorized representative
2. It should be in language understandable to the subject or his or her legal representative
3. It should be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence

3.20.1 Additional Elements of Informed Consent

When required by the IRB, one or more of the following elements shall be provided to each subject:

- Statement that procedure may involve unforeseeable risks to the subject
- Description of circumstances under which the subject’s participation may be terminated by the investigator without the subject’s consent
- Additional costs to the subject resulting from participation in the research
AOMA IRB

- Consequences of the subject's decision to withdraw from the research and procedures for termination of participation by the subject
- Statement that significant new findings developed during research, which may relate to subject's willingness to continue, will be provided to the subject
- Approximate number of subjects involved in the study

3.20.2 Exceptions from Requirements for Informed Consent

The IRB may waive the requirement to obtain a signed consent form for some or all subjects if the only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from breach of confidentiality, or the research presents no more than minimal risk and involves no procedures for which written consent is normally required.

In cases where documentation is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

3.20.2.1 DHHS Exceptions

The IRB may approve a consent procedure which does not include, or which alters, some or all or the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents:

- The research involves no more than minimal risks
- The rights and welfare of subjects will not be adversely affected
- The research could not practicably be carried out without the waiver or alteration
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- The research is to be conducted for the purpose of demonstrating or evaluating federal, state, or local service programs which are not research programs, etc.

3.20.2.2 FDA Exceptions

Obtaining informed consent may be waived if both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

- Subject is in a life-threatening situation necessitating use of test article
- Consent cannot be obtained because of an inability to communicate with or obtain consent from the subject
- Time is not sufficient to obtain consent from subject's legal representative
- No alternative, generally approved method is available

If immediate use of the test article is required to save the life of the subject and time is not sufficient to obtain independent determination by another physician, a determination by the investigator shall be made.

This determination by the investigator is to be reviewed and evaluated by a physician who is not participating in the investigation within five (5) days after the use of test article.
The documentation required above must be submitted to the IRB within five (5) working days after the use of the test article.

3.20.3 Documentation of Informed Consent

Informed consent will be documented by using a written consent form approved by the IRB. The subject or the subject’s authorized representative will sign the form. A copy will be given to the person signing the form.

Two types of consent forms are permissible: 1) Full Consent Form, and 2) Short Consent Form

3.20.3.1 Full Consent Form

The Long Consent Form includes all of the following basic elements:

a) A statement that the study involves research
b) An explanation of the purpose of the research and the expected duration of the subject’s participation
c) A description of the procedures to be followed and the identification of any procedures which are experimental
d) The disclosure of alternative procedures
e) A description of risks and possible discomforts to the subject
f) A description of foreseeable benefits to the subject and others
g) A description of the extent to which confidentiality will be maintained
h) An explanation as to whether compensation or medical treatments are available if injury occurs (for research involving more than minimal risk)
i) An explanation of whom to contact if questions arise or injury occurs
j) A statement that participation is voluntary, that refusal to participate involves no penalty, and that the subject may discontinue participation and have any data already collected destroyed at any time
k) No language through which the subject is made to waive any of his/her legal rights or which releases the investigator, the sponsor, or the institution from liability for negligence

3.20.3.2 Short Consent Form

The Short Consent Form states that the elements of informed consent have been obtained from the subject. When the short form is used, the following conditions must be met:

l) The written summary of what is to be said receives prior approval of the IRB
m) A witness must be present at the oral presentation
n) The short form is signed by the subject or his or her representative
o) The witness signs both the short form and the written summary
p) A copy of both the short form and the written summary is given to the person(s) signing the form

3.21 Informed Consent Form Checklist
This form must be submitted with the research protocol and informed consent form. Failure to do so will cause review of your protocol to be deferred. Informed consent is one of the primary ethical requirements for research with human subjects; it reflects the basic principle of respect for persons. No principal investigator may involve a human being as a subject in research, as defined by Institutional Review Board Policy and Procedure Manual for Research with Human Subjects, unless the investigator has obtained the subject's informed consent. The process of informed consent is constituted on two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced; i.e., his or her consent is voluntary.

The checklist below is provided to ensure that each of the following components is included in your Informed Consent form.

- The Informed Consent form is written in a language understandable to the subject or his/her legal representative
- The Informed Consent form is written in a consistent voice, either first, second, or third person (not a combination), with the exception of the Voluntary Consent section, which is written in the first person
- Each page of the Informed Consent form is on original AOMA letterhead, except in cases of collaborative projects when the letterhead from a hospital, university, etc., is acceptable
- If the research is externally funded, the funding agency is listed under funding source
- The title of the study and the name, address, and telephone number of the investigator(s)
- If the investigator initiating the research is a student, his/her faculty research advisor(s) is listed as the PI. In addition to the contact information for the Study Coordinator, the IRB application must include the PI's address, email, and phone number
- The phone number ####### for the IRB Office.
- A statement that the study involves research and an explanation of the purpose of the research.
- A concrete description of the study procedures, including the amount of time subjects are being asked to contribute and the nature of the questions or data to be collected
- Any procedures which are experimental are identified and any alternative procedures disclosed
- A description of risks and possible discomforts to the subjects, if any
- A description of any benefits to the subjects. If no benefits are expected, this is stated
- A statement describing the extent to which confidentiality will be maintained
- If subjects will be compensated for their participation, a statement addresses this
- A statement that participation is voluntary, that refusal to participate involves no penalty, and that the subject may discontinue participation and have any data collected destroyed at any time
- A statement indicating who the subject can contact for any questions about the study
- The Informed Consent contains no language through which the subject is made to waive any of his/her legal rights or which releases the investigator, the sponsor, or the institution from liability for negligence
- The final sentence under Section VI-Voluntary Consent on the Informed Consent form begins, "I hereby agree to participate..."
AOMA IRB

- A space for the subject's signature, the date, and the signature of a witness
- An assent form is included for subjects 7-17 years of age

### 3.22 Informed Consent Form Instructions for Completion

Consent forms should contain the basic elements, or additional elements, as appropriate, included in the Informed Consent section and follow the format outlined below:

Each page of the consent form should be on AOMA letterhead, except in cases of collaborative projects when the letterhead from a hospital, university, etc. is acceptable. All letterhead must be the original, not a copy. The official stamp of the IRB will indicate the date of approval. The consent form should be in language understandable to the subject or his or her legal representative. It must be written in a consistent voice: either first, second, or third person (not a combination).

If the research is externally funded, the funding agency should be listed under funding source. The title of the study and the name, address, and telephone number of the investigator(s) follow immediately after funding source. The Principal Investigator's address and phone number, and the name, email and number of the IRB Chair, Dr. Raja Mandyam, MD (India): aoma-irb@aoma.edu, 512-492-3036, must appear on the consent form. If the investigator initiating the research is a student, his/her faculty research advisor(s) is listed as the PI. In addition to the contact information for the Study Coordinator, the IRB application must include the PI's address, email, and phone number.

**Section I - Description.** This section should include a statement that the study involves research, the purpose of the study, the reason for selecting the subject, the procedures to be used and identification of any procedures which are experimental, and the expected duration of the subjects’ participation, including anticipated follow-up.

**Section II - Risks and Benefits.** Subjects should be informed about direct or indirect potential benefits to them or others, or the absence of benefits. Potential or anticipated risks should also be specified. For research involving more than minimal risk, an explanation is required as to whether compensation or medical treatments are available if injury occurs. The section must include the following: "If [I/you] have any concerns about the risks or benefits of participating in this study, [I/you] can contact [name of principal investigator and advisors/collaborators] or the IRB office at the numbers indicated above."

**Section III - Costs and Payments** should be addressed explicitly, including a statement that payments will not be given, if that is the case.

**Section IV - Confidentiality** must be specified as well as a description of procedures for protecting privacy, including specific information regarding how data will be stored to ensure security and confidentiality.
Section V - Right to Withdraw. must include a statement that the subject understands s/he is free to refuse to participate in or withdraw from the study at any time without adverse events or loss of benefits, and that, if the participant withdraws, the data will be destroyed.

Section VI - Voluntary Consent. The following voluntary consent paragraph must be used in all consent forms: "I have read the following or it has been read to me and I understand the contents. All of my questions concerning this research have been answered. If I have any questions in the future about this study they will be answered by the investigator listed above or his/her staff. A copy of this form has been given to me."

Section VII - Other Considerations. Subject needs to be informed if significant new information relating to the study becomes available which may relate to his/her willingness to continue to participate, and this information will be provided to him/her by the investigators.

Consent forms must provide space for the subject's signature, the date, and the signature of a witness, generally the member of the research staff obtaining the consent.

One significant outcome of the Nuremberg medical trials was the establishment in 1947 of the Nuremberg Code, which set forth ten principles for conducting research involving human subjects. The first of those principles states, "The voluntary consent of the human subject is absolutely essential." Thus, no investigator may involve a human being as a subject in research, as defined in this policy and procedure manual, unless the investigator has obtained the subject's informed consent. The process of informed consent is constituted by two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced; i.e., his or her consent is voluntary. Once informed consent is obtained, documentation to that effect shall follow the procedures outlined in this manual in the "Documentation" section below.

Additionally, the researcher should be aware that litigation against AOMA is always a possibility. From this perspective, even an ethical informed consent is not sufficient. Rather, we need an ethical informed consent which is legally valid and the legal validity of which can be demonstrated, should such a need arise.

3.23 Safeguards for Special Populations

The federal government has extensively regulated and provided additional safeguards with respect to research, development, and related activities involving "special populations"; these include pregnant women and fetuses, prisoners, and children. The following are guidelines for the inclusion of these special populations as subjects in research. If faculty, staff, and students need additional information and/or clarification regarding special populations, they are to contact the IRB Chair, the Chair's designee, or the Office of Grants and Contracts.

3.23.1 Pregnant Women and Fetuses

No research activities involving pregnant women and fetuses may be undertaken unless appropriate studies on animals and non-pregnant individuals have been completed; the purpose of the activity is to meet the health needs of the mother or the particular fetus; the
risk to the fetus is minimal, and, in all cases, is the least possible risk for achieving the objectives of the activity; individuals engaged in the activity will have no part in 1) any decisions as to the timing, method, and procedures used to terminate the pregnancy, 2) determining the viability of the fetus at the termination of the pregnancy; and 3) no procedural changes which may cause greater-than-minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

3.23.1.1 Pregnant Women as Subjects

No pregnant woman may be involved as a subject in any research activity unless the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or the risk to the fetus is minimal.

Any activity permitted above may be conducted only if the legal guardian/s legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus. The father's informed consent need not be secured if the purpose of the activity is to meet the health needs of the mother; his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape.

3.23.1.2 Fetuses in utero as Subjects

No fetus in utero may be involved as a subject in any research activity unless the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

Any activity permitted above may be conducted only if the mother and father are legally competent and have given their informed consent. The father's informed consent need not be secured if his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape.

3.23.1.3 Fetuses ex utero, Including Nonviable Fetuses, as Subjects

Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in any research activity unless there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

No nonviable fetus may be involved as a subject in any research activity unless vital functions of the fetus will not be artificially maintained; experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed; and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.
In the event the fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements included herein.

Any activity permitted above may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if his identity or whereabouts cannot reasonably be ascertained; he is not reasonably available; or the pregnancy resulted from rape.

Activities involving a dead fetus, macerated fecal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable state or local laws regarding such activities.

3.23.1.4 Prisoners

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, additional safeguards for their protection must be adhered to.

With respect to research involving prisoners, the IRB shall also meet the following specific requirements:

A majority of the Board (exclusive of prison members) shall have no association with the prison(s) involved, apart from their membership on the Board. At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

The following research involving prisoners is permitted:

Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if 1) the institution has certified to DHHS that the IRB has approved the research, and 2) and in the judgment of the agency, the research involves solely the following: study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects; study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects; research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere); and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults only after the Secretary of the DHHS has consulted with appropriate experts, and published in the Federal Register his or her intent to approve such research; or research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the research
AOMA IRB

may proceed only after the Secretary of the DHHS has consulted with appropriate experts, and published in the Federal Register his/her intent to approve such research.

3.23.1.5 Children

Research involving children is permitted if the IRB finds that no-greater-than-minimal risk to children is present. Adequate provisions must be made for the assent of children and the permission of parents or guardians.

The IRB may find an intervention or procedure holds more than minimal risk to children. If there is the prospect, however, of direct benefit to the subject, a study may be permitted. This may take place only if there is a monitoring procedure that is likely to contribute to the subject's well-being. A study with more than minimal risk may be conducted only if IRB finds:

1. The risk is justified by the anticipated benefit to the subjects
2. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches

3.23.1.6 Wards

Children who are wards of the state of any other agency, institution, or entity can be included in the research only if such research is: 1) related to their status as wards, or 2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the IRB approves the research, it shall require the appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way with the research, the investigator(s), or the guardian organization.

3.23.1.7 Requirements for Parental/Guardian Permission and for Assent by Children

The IRB shall require that adequate provisions are made for soliciting the permission of each child's parents or guardians. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient if the research does not involve greater-than-minimal risk, or does involve greater-than-minimal risk, but presents the prospect of direct benefit to the individual subjects. If the research involves greater-than-minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizing knowledge about the subject's disorder or condition, the IRB will require both parents' permission. Exceptions would include: 1) one parent is deceased, unknown, incompetent, or not reasonably available, or 2) when one parent has legal responsibility for the care and custody of the child.

Permission by parents or guardians shall be documented in accordance with and to the extent required under the Informed Consent section of this manual.
The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved or for each child, as the IRB deems appropriate.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

3.24 Experimental Subject's Bill of Rights

AOMA IRB requires that the rights of a subject in a medical experiment are specified, and the subject or subject’s legally authorized representative are provided, in the Experimental Subject's Bill of Rights, prior to consenting to participate in any medical experiment. Upon review by the subject, or the subject’s legally authorized representative, the Experimental Subject's Bill of Rights is to be dated and signed by the subject or the subject’s legally authorized representative. A copy of the signed Bill of Rights is to be provided to the subject or the subject’s legally authorized representative.

Experimental subject’s Bill of rights

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

1. The nature and purpose of the study
2. The procedures in the study and any drug or device to be used
3. Discomforts and risks to be expected from the study
4. Benefits to be expected from the study
5. Alternative procedures, drugs, or devices that might be helpful, and their risks and benefits
6. Availability of medical treatment should complications occur
7. The opportunity to ask questions about the study or the procedure
8. The opportunity to withdraw at any time without affecting your future care at this institution
9. A copy of the written consent form for the study
10. The opportunity to consent freely to the study without the use of coercion
11. Statement regarding liability for research-related injury, if applicable
AOMA IRB

I have carefully read the information contained above and I understand fully my rights as a potential subject in a medical experimentation involving people as subjects.

Date: ___________________________ Time ___________________________

Signature: _______________________________________________________

(research subject)

Signature: _______________________________________________________

(parent/legally authorized representative of research subject)

If signed by other than patient, indicate relationship: ___________________
4 Research Protocol Guidelines

(YOUR) PROTOCOL NUMBER:

TITLE:

Study phase:

STUDY ARMS:

IND OR IDE #:

PRINCIPAL INVESTIGATOR(S): NAME
   Address
   Telephone
   Fax

CO-INVESTIGATOR(S):

Sponsor:

PARTICIPANTS/LOCATIONS:

AMENDMENTS/REVISIONS:

**********************************************************************************************************************

**
THIS IS AN EXAMPLE OF INFORMATION THAT SHOULD USUALLY BE INCLUDED IN A CLINICAL PROTOCOL FOR THERAPEUTIC RESEARCH AND SHOULD BE USED AS A USEFUL GUIDE

**********************************************************************************************************************

**
TABLE OF CONTENTS

SCHEMA, Synopsis, OR STUDY SUMMARY
   Page
1.0    INTRODUCTION, BACKGROUND, AND HYPOTHESES    
2.0    OBJECTIVES and SPECIFIC AIMS    
3.0    Study Design    
4.0    DRUG/DEVICE INFORMATION    
5.0    SELECTION and withdrawal of subjects    
6.0    DESCRIPTIVE FACTORS/STRATIFICATION/RANDOMIZATION SCHEME    
7.0    STUDY AGENT ADMINISTRATION OR INTERVENTION AND TOXICITY MANAGEMENT PLAN    
8.0    Assessment of efficacy and safety    
9.0    CLINICAL AND LABORATORY EVALUATIONS    
10.0    CRITERIA FOR EVALUATION AND ENDPOINT DEFINITIONS    
11.0    SPECIAL INSTRUCTIONS    
12.0    Data collection and monitoring    
13.0    STATISTICAL CONSIDERATIONS    
14.0    REGISTRATION GUIDELINES    
15.0    biohazard containment    
16.0    Ethical and Regulatory Considerations    
17.0    REFERENCES    

APPENDICES
4.1 Introduction, Background, and Hypotheses

The background is the justification for the proposed study. It should summarize the results of similar studies and should outline the unanswered questions which the study will address.

This section should include the referenced details of therapeutic effectiveness, and the toxicity of the proposed regimen, if known. Information obtained in animal studies or in similar studies performed in humans should be included. Background information is required on all modes of treatment which will be used or studied.

For those studies evaluating a totally new treatment regimen (such as an investigational drug for a new dose or schedule), pilot or phase data, if it exists, should be included and justify testing the new therapy. It is usually very helpful if the Background and Hypotheses section is subdivided into components and numbered as items 1.1, 1.2, 1.3, etc. In many cases, section 1.1 should summarize the specific clinical problem (e.g., a brief summary of disorder, etc.). Section 1.2 and thereafter should summarize background information regarding the new drug(s)/device to be used, pharmacokinetics, basic science for translational aspects, etc. The final section(s) should be the central hypothesis (hypotheses). All references should be numbered in the order they appear in the text, with references included in the reference section.

At the end of the Background Section, there must be an explicit statement of the central hypothesis (hypotheses) that the proposed clinical trial will attempt to prove. The Background Section should contain sufficient information to support the hypothesis (hypotheses).

4.2 Objectives and Specific Aims

The objectives of a study should be specifically outlined in this section. These objectives should pose important scientific questions which will be answered by the final outcome or analysis, whether it will be the value of a new investigational drug or a new combination of treatments, or a comparison between standard therapy and innovative new treatment. The objectives should be answered with the sample size of the study.

Only specific aims which are supported in the Background and Hypotheses section should be listed. All itemized aims should be addressed in section 10.0 (Criteria for Evaluation and Endpoint Definitions) and section 13.0 (Statistical Considerations).

Be concise and focused.

The following items should also be considered in this section:

2.1 The most important or primary aim of the study should be listed as item 2.1
2.2 Less important or secondary aims should follow.
4.3 Study Design

Describe the study design. Procedures which are considered experimental as well as procedures performed exclusively for research purpose should be identified.

4.4 Drug/Device Information

4.4.1 All drugs and/or device being used in the proposed study should be described

4.4.2 The drugs should be listed in alphabetical order

4.4.3 IND number and IDE number should also be provided

4.4.4 The supplier of each substance and device should be identified

4.4.5 For investigational agent studies, the toxicity and chemical make-up of the drug will already be outlined in the background; however, it should be condensed for the drug information section and should include toxicity, pharmaceutical data, storage, and stability

4.4.6 If an investigational device is used, determination of significant and non-significant risk should be described (for example: the sponsor's risk assessment determination; the rationale for the non-significant risk determination). If the device has been reviewed by the FDA, the FDA's assessment of device risk should be provided

4.5 Selection and Withdrawal of Subjects

Selection criteria will include such factors as allowable disease sites, disease status or characteristics, age, prior therapy, required tests, informed consent, etc. Subject withdrawal criteria should describe when and how to terminate investigational product treatment/trial treatment.

4.5.1 Inclusion Criteria
4.5.2 Exclusion Criteria
4.5.3 Withdrawal Criteria

4.6 Stratification/Descriptive Factors/Randomization Scheme

Stratification factors, other important, pretreatment descriptive factors, and randomization plan (if applicable) should be identified. If there is no randomization or important patient characteristics that will be used in treatment allocation or data analysis, a statement to this effect should be included.

4.6.1 Stratification factors – pretreatment patient characteristics which either will be balanced across treatment arms or will be used to determine initial dose. Stratification factors should be limited to the 2 or 3 most important variables.
AOMA IRB

4.6.2 Descriptive factors—patient characteristics to be taken into account at the time of study analysis, but which do not affect treatment assignment.

4.6.3 If applicable, the details of the randomization plan should be given. This should be written in conjunction with the statistician.

4.7 Intervention and Toxicity Management Plan

4.7.1 The entire treatment or treatments should be outlined. For those studies which will include randomization, the separate regimens should be labeled with suitable abbreviations which need to be consistent with the rest of the protocol. If applicable, it should be stated if the patients will be restaged and if a second registration will be required at that time. Indicate when any other registrations/randomizations should occur.

4.7.2 The dose(s) of drugs used, the schedule of the agents, and the number of courses should be clearly outlined for each treatment. Include a table for each treatment with the same labels as in 4.6.1, using the following general format.

(Example)

<table>
<thead>
<tr>
<th>AGENT</th>
<th>DOSE</th>
<th>ROUTE</th>
<th>DAYS</th>
<th>ReRx INTERVAL</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>50mg/m²</td>
<td>i.v. over 5 min</td>
<td>1</td>
<td>4 weeks</td>
<td>maximum cumulative dose 500mg/m²</td>
</tr>
<tr>
<td>CDDP</td>
<td>60mg/m²</td>
<td>i.v. over 2 hr in 1000 ml ½ normal saline + 25 gm Mannitol</td>
<td>1</td>
<td>4 weeks</td>
<td>Give ADR before CDDP</td>
</tr>
<tr>
<td>Prednison</td>
<td>30mg</td>
<td>p.o.</td>
<td>1-7</td>
<td>4 weeks</td>
<td></td>
</tr>
</tbody>
</table>

When different modes of therapy are being used, such as surgery or radiation therapy, each should be given in one complete section of the treatment plan. For the more complex protocols (Phase III) which contain two or more treatment modalities, the different modalities should be divided and included under separate headings, such as:

4.7.2.1 Treatment Plan – Chemotherapy
4.7.2.2 Treatment Plan – Radiation Therapy
4.7.2.3 Treatment Plan – Surgery

4.7.3 Criteria for removal from treatment (such as undue toxicity, progression of disease, etc.) are to be outlined. Be sure these are consistent with 4.5 (withdrawal) and 4.7 (toxicity). Some examples follow. Make sure that the treatment program for all
patient subgroups has a clearly defined stopping point, or if treatment is to continue indefinitely that this is stated.

Example:

4.7.3.1 After eight weeks of treatment (2 courses), patients with stable disease should be taken off treatment. Patients with complete or partial responses will continue treatment. (Note: “moderate” toxicities should be defined in Section 4.8.1.)

4.7.3.2 Patients will discontinue treatment after disease progression at any time.

4.7.3.3 Treatment will be discontinued if patients experience moderate or worse renal toxicity, or any neurologic toxicity. (Note: “moderate or worse” should be defined in Section 4.8.1.)

4.7.3.4 A patient may always be removed from treatment whenever he/she wishes.

4.7.4 Ancillary treatments. If applicable, specify concurrent treatments that are not allowed.

4.8 Assessment of Efficacy and Safety

4.8.1 Side effects/Toxicities to be monitored.

4.8.1.1 List all side effects/toxicities that the patient is to be asked about at each evaluation while on treatment and those to be measured.

4.8.1.2 Long-term toxicities to be monitored after completion of therapy. List side effects/toxicities and define levels.

4.8.2 Dosage change based on toxicity. Dosage change (increase and decrease) should be either given in a table or clearly described in this section. Include instructions on restarting treatment after delays due to toxicity.

4.8.3 Adverse Event Reporting: Procedures for reporting unexpected and fatal toxicity should be explained.

4.8.3.1 Type of event to be reported and timing of reports

4.8.3.2 Places for submitting reports: IRB, Sponsor, Investigational Drug Branch, etc.

4.8.3.3 Data Monitoring Committee (if applicable)

4.9 Clinical and Laboratory Evaluations and Study Calendar

The Study Calendar is included in a chart on a separate page. These calendars should outline every parameter/test which will be performed while the patient is on the study, along with the
actual therapy. Write it so that it can be copied for each patient and used by the nurse/data manager/physician for patient management.

Categories to be listed are as follows (in this order): Physical; Laboratory; Disease Assessment; Treatment; and Forms submission. Every test, whether it is being done pre-study only or continuously throughout the study should be noted. It is not necessary to list every day or week throughout the life of the study; rather, only those days in which either therapy or tests are being performed. Asterisk and footnote special instructions. All tests that will be continued after the patient stops therapy should also be indicated, along with the time point at which they should be performed.

An example of the Study Calendar is as follows:

(Example)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Pre-Treatment</th>
<th>Day 3</th>
<th>Each cycle (Day 1)*</th>
<th>End of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comprehensive History &amp; Complete Physical Examination</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Targeted History &amp; Directed Physical Examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete Blood Count (CBC)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Monitoring Chemistry Panel</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver Enzyme Tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinalysis</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Electrocardiogram (EKG)</td>
<td>X</td>
<td>X(^1)</td>
<td>X(^1)</td>
<td></td>
</tr>
<tr>
<td>Chest x-ray &amp; scans</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agent administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood for research testing</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) As clinically indicated.
* Each cycle consists of XX days with treatment on Day 1.

4.10 Criteria for Evaluation and Endpoint Definitions

The outcome status (in terms of toxicity, response, reason off study, progression, and survival) of all eligible patients will be reported. All eligible patients who begin treatment will be included in the analysis of survival and time-to-failure.

Endpoint Definitions:

4.11 Special Instructions
This section should include detailed descriptions of how specimens for pharmacokinetics, pharmacodynamics, correlative molecular studies, or other translational studies will be obtained, transported, shipped, and assayed.

4.12 Data Collection and Monitoring

This section should include the following information: Case Report Forms; Source Documentation and Timeliness of CRF Completion; Retention of Study Record; Data Management; Data Monitoring. Provide details on the type and timing of data collection, the types of data being collected, the protection of protected health information (PHI), the secure collection and storage of research data, and management of access to research data.

4.13 Statistical Analysis Plan

4.13.1 The statistical section will typically include:

- A recapitulation of study objectives
- The anticipated accrual rate, the accrual goal for the study, including accrual goals by strata, if appropriate
- The study design, including contingencies for early stopping, any stratification factors, and any characteristics to be incorporated in analyses
- The power of the study to address the major objective(s), the assumptions involved in the determination of power, tables of power under various alternatives
- The power of the study to address the other objective(s), the assumptions involved in the determination of power

In order for a statistician to write this section, the investigator must supply the statistician with an expected accrual rate, reflecting recent experience with the disease; certain background information for each study objective; and basic assumptions, if necessary, to create a basis for statistical analysis (e.g., assume the new regimen will produce an 80% response rate). For non-comparative studies with the objective of ESTIMATING toxicity, response rate, survival time, response duration, time to progression, etc., the statistician will need at least an idea of the expected rate (duration) and the desired precision of the estimate. Useful information to provide would be results from other studies. If the objective is to evaluate an endpoint, specify what values would be of interest or not of interest to discern with the study. If there is a translational component to the study, indicate how the statistical analysis/correlation will be done.

For randomized studies with the objective of COMPARING two or more groups, then in addition to the expected results for each group, a minimum difference of clinical interest to be detected should be specified.

If a SUBSET of the patients accrued to the study is identified for separate analysis in an objective, the proportion of patients expected to qualify must be given (examples are patients without a specific prior therapy or responders when looking at duration of response). Again, background information about this patient subset is desirable.
Since the objectives section and the statistical section should correspond, any objective for which analysis is unfeasible should be deleted. Also, the estimates and non-statistical assumptions of the statistical section should be supported by discussion in the background section.

4.13.2 For randomized studies comparing a new therapy to a standard therapy, a separate paragraph is required to show that the analysis will lead to valid conclusions about minorities and/or women. Consult statistician.

4.14 Registration Guidelines

4.14.1 Specify phone number to register the patients. Also identify whether the patients will be randomized or stratified.

4.14.2 Specify the forms and records needed for registration: Informed Consent, Registration/Eligibility Worksheet, Flow Sheet, etc.

Note: At the time of registration, two copies of a signed and dated patient Informed Consent form with Bill of Rights must be available (an original for patient’s medical chart; one copy for the patient, and the other for the PI’s file).

4.15 Biohazard Containment

Describe how to deal with biohazard materials. Describe Radiation Safety Committee and/or Biohazard Committee activities, if applicable.

4.16 Ethical and Regulatory Considerations

The following statement should be included in this section: All institutional and Federal regulations concerning the Informed Consent form will be fulfilled. The study will be conducted in adherence to ICH Good Clinical Practice.

4.17 References

4.17.1 All references should be numbered and listed in the order that they appear in the protocol. The general rules to be followed when listing these references are outlined below:

A. Punctuate names only by a comma between complete names; no internal punctuation (Coltman CA Jr, Knight WA III).

B. Capitalize only the first word in the title of an article or chapter, unless there are proper names included (drugs, people, etc.)

C. Follow the names of the authors with a period before the title of the article.
D. No punctuation is needed between the journal name and year of publication.

E. Always include the page numbers of the article, volume number, and year of publication.

F. Double space between each complete citation.

Examples:


4.18 Appendices

(Include any desired tables, scales, questionnaires, etc.)

Appendix I: Toxiciy Scale (if applicable)
Appendix II: Informed Consent, Parental Permission, Child &/or Adolescent Assent (if applicable)
Appendix III: Questionnaires &/or Survey Forms (if applicable)
5 The HIPAA Privacy Rule

5.1 What Is the HIPAA Privacy Rule?
The Health Insurance Portability and Accountability Act privacy regulation (HIPAA Privacy Rule) is a new law that went into effect April 14, 2003. The law generally prohibits health care providers (such as health care practitioners, hospitals, nursing facilities, and clinics) from using or disclosing "protected health information" without written authorization from the individual. "Protected health information" is any identifiable health information relating to the individual's past, present, or future physical or mental health condition, or payment for health care. Examples of protected health information include:

- medical records
- billing records

The HIPAA Privacy Rule creates a federal standard for protecting the privacy of health information, which is in addition to existing state laws.

5.2 How Does HIPAA Affect the Use of Health Information for Research?
Currently, many researchers collect and use protected health information in their research projects. For example, researchers may review medical records to screen and recruit potential subjects. In other cases, researchers may need past or current patient health information to conduct clinical trials.

The HIPAA Privacy Rule generally prohibits health care providers from using or releasing protected health information (PHI) for research purposes unless the patient has given prior written authorization to the provider permitting the disclosure of such information. For example, AOMA researchers generally will not be permitted to obtain medical records or other patient identifiable information from their respective clinical departments for research purposes (e.g., clinical trials) without a patient’s authorization, unless an exception applies (described below). This also means that researchers will not be able to obtain patient records (including records from AOMA's hospital partners) or records of community practitioners for research purposes unless the patient whose health information the researcher is attempting to obtain has authorized the release of the requested information. The regulations are specific as to what provisions must be included in the authorization for it to be valid.

Examples of when authorizations generally will be required include:

- Clinical trials
- Database research (e.g., using or disclosing protected health information maintained in a database for research purposes)
- Enrollee recruitment (if the health information belongs to a non-AOMA provider, such as a non-AOMA physician or a hospital or clinic, unless the researcher obtains an IRB waiver as discussed below)

Although the regulations permit researchers to integrate the authorization requirement into their informed consent documents, state law does not. Therefore, it will be necessary to
append a HIPAA-compliant authorization to your informed consent document and have the subject sign and date the HIPAA authorization separately. AOMA has prepared HIPAA-compliant template language to append to your informed consent documents that satisfies this authorization requirement. Additional information is included later in this document.

5.3 Is an Authorization Required to Obtain PHI for Research?
As a general rule, an authorization is required before a health care provider can use or release protected health information for research purposes. However, there are several exceptions. Those are:

- **De-identification.** The information is "de-identified" prior to transfer from the care provider so that no non-providers can identify the patient with the protected information. The HIPAA Privacy Rule contains eighteen categories of information that must be removed from the information for it to be "de-identified," including direct or facial identifiers, ZIP Codes, dates of services, dates of birth and death, and geographic information.

- **Limited Data Set.** The information is limited to a "limited data set" and the recipient signs a data use agreement. A limited data set must not include direct or facial identifiers like name, Social Security number, full-face photos, or medical record number. A "limited data set" may include, however, ZIP Codes, dates of service, dates of birth and death, and geographic information. A researcher obtaining a limited data set must sign a data use agreement, which identifies and limits the permitted uses of the information, restricts who can use the data, and requires the recipient to agree not to re-identify the data or contact the individual.

- **IRB Waiver.** The need for patient authorization is "waived" by the IRB, based on a determination that the research could not practically be conducted without the waiver and there are adequate protections to minimize the subject’s privacy risks. The authorization waiver criteria are similar to the criteria for waiving informed consent.

- **Preparatory to Research.** The activity qualifies as "preparatory to research." The researcher must certify in writing that all of the following criteria are met:
  a) the protected health information is used only to prepare a research protocol
  b) the protected health information is not removed from the AOMA premises
  c) the protected health information requested is necessary for the research purpose
  This exception may be used by AOMA researchers to access AOMA-owned records to recruit subjects to a research protocol provided the above criteria are met. This exception cannot be used to recruit subjects in those cases where the records are not AOMA’s (e.g., records maintained by AOMA’s hospital partners).

- **Decedents Research.** The researcher is accessing information solely on decedents. The researcher must certify in writing that all of the following criteria are met:
  a) the patient is deceased
  b) the research is solely on deceased patients
AOMA IRB

c) the use of the protected health information requested is necessary for the research

5.4 How will the HIPAA Privacy Rule be implemented at AOMA?

5.4.1 HIPAA Education
Prior to submitting new protocols or applications for continuing review to the IRB, all AOMA faculty members, staff and students who conduct human subjects research and use protected health information MUST complete an educational program about the HIPAA Privacy Rule. AOMA has developed an online educational program to comply with the HIPAA Privacy Rule's mandate. The program can be accessed through the AOMA Office of Compliance website at www.AOMA.edu/compliance. You will receive a certificate upon completing the program, which should be provided to the IRB as proof of completion.

AOMA faculty, staff, and students involved in the conduct of human subjects' research must complete AOMA's web-based HIPAA education program before submitting new protocols or applications for continuing review to the IRB.

The IRB will not approve new or continuing proposals for projects that use protected health information unless the investigators of the project and their research staff have completed AOMA's HIPAA educational program.

5.4.2 HIPAA Requirement for PHRP
AOMA researchers are required to comply with the Health Insurance Portability and Accountability Act privacy regulation (HIPAA Privacy Rule) regarding the confidentiality of protected health information (PHI).

The HIPAA privacy regulations will immediately impact you in the following ways:

5.4.2.1 Identifiable Protected Health Information (PHI)
The Informed Consent documentation must include a HIPAA-compliant provision for all subjects enrolled in any protocols on or after April 14, 2003. Template provisions and other information about this requirement are discussed in section 6 as well as in the application.

5.4.2.2 HIPAA Authorization and Informed Consent
A patient's written authorization for use of his/her protected health information must contain specific language under the HIPAA Privacy Rule.

The AOMA has developed appropriate language to fulfill these requirements. The document is available electronically by request from the Compliance Office, 512-454-1188.

Researchers should attach the HIPAA authorization as an addendum to their existing informed consents. Specifically, the document titled "HIPAA Authorization Addendum to Informed Consent" should be stapled to the last page of the informed consent document, and the subject's signature and the date of signature should be obtained on both documents (the informed consent document and the addendum).

The IRB will provide additional guidance on how to incorporate the HIPAA authorization into the informed consent documentation.
5.5 What Do I Do Once I Obtain a Patient's Informed Consent or an IRB Waiver of Authorization?

If you need to obtain medical records or other protected health information from a health care provider, you should provide a copy of the signed informed consent document and authorization to the provider, OR, if you or the patient do not wish to provide a copy of the informed consent, you should ask the patient to sign an "Authorization to Release Existing Medical Records," which can be provided directly to the health care provider. Copies can be downloaded from the IRB or compliance websites or the AOMA policies website.

If the IRB has waived the need for an authorization, you should provide a copy of the authorization waiver to the health care provider (or applicable medical records department).

5.6 HIPAA Authorization Inquiries

Please contact the AOMA Office of Compliance at 512-454-1188 if you have any other questions or need further details about the HIPAA Privacy Rule and their relevance to AOMA researchers. In addition, please refer to the Office of Compliance website for further information and guidance regarding the HIPAA Privacy Rule and AOMA's implementation efforts. We will continue to provide you with relevant information in the coming months.
6 Introduction to Informed Consent

The purpose of this guide is to assist the investigator on how to prepare and obtain valid informed consents from prospective research subjects. The IRB informed consent requirements are based on the Department of Health and Human Services (DHHS) Regulations 45 CFR 46.116; Food and Drug Administration (FDA) regulations 21 CFR 50.25; and the Nuremberg Code and the Principles of the Declaration of Helsinki.

“To respect autonomy is to give weight to the autonomous persons considered opinions and choices while refraining from obstructing his or her actions...”
—Belmont Report

6.1 Principle of Informed Consent

The Belmont principle of respect for persons is primarily applied by requiring that all human subjects’ research participants provide voluntary informed consent to participate in research. The three fundamental aspects of informed consent are:

Voluntariness
Individuals’ decisions about participation in research should not be influenced by anyone involved in conducting the research: “...consent must be freely given or truly voluntary.”

Comprehension
Individuals must have the mental or decisional capacity to understand the information presented to them in order to make an informed decision about participation in research.

Disclosure
HHS regulations (45 CFR 46.116(a)) require that researchers disclose:
   i. The purpose of the study
   ii. Any reasonably foreseeable risks to the individual
   iii. Potential benefits to the individual or others
   iv. Alternatives to the research protocol
   v. The extent of confidentiality protections for the individual
   vi. Compensation in case of injury due to the protocol
   vii. Contact information for questions regarding the study, participants’ rights, and in case of injury
   viii. The conditions of participation, including right to refuse or withdraw without penalty
   ix. This disclosure must be made in such a way that it provides a reasonable person the information she or he would need in order to make an informed decision
   x. The HHS regulations (45 CFR 46.116) require that investigators obtain legally effective informed consent from prospective participants in a way that allows them to consider whether or not to participate and that minimizes the possibility for coercion or undue influence
   xi. Potential participants must understand that enrolling in the research is voluntary and that they may withdraw from the study at any time without penalty or loss of benefits
xii. In order for participation in research to be voluntary, the potential for coercion and undue influence must be minimized.

The complexity of both the consent form and the process of informed consent will vary according to the nature of the research and the level of associated risk. Thus, while the principle of informed consent remains constant – i.e., "respect for a person's autonomy" – the requirements for informed consent are less rigorous for less-than-minimal risk studies as opposed to minimal risk or greater-than-minimal risk research. The IRB allows investigators considerable latitude in designing the consent form to be used in any exempt research that ethically requires written informed consent. However, consent forms for non-exempt research must conform to all the requirements stated in these guidelines, unless a waiver is granted by the IRB. This document provides the current provisions required for developing an informed consent. Alterations or waiver of any elements must be specifically reviewed and approved by the IRB.

6.2 Minimal Risk

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

6.3 Exempt Research

Exempt research means projects in which the only involvement of human subjects will be in one or more of the following research categories, unless the project involves research which includes vulnerable subject populations such as prisoners*, or children** as research subjects [45CFR46.101b]:

i. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   a. research on regular and special education instructional strategies, or
   b. research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods

ii. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified directly, or through identifiers linked to the subjects

iii. Research involving survey or interview procedures, except where all of the following conditions exist:
   a. if the subjects responses became known, they could place the subject at risk of criminal or civil liability, or be damaging to the subject's financial standing or employability
   b. the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol

iv. Research involving survey or interview procedures when the respondents are elected or appointed public officials, or candidates for public office

v. Research involving the observation of public behavior, except where responses are recorded in a manner that subjects can be identified, and
a. if the subject's responses became known, they could place the subject at risk of criminal or civil liability, or be damaging to the subject’s financial standing or employability, or

b. the research deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol

vi. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified

vii. Prisoners* (45CFR46 Subpart C): The exemptions do not apply to research involving prisoners

viii. Children** (45CFR46 Subpart D): Exemptions (1) and (3) through (6) are applicable. Exemption (2) regarding educational tests is also applicable, but for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

6.4 The Informed Consent Process

The investigator has a legal and an ethical obligation to ensure that the prospective subject has sufficient knowledge and understanding of the elements of informed consent. This means the prospective subject must be able to make an informed, educated, and enlightened decision to participate in the particular research study. Obtainment of valid informed consent should be accomplished by using a simple but complete IRB-approved consent form written in “lay language” (i.e., language understandable to the subjects invited to participate). The consent form, however, does not by itself constitute informed consent. The consent document is a written summary of the information that should be provided to the subject, and can be used as a guide for the verbal explanation of the study.

The entire informed consent process involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject to consider all options, responding to the subject’s questions, ensuring that the subject has comprehended this information, obtaining the subject’s voluntary agreement to participate, and continuing to provide information as the subject or the situation requires.

In some cases, the consent process should be extended over several days and involve other individuals such as the prospective subject’s spouse, nurses, and other ancillary personnel. It must, however, be remembered that the principal investigator bears full and ultimate responsibility for obtaining valid informed consent from the subject.

During the consent process for enrollment of a subject in non-exempt research, the investigator should explain to the subject his/her rights as a research participant as summarized in the Experimental Subject’s Bill of Rights (see page 31).

6.5 Documentation of Informed Consent
After the investigator has determined that the prospective subject has sufficient knowledge and comprehension of each element of consent, the subject should voluntarily sign and date the consent form in the presence of the investigator and a witness (if required). The research subject should date the consent in his/her own handwriting. This date should indicate the subject consented to enter the study at a point prior to the initiation of his/her participation in the study. If the date the subject signs the consent is the same as the date of the initiation of his/her participation, a statement should be made to clarify that the subject signed the consent prior to the initiation of his/her participation in the study. At AOMA, the signature of a witness is required for all research studies involving greater-than-minimal risk. This requirement adds legal protection for the investigator and the institution.

The investigator should sign and date the consent form in the presence of the subject and the witness (if required). It is recommended that either the principal or co-investigator sign the consent form. If someone other than the principal or co-investigator conducts the interview and obtains consent, this responsibility must be formally designated by the principal investigator in the IRB application form and agreed to by the IRB. Professionally qualified participating personnel may sign a consent form for a given research protocol only if they possess sufficient information about the research protocol. In general it is preferred that they be legally authorized, according to professional licensure, to obtain informed consent for the specific procedures involved in the research. For example, an RN may not be appropriate to obtain consent for an investigational drug study but would normally be authorized to obtain consent for procedures such as routine venipuncture and non-invasive monitoring. All participating personnel can, however, be extensively involved in the process of informed consent; i.e., explanation of the research and preliminary assessment of the prospective subject’s level of comprehension. The IRB requires that all personnel complete a human Subjects Education course before their involvement in any Informed Consent process.

A copy of the signed informed consent form should be given to the subject, a copy should be retained by the investigator, and, if the study involves medical research, a copy should be placed in the medical record.

**6.6 General Requirements on Informed Consent Form**

**6.6.1 Stationery**
Consent forms must be printed on the stationery where the research will be conducted. If the research will be conducted at more than one location, it is acceptable to include the address and telephone number for each location at the top of each page of the informed consent.

**6.6.2 Identification**
In order to readily identify the type of consent form, one of the following labels should be placed at the top of the first page where applicable: "Adult Informed Consent Form"; "Parental Permission (Consent) Form"; "Youth Assent Form"; or "Child Assent Form".

**6.6.3 Style**
The informed consent form should be written in the second person throughout (e.g., you are invited to participate; you will be assigned, etc.). This second-person writing style helps to communicate that there is a choice to be made by the prospective subject. Use of the first
person ("I understand that") may be interpreted as suggestive, and can constitute coercive influence over a subject.

If the consent form will be used for parents or other legally authorized representatives consenting on behalf of a minor or other legally incompetent subject, the consent form should be written in a style that reflects the fact that the consenter is specifically agreeing to allow the subject to participate in the study.

6.6.4 Readability
The most common deficiency in the consent form is the inability of a lay person to understand the document. The informed consent form must be written in simple enough language so that it is readily understood by the least educated, least sophisticated of the subjects to be used. It is recommended that the language consist of short concise sentences arranged in relatively short simple paragraphs. Medical or scientific terms should be avoided; when necessary, they should be defined and explained. Common words in science or medicine, such as catheter, intravenous, prognosis, symptomatology, randomly assigned, efficacy, placebo, blinded, cognitive style, attribution, social sufficiency, maximal oxygen consumption, isokinetic, or isometric require simplification. If there is any doubt that a term may not be understood, a simpler term should be used. If possible, an Informed Consent’s reading grade level should be at or lower than 8th grade.

Rather than abbreviating such words as teaspoon and tablespoon, spell them out. Rather than using ml or cc as a volume representative, give a volume equivalent in teaspoons or tablespoons. Use the conversion of 5 ml (or cc) = 1 Teaspoon; 15 ml (or cc) = 1 Tablespoon. Define acronyms such as “COPD” and “GVHD” the first time used before referencing the abbreviation throughout the text. Do not use symbols such as “>”; use “greater than”. Describe study design procedures such as “double blind”, “randomized”, and “placebo controlled” when the concept(s) is/are first introduced. Keep sentences simple and short when possible.

6.6.5 Length
The informed consent form should be lengthy enough to explain consent factors adequately, but not so lengthy or detailed as to lose the attention of the subject or to cause confusion. Consent forms should be printed single-sided and single-spaced. Signature blanks should not be placed on a separate page without the presence of any of the preceding elements of informed consent. All informed consents should have 1-inch margins. Each page of the consent form should be full (i.e., sections can be split with some information on one page and the remainder on the next page) so that large blank areas do not exist. All pages of the informed consent must be numbered (using the approach “page x of y”), and contain a version date.

6.6.6 Format
If the research is exempt but requires written informed consent (e.g., an educational study requiring parental permission) or if the research involves procedures which are clearly less-than-minimal risk (refer to definition of minimal risk, Glossary of Terms), a narrative consent form format may be used at the discretion of the investigator. This means that all necessary elements of consent should be present on the consent form, but the elements need not be
identified by subheadings. In addition, the simplified concluding consent statements for exempt/less-than-minimal risk research may be used.

If the research involves procedures which are minimal risk or greater (refer to definition of minimal risk, Glossary of Terms), the consent form format described below must be used. All required elements must be identified by the appropriate subheadings as listed below in Elements of Informed Consent. In addition, the Informed Consent Agreement statements for research which is minimal risk or greater must be used.

6.6.7 Exculpatory Language
The informed consent form must not contain any exculpatory language through which the subject or the subject's representative waives or appears to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

6.7 Elements of Informed Consent
The elements of informed consent represent the information that must be provided to each subject as per 45 CFR 46.116 and 21 CFR 50.25. In order to increase the subject's ability to understand the informed consent document, the consent form should be written to include the appropriate elements of consent in the same sequence as described in this document.

If the research is classified as minimal risk or greater, each element should be identified by the listed subheading in bold type. Use of a subheading increases readability and helps the prospective subject focus attention on each element of consent. Subheadings are not, however, required for exempt research or research classified as less-than-minimal risk because, in general, this kind of research is less complex. If, however, an investigator of such a study prefers to use subheadings to increase the readability of the consent form, this is entirely acceptable.

The informational content of the elements should normally not be mixed or repeated unless necessary. Information presented under any given element should be complete and restricted to content appropriate to that element. When an element has a standard statement, the consent form should include the standard statement.

6.7.1 Title of the Research Study
In order to facilitate maintenance of records, the identical title should be used on the IRB Application, protocol, and consent forms. It is important for subjects to be aware of the official title of the research study, even if it is written in scientific terms.

6.7.2 Identification of the Investigators
The Identification of the Investigators section of the consent form should be placed at the top of the form. In this section the name, professional degree(s), school, department, and telephone number(s) of the investigator(s) must be provided. Investigators should be classified as Principal Investigators or Co-Investigators. For research studies involving greater-than-minimal risk, the emergency phone number(s) of the investigator(s) must be provided. All research projects conducted by students, interns, residents, and Fellows must list the student's advisor as a co-principal investigator. Since it is the responsibility of the advisor to supervise the
student’s research project, classification of the advisor as a co-principal investigator provides a clear indication of that responsibility.

Federal Regulations specify eight basic general requirements and six additional elements for Informed Consent (45CFR46.116 and 20CFR50.25). AOMA’s Sample Informed Consent was developed based on these requirements. For a copy of the Sample Informed Consent, go to an IRB website.

6.7.3 Why Is This Study Being Done? (General Requirement)
Under this subheading the following should be included:
   a) An invitation to participate
   b) A statement that the study involves research
   c) An explanation of the purposes of the research. This should be restricted to a clear and accurate statement of the scientific purpose or objectives of the research. This should help the subject assess the importance of the study relative to individual values. When appropriate, this statement should include not only the immediate purpose of the study, but also any larger, ultimate purpose. The purpose of the study statement should not reflect a potential benefit that may accrue to the subject or be directed toward the subject in any way.
   d) If applicable, the purpose of the study section should also include the FDA status of any study drugs or medical devices.
   e) If applicable, the purpose of the study section should state whether or not the procedures being tested are experimental.
   f) A statement concerning why the subject is selected or eligible to participate
   g) When appropriate, criteria for subject exclusion should be stated.
   h) When appropriate, the approximate number of subjects involved in the study. (In the case of multi-center protocols, provide the total number of subjects, in addition to the number of subjects to be enrolled at this site.)

The following text should be used:
“We invite you to take part in a research study. This study is about ___________. We hope to learn __________. You are invited as a possible participant, because __________. About ____ subjects will take part in this study.”

If the study involves deception or the withholding of information as a necessary and justifiable research strategy, the purpose of the study statement should be written in such a way whereby the least possible deception and/or withholding of information occurs.

6.7.4 What Is Involved in the Study? (General Requirement)
Describe the procedures chronologically using simple language, short sentences, and short paragraphs. The use of subheadings helps to organize this section and increases readability. This section should be restricted to a description of the procedures only, without including information that belongs in other sections of the informed consent. In general, the Procedures section of the consent form should include the following:
   a) A description of the study design. If appropriate, include a description of double-blind such as: “You will not know which drug you are receiving, and neither will your doctor.
In an emergency, you and your doctor can find out which drugs you have received.” If a placebo (“pill or liquid without medication”) or control group will be used, it should be defined.

b) Method of subject assignment to groups and probability of assignment. If applicable, discuss and define randomization (“drawing/pulling a number from a hat”). It should be stated if the subject’s chances of receiving any of the treatments are equal. Despite the fact that subjects may be kept unaware of treatment assignments in blinded studies and research involving placebos, subjects must be made aware of all the possible interventions and the method of assignment.

c) A sequential description of each procedure used and how often it will be performed. Define the length of time for participation in each procedure, total length of time for participation in the study, frequency of procedures, and the location of procedures. All procedures, both experimental and non-experimental, must be disclosed and described. Procedures that are experimental or performed for research purposes only should be identified as such. It should be easy for the subject to identify and understand which procedures are standard-of-care versus those procedures performed for research purposes. It may be appropriate to identify the individual(s) who will perform the procedures in some research projects. The Procedures section should not contain detailed instructions to the subject that do not impact significantly on the consent process. Detailed instructions should be placed on a separate handout and referenced in the informed consent.

d) If appropriate, a statement concerning any medications or other substances that are contraindicated/disallowed either before or during participation in the study, including a clear description of any drug "washout" period.

e) For some studies it is appropriate to sequentially list the visits and what will be done at each visit.

f) If the research study involves incomplete disclosure or deception, all subjects must be debriefed as soon as possible after participation. The consent form for non-disclosure/deception studies should normally contain a statement concerning when and where the debriefing session will be held.

g) If the study involves research specimen testing, including genetic testing, an appropriate description of disclosure of the results of the research testing should be provided:
   a) criteria for disclosure: if the results are of material interest to the subject, or an explanation of why the subject will not be informed
   b) the process of disclosure: disclosure of the results to other parties, including physician or family members, and how disclosure of results to minors will occur, if appropriate

The following text should be used to initiate this section:
“If you decide to take part, this is what will happen: (describe the procedure(s) to be followed, how long the procedure(s) will take and the frequency – see above details).”

6.7.5 Information about Tissue and/or Fluid Samples Collected as Part of This Research

The consent should disclose if specimens (blood, tissue, etc.) are collected as part of the research or excess tissue from routine tests are used. If the specimens are to be stored for future research, this should be disclosed. A check box should be considered for the subjects to
indicate their consent. Whether the subject’s consent will be sought for this and how confidentiality will be maintained should also be disclosed.

If specimens collected as part of the research (blood, tissue, etc.) are to be shared with other researchers or other studies, this should be disclosed and the subject specifically asked to indicate permission whether they agree to the sharing of specimens with other researchers. A check box should be considered for the subject to indicate their consent. If information concerning the study subject will be provided to the other researchers, it should be disclosed. Whether the subject’s consent will be sought for this and how confidentiality will be maintained should be disclosed. Whether or not results of research testing of the specimens will be given to the subject or their physician should be disclosed. If appropriate include:

“You (and your doctor) will not learn the results of research testing. Your doctor will not use these results to plan for your treatment, since we do not yet know how to apply these results to the treatment.”

If a cell line is established as part of this research, include:

“Cells from your body may be used to start a cell line. A cell line is one that will grow in the laboratory. This cell line may be shared in the future with other researchers.”

6.7.6 What Are the Possible Risks and Discomforts? (General Requirement)

A risk is the potential for harm or injury associated with the research that a reasonable person, in what the investigator knows or should know to be the subject’s position, would be likely to consider significant in deciding whether or not to participate in the research. The concept of risk includes discomfort, burden, or inconvenience that a subject may experience as a result of the research procedures. There are five major types of risks to be considered:

a) physical risk - pain and bruising from venipuncture; side-effects from drugs; or a heart attack induced by a maximal-exercise test
b) psychological risk - depression or confusion as a side effect of drugs, feelings of guilt precipitated by a sensitive questionnaire
c) social risk - invasion of privacy, loss of standing in the community
d) legal risk - criminal prosecution or revocation of parole
e) economic risk - loss of employment or loss of potential monetary gain

Disclosure of risks should be based upon what a reasonably prudent person might wish to know. Consent to participate in research demands a higher standard of disclosure of risks than consent to medical treatment. A material risk approach discloses anything that a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to in deciding whether or not to forego the proposed therapy. A material risk approach, which requires disclosure of the risks based upon the information a patient needs to make an informed decision whether or not to undergo the proposed therapy is more appropriate than disclosure of “reasonably foreseeable risks.”

When a procedure inherently involves a known risk of death or serious bodily harm, the potential research subject must be informed of all but extremely remote risks. If the potential injury is slight, then the research subject needs to be informed only of those risks which might well occur.
Nondisclosure of potential risks based upon a physician's judgment that it is not in the patient's best interest to know is not acceptable in the research setting.

Disclosure of the risks of research is linked to the therapeutic alternatives—enabling the potential subjects to determine for themselves the direction in which they believe their interests to lie.

Risks should not be understated or overstated. In some cases it is appropriate to cite statistical probability of risk occurrence, risk prevention measures, reversibility, and how these will be managed (treated). Where possible, the quantified comparative estimates of risk and benefits should be included. The most serious and common risks should be addressed first, followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Both immediate and latent risks of each procedure/intervention carried out for research purposes should be clearly described. It is often advantageous to also disclose the risks of procedures carried out solely for therapeutic purposes with an appropriate qualifier.

The terms less-than-minimal risk, minimal risk, greater-than-minimal risk, and significant risk should not be used in the consent form. If there are no known risks (including discomfort, burden, inconvenience), this should be so stated (e.g., "There are no known risks associated with this research") as opposed to "There are no risks associated with this research"). In some research projects the consent form should state “There may be risks associated with the research that are currently unknown” or “There may be other risks that the investigators did not expect. The investigators will monitor to see if you are experiencing any other risks.”

6.7.7 What about Pregnancy? (Additional Element)

If appropriate, include a statement that the particular treatment or procedure may involve risks which are currently unforeseeable to the subject or to the embryo or fetus, if the subject is or may become pregnant:

“We do not know whether this study drug/procedure might hurt your unborn baby. If you are pregnant, you may not be able to take part in this study. If you are a woman who could become pregnant, you must have a pregnancy test to make sure you are not pregnant. You must use birth control while on this study. These are some birth control methods that you can use:“

“If you are breastfeeding, and do not want to stop, you may not join this study. The only way you can take part in this study is to stop breastfeeding and not use your breast milk to feed your child until your doctor tells you it is safe.”

Research that involves genetic testing (either as a direct result of the research, or as a result of incidental findings) may include the risks of: psychological or emotional burden at being informed of a potentially serious genetic defect or predisposition; impact on family relationships; discrimination in employment and insurability; and psychosocial impacts upon disclosure of false negative or false positive results (i.e., foregoing potentially preventive, screening, or therapeutic interventions, or undergoing potentially harmful preventive, screening, or therapeutic interventions).
6.7.8 What Are the Possible Benefits of Taking Part in This Study? (General Requirement)

The consent form should state whether there are any direct benefits to the subject that may reasonably be expected as a result of participation in the study. Examples of direct benefit to the subject include treatment of an illness, or knowledge of value to the subject. The potential benefits to the subject must not be overstated, coercive, or guaranteed. If there are no benefits to the subject, it should be so stated. The following text should be considered:

“The possible benefits for you to take part in this study include..... However, we cannot promise that you will benefit from taking part in this study.”

State the benefit(s) to society in terms of advancement of medical knowledge and/or ultimate possible therapeutic benefit to future patients. If there are no personal benefits to the study subject, it is suggested to state:

“You are unlikely to benefit from taking part in this study. We hope the information learned from this study will help us understand _____ in the future.

The Benefits section of the consent form should not describe financial compensation or other forms of remuneration. Compensation should be described only under the Compensation section of the informed consent document.

6.7.9 What Other Options Are There? (General Requirement)

The consent form must state any therapeutic alternatives available to the subject in the non-research and/or research context that may be of reasonable benefit to the subject. Describe appropriate alternative therapeutic, diagnostic, or preventive procedures that would be offered to the subject if they decide not to participate in the study, if applicable. Any standard treatment that is being withheld must be disclosed.

For patients in palliative care:

- If prospective subjects are suffering from a terminal illness, and there are no alternative treatments available, it should be so stated.
- Do Not Resuscitate (DNR) documents must be followed.
- The individual holding power of attorney on behalf of a patient has the right to determine the course of action.
- There must be a statement to the effect that treatment of symptoms and pain control are available through risks/benefits of the therapeutic alternative versus the research. It may be supportive care such as hospice, home health care, clinics, and physicians.
- Describe opportunities for managing symptoms, improving ability to function, etc., so that it does not appear as if the subject will be abandoned if he/she does not agree to participate in the research.

“There may be other treatment(s) for your disease. These include _____. Your doctor will explain their risks and benefits to you.”

“You may receive (study treatment or drugs) even if you do not take part in this study.”
In non-therapeutic research the consent form must state any alternatives which may be advantageous to the subject. In some settings it may be appropriate to state:

"An alternative would be to not take part in this study."

6.7.10 Will Your Information Be Kept Private? (General Requirement)
This section of the informed consent should state that any information obtained in connection with the study and that could identify the subject will remain confidential and will be disclosed only with the subject’s permission. The Confidentiality Statement should give a brief description of how personal information, research data, and related records will be coded, stored, etc., to prevent access by unauthorized personnel. Explain how specific consent will be solicited, if any other uses are contemplated. If the investigator intends to release any information, the standard statement of confidentiality should be modified to state the person(s) or agency to whom information will be furnished, the nature of the information to be furnished, the purpose of the disclosure and whether the subject’s name will be used. It is strongly recommended that a code be used as a subject identifier. When appropriate, the ultimate disposition of data should be described. If applicable, state if and when individual responses to survey questionnaires will be destroyed, following analysis of the data. If the study and the records are not subject to inspection by a funding agency, the Food and Drug Administration (FDA), or a sponsor, use the following:

“We will make every effort to keep your medical records for this study private as far as the law allows. We may publish in journals or present the information from this study at meetings. If we do, we will not use your name.”

If this study and the records are subject to inspection by a funding agency, the Food and Drug Administration (FDA), or a sponsor, use the following:

“The investigator and the Institutional Review Board (IRB) will keep your medical records private as far as the law allows. Officials sent by the Food and Drug Administration (FDA), the sponsor who is _____, or the funding agency who is _____ will look at your records. Unless otherwise required by law, your medical records will be kept confidential. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.”

If photographs, videos, or audio-tape recordings will be used, state how identity will be protected or disguised. Describe the subject’s rights to review/edit the tapes; who will have access; and when they will be erased. Describe how personal identifiers will be shielded, disguised, etc. If the research data are considered sensitive (e.g., HIV status of subjects, sensitive survey data), the standard statement of confidentiality should be modified by adding a description of the method(s) to be employed in order to preserve confidentiality (i.e., stored in a locked cabinet, etc.).

6.7.11 What Are the Costs? (Additional Element)
State the financial obligations of the subjects relative to their participation in the study, including responsibility for related care, hospitalization, physician and dentist fees, medication, pharmacy dispensary charges, laboratory tests, post-treatment follow-up. If the research includes interventions or additional hospitalization that could not reasonably be considered standard of care and, therefore, may not be covered by health insurance, it must be disclosed. If appropriate, itemize and estimate the charges that subjects participating in the research will be expected to pay if the charges are not paid by their insurance or third-party payer.
It should be outlined here if any procedures, exams, study medications, etc., will be provided to the subject free of charge. If there is the potential of additional cost to the subject as a consequence of procedures carried out for research purposes (e.g., extended hospitalization, additional tests), it must be disclosed. Possible texts include:

“If you take part in this study, your insurance company may not pay for some or all of the treatments and tests. If that happens, you need to provide for payment for these procedures, treatments and tests. (Provide as many details as possible.)”

Or

“The following (procedures, exams, study medications, etc.) will be provided to you free of charge.”

Or

“Neither you nor your insurance company will be billed for your taking part in this study.”

6.7.12 Are There Any Payments to You for Taking Part in the Study? (Additional Element)

Any compensation for participation should be clearly stated in this section of the consent form. Cash payments should be stated in dollar amounts, and any conditions such as partial payment or no payment for early termination should be stated. However, a prorated payment system should be used whenever possible.

The nature, amount, and method of payment of financial or other compensation must not constitute undue inducement of the subject (e.g., the compensation alone should not serve as sufficient inducement for the subject to volunteer). When establishing the amount/type of compensation, the investigator should consider the background and socioeconomic status of the subject population. Compensation for children involved in research is generally discouraged. Patient payment should be provided after each visit and cannot be withheld until the patient completes the study. As a general rule the IRB accepts that outpatients may be compensated up to $50.00 per visit, and subjects admitted for overnight stays may be compensated up to $300.00 per day. If the payment is for reimbursement, the investigator should get some verification of expenses for reimbursement (i.e., receipts for parking, babysitting, etc., or itemized expenses). If expenses are more than $75, receipts must be required for reimbursement. If the subject receives more than $600 per year for participating in one or more research studies, the research subject may receive IRS tax form 1099. However, this ($600) does not include any reimbursement payments.

If applicable, the following text should be considered:

“You will receive $_____ for travel and other inconveniences in taking part in this study. You will also be reimbursed for ______.”

“If you receive more than $600 per year for taking part in one or more research studies, you may be required to pay taxes on that money. This does not include any payments you may receive to reimburse you (pay you back) for certain expenses like parking fees. You may receive an Internal Revenue Service Form 1099 if you receive more than $600 in one year for taking part in one or more research studies.”
If no compensation is provided, then state that fact.

6.7.13 What Happens If You Get Injured or Need Emergency Care? (General Requirement)
For research studies involving greater-than-minimal risk, an Injury clause must be included in the consent form. If applicable, add a statement regarding the sponsor’s responsibility for research-related injuries as a result of study participation:
“If you get hurt or sick from taking part in the study, we will give you the medical care you need. You must pay for the care. You will not receive any compensation if you get hurt or sick.”

The standard compensation statements should not be used when a commercial sponsor has agreed to provide compensation for subject injury. If the commercial sponsor has agreed to provide compensation in case of injury to research subjects, the extent/limitations of the compensation should be stated clearly. The following statement should be considered and agreed to by the sponsor:
“If you are injured as a direct result of these research procedures, you will receive.... (explain the compensation for medical treatments that are available if injury occurs, and describe the extent and nature of the compensation or payment).”

For studies performed entirely or partially in the General Clinical Research Center, use this standard clause:

“You are participating in this study under the supervision of Dr. ________. Some or all of the study procedures will be performed in the GCRC. If you get hurt or sick from participating in the study, you will be offered treatment for the injury. Who will pay for the treatment depends on how and where it occurs. If the injury is from the study medication or procedures performed or directed by Dr. ______ or his/her staff, .... (PI TO STATE HIS/HER POLICY AND, IF APPLICABLE, SPONSOR RESPONSIBILITY). If you get hurt from a procedure performed by one of the GCRC staff that was not under the direction of Dr. ________ or his or her staff, the GCRC Advisory Committee will review your case and decide whether to pay for part or all of that care. The GCRC will not provide any other money for the injury.”

6.7.14 Will You Receive New Information about This Study? (Additional Element)
If appropriate the following separate standard statement must be included in this section of the consent form:
“During the study, we may learn new things about the risks or benefits of being in the study. If we do, we will share this with you. You might change your mind about being in the study based on this information. If new information is provided to you, we will ask for your agreement to continue taking part in this study.”

6.7.15 Under What Circumstances Can Your Participation Be Terminated? (Additional Element)
When appropriate, the consent form should state any anticipated circumstances (e.g., adverse reactions, non-adherence to protocol instructions) under which the subject’s participation may be terminated by the investigator or sponsor without regard to the subject's consent, such as:
“If you do not follow your doctor’s instruction, your disease gets worse, or the sponsor closes the study, you may be removed from this study. If this happens, your doctor (the investigator) will discuss other options with you.”
When appropriate, the consent form should state the consequences (e.g., medical/health) of a subject's decision to withdraw from the research.

6.7.16 What Are Your Rights as a Participant, and What Will Happen If You Decide Not to Participate? (General Requirement)
This section of the consent form must contain the following standard IRB non-coercive disclaimer:
“Your participation in this study is voluntary. Your decision whether or not to take part will not affect your future care at this institution. You are not waiving any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time.”

If applicable, add the consequences of a subject's decision to withdraw from the research study, and state whether withdrawal must be gradual for safety reasons. Also, list the procedures for orderly termination of participation by the subject.

6.7.17 Are There Any Potential Conflicts of Interest? (Additional Element)
A clinician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the clinician's professional judgment; and a clinician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of confidentiality. The nature of the interest must be included, such as a paid consultant, a lecturer, a board member, an equity ownership, a management or supervisory role in the sponsoring company, etc. Such conflicts should be referred to the Director of Research for resolution.

If appropriate include the following statements:
“AOMA, or the biotechnology company (provide the name of the company), may use your _____ for other research studies. Those studies may develop products that can be sold. If they make money from these products, you will not receive any money.”

“The investigators of this research do not have any financial interest in the sponsor or in the product being studied.”

“_____ has a financial interest in the company sponsoring this study. (Describe briefly your financial interest.) The nature of this financial interest and the design of the study have been reviewed by the institutional committees.”

If the investigator is getting financial support, other than study-related expenses, he/she must disclose that fact in this section. The study-related expenses should be described in the budget, which needs to be submitted to the IRB.

“The investigator (study clinician) is receiving _____.” (Describe briefly the nature of financial support other than study-related expenses from the sponsor.)

If the investigator is the treating clinician and he/she is getting financial support from the sponsor to conduct the study, then the following statement can be added:
“Your study clinician is receiving financial support from the study sponsor, __________, to conduct the study. (Describe briefly the nature of financial support from the sponsor.) As a researcher, the clinician is trying to improve your health condition and conduct good research at the same time. If you wish, you may get a second opinion about your care from another clinician who is not involved with this study. You are free to decide to not take part in any studies you may be offered by your healthcare provider.”

6.7.18 Whom Do You Call If You Have Questions or Problems? (General Requirement)
For all research studies involving greater-than-minimal risk, the following standard statement must be included in the consent form:
“You will be under the care of ___________MD at __________. You may contact your doctor or clinician with any questions about your care. If you have any questions about study-related problems, you should contact _______ at _________. If you have any questions regarding your rights as a study subject, you may contact the Institutional Review Board Office at 4701 WESTGATE BLVD., AUSTIN TX 78745. Phone: 512-454-1188. You will get a copy of this consent form.” If it is more appropriate for the subject to contact an emergency telephone number or other contact mechanism for in-patients, the above statement should be modified.

Use the following statement for non-treatment studies:
“You may contact _________ (clinician) at ____________ with any questions or concerns about this study. If you believe you have been hurt by taking part in this study, please contact _________ (clinician) at ___________. If you have any questions regarding your rights as a study subject, please contact the Institutional Review Board Office at 4701 WESTGATE BLVD., AUSTIN TX 78745. Phone: 512-454-1188. You will get a copy of this consent form.”

6.7.19 Informed Consent Agreement

The following text should be included in the agreement section above the signature lines:
“I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions were answered. I have decided to sign this form in order to take part in this study.”

<table>
<thead>
<tr>
<th>Name of Subject</th>
<th>Signature</th>
<th>Date Signed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Witness</td>
<td>Signature</td>
<td>Date Signed</td>
</tr>
</tbody>
</table>

The last section of the agreement is for the signature of the person who is obtaining informed consent from the study subject:
“I have personally explained the research to the subject (and the subject’s legally authorized representative) and answered any questions they posed. I believe that he/she understands the information described in this informed consent and freely consents to participate.”
If the subject recruitment process (e.g., mailed consent form) precludes use of the investigator's concluding consent statement, it should be omitted. If it is logistically impossible or unwarranted to ask the subject to sign and return the consent form, the subject's concluding consent statement should be modified as needed.

The date the consent form was approved by the IRB (date of official letter of approval and release) and the date when this form may no longer be used (annual expiration of study approval) will be placed by the IRB office below this section as soon as it is approved by the IRB. Investigators must use a photocopy of the document that has been stamped by the IRB.

### 6.8 Storage of Informed Consent Forms

Signed copies of informed consent forms for non-exempt research must be maintained by the principal investigator and be stored in a secure manner. Unless otherwise specified by Federal and/or state regulations, retention shall be for a period of at least three (3) years beyond the termination of the study. If the investigator resigns from the AOMA before the end of the designated period, the informed consent forms must be maintained by the department of record, unless otherwise specified.

If the subject is a hospital or clinic patient, a copy of the signed informed consent form must be placed in the patient’s medical records. Upon request and justification, exceptions will be made in sensitive research such as genetic testing.

### 6.9 Alterations and Waiver of Informed Consent

Under justified circumstances, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent; or the IRB may waive the requirements to obtain informed consent. Before a waiver can be issued for non-exempt research, the IRB must determine that all of the following conditions exist as per requirements of 45 CFR 46:116d:

a) the research involves no more than minimal risk to the subject  
b) the rights and welfare of the subject will not be adversely affected  
c) the research could not practicably be carried out without the waiver or alteration  
d) if possible, the subject will be fully informed after the project has been completed

This waiver does not apply to FDA-regulated research. Under 21 CFR 50.23 the FDA allows a waiver of informed consent only under emergency conditions. In other words, waiver of Informed Consent in FDA-regulated studies is permissible in the case of life-threatening situations, inability to communicate, not sufficient time and no alternative method, even if research presents more than minimal risk. In exempt research where informed consent would normally be required, the IRB will request that justification be provided by the investigator for a waiver.
As per 45 CFR 46:117c, the IRB may waive the requirement of the investigator to obtain a signed consent form for some or all subjects or their parents/guardians, if the IRB finds either:

a) the only reason linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; or

b) the research presents no more than minimal risk (as defined by 45 CFR 46:102i) of harm to subjects and involves no procedures for which written consent is normally required outside the research context. In exempt research where a signed consent form would normally be required, the IRB will request that justification be provided by the investigator for a waiver. Under justifiable circumstances, the IRB may waive its consent form format and style requirements.

Under justifiable circumstances, the IRB may approve a verbal consent procedure.

6.10 Consent/Assent Procedures for Research Subjects Who Are Children

Legally, children cannot give consent on their own behalf. The permission (consent) of their parent(s) or a legal guardian is, therefore, required before they can participate in any non-exempt (and some exempt) research projects. A minor may, however, with IRB approval, legally consent on his/her own behalf (as a mature minor) if the research involves a treatment for which a minor's consent is permissible under applicable law (e.g., use of contraceptives). If a subject under the age of 18 is legally declared to be emancipated, he/she may consent to participate in research.

If the research involves activities that are no-greater-than-minimal risk or of direct benefit to the child, consent of only one parent must be obtained. If, however, the research involves greater-than-minimal risk activities, consent of both parents must be obtained unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has the legal responsibility for the care and custody of the child.

In addition to the obtainment of parental/legal guardian consent, the investigator must also solicit assent of minor subjects age 7 or older, unless the subject displays intellectual/emotional development below that of the average 7-year-old child. Obtainment of assent shows respect for a child's developing autonomy.

In most circumstances, a child's deliberate objection should be regarded as a veto to their involvement in the research. However, parents or guardians may, with IRB and physician approval, override a young child's objections to interventions that hold the prospect of direct benefit to the child.

6.10.1 Parental Permission (Consent) Form

If the subject is under the age of 7, only a Parental (legal guardian) Permission (Consent) Form is required. The Parental Consent Form should include all relevant elements of informed consent as outlined previously and be written in a proxy consent style that indicates it is the parent or legal representative who is consenting to allow the minor to participate in the study. Note the modified standard statements.

6.10.2 Child and Youth Assent Form

If the subject is 7-17 years of age, a Child-Youth Assent Form is required. The Child-Youth Assent Form must contain simple language written at the appropriate educational level of the
youngest prospective subject in the youth age range. In some research projects it may be necessary to use two assent forms, written to accommodate subjects at either end of the age range. The Youth Assent Form must contain all required elements of assent identified by subheadings (minimal risk or greater studies) and arranged in sequence.
6.10.3 Consent/Assent Agreement for Children

For studies involving individuals who are not competent to consent, the consent of the legally authorized individual* must be obtained and the following should be added:

<table>
<thead>
<tr>
<th>Name of Legal Representative</th>
<th>Signature</th>
<th>Date Signed</th>
</tr>
</thead>
</table>

The decision makers are listed in the following **descending order of priority:**
1. The person's agent pursuant to an advance health care directive
2. The conservator or guardian of the person having the authority to make health care decisions for the person
3. The spouse of the person
4. An individual as defined in Section 297 of the Family Code
5. An adult son or daughter of the person
6. A custodial parent of the person
7. Any adult brother or sister of the person
8. Any adult grandchild of the person
9. An available adult relative with the closest degree of kinship to the person

When there are two or more available persons who are in different orders of guardianship, refusal to consent by a person who is a higher priority surrogate shall not be superseded by the consent of a person who is a lower priority surrogate.

If the consent form is verbally translated to the study subject the following should be added: “I have verbally translated this informed consent form document to the study subject.”

<table>
<thead>
<tr>
<th>Name of Translator</th>
<th>Signature</th>
<th>Date Signed</th>
</tr>
</thead>
</table>

For studies involving children who are of an age to assent (generally over the age of 7), a child’s assent form should be submitted or, if appropriate, the following should be added:

“Is your child able to understand what will be expected of him/her? □ YES □ NO

If yes, please have your child indicate his/her willingness to participate by signing here:”

<table>
<thead>
<tr>
<th>Name of Child</th>
<th>Child’s Signature</th>
<th>Date Signed</th>
</tr>
</thead>
</table>

For studies involving children, the consent of the both parents may be required (see section 6.10) or guidance on when both parents are required) and the following should be added:

<table>
<thead>
<tr>
<th>Name of Father of Child</th>
<th>Father’s Signature</th>
<th>Date Signed</th>
</tr>
</thead>
</table>
AOMA IRB

Name of Mother of Child                  Mother’s Signature                  Date Signed

For studies involving pregnant women, the consent of the father may be required and the following should be added:

Name of Father of Unborn Child          Father’s Signature                  Date Signed

6.11 Research Subject Information and Consent Form (Template)

RESEARCH INFORMATION AND INFORMED CONSENT FORM

Sites of Research Protocol:
(List each site where study will be conducted, using full site name.)

<table>
<thead>
<tr>
<th>Patient I.D. Plate</th>
</tr>
</thead>
</table>

Title: (Use the complete title of the research study. If multiple consent forms will be used, add subtitles to clarify the target population.)

Protocol No.

Sponsor:

Principal Investigator:

Co-Investigator(s):

Date/Revision: 00/00/00

Explanation of Research Project to Subject:

PURPOSE OF RESEARCH STUDY:

• Start with the statement “The purpose of this research study is...”
• Clearly describe the purpose of the study in non-scientific language.
• Describe who may join (basic inclusion criteria): “People with _____ may join.”
• Give approximate number of subjects expected to participate, if appropriate.

PROCEDURES:

• Start with the statement “If you agree to join this research study,...”
• Describe the procedures to be followed in chronological order. The procedures must match those listed in the protocol.
• Identify which procedures, if any, are experimental.
AOMA IRB

• Describe randomization in understandable language. For example, “In order to know whether the experimental treatment works, it is necessary to compare the experimental treatment with standard treatment or placebo (something that is not expected to produce effects). You will be assigned to a group given the experimental treatment or standard treatment/placebo by chance (like flipping a coin). In the event of an emergency, the investigator can find out which group you are in.”

• State the number of and expected duration of study visits. State the total duration of the subject's participation.

RISKS/DISCOMFORTS:

• Describe foreseeable risks or discomforts for ALL study procedures.
• The description of risks should be clear and not minimize the known adverse events. Risks listed in the protocol must be stated in the consent form.
• If appropriate, end with the statement "There may be side effects and discomforts that are not yet known."

PREGNANCY RISKS:

• If appropriate, include this section when women of childbearing potential may participate.
• Use the statement, “If you are pregnant or become pregnant during your participation in this study, (Describe foreseeable risks to a fetus).”
• Use this statement at the end: “This research may involve risks to an embryo or fetus which are currently unknown.”

BENEFITS:

• Describe benefits to the subject, if any, and describe the societal benefit that may reasonably be expected from the research.
• The description should be clear and not overstated.
• If no personal benefit exists, include a statement like “There are no direct health benefits to you by joining in this study. The results of this work may benefit the health of society if the findings contribute to a better understanding of ____.”

COSTS/COMPENSATION:

• List any costs to the subject that may result from participation in the research and who will pay for them.
• If all costs are paid by the sponsor of the study, state “All costs of study procedures will be provided at no cost to you.”
• Include all payments to subjects (parking reimbursement, transportation reimbursement, etc.). Include details of payment methods or bonuses. For example, “If you satisfactorily complete the study, you will receive $XXX to compensate you for your participation in the study. $XXX.00 of this is a bonus, which you will be eligible to
receive if you have shown up on time for all study visits as scheduled and taken your medicines correctly. All payments are made by check at the end of the study. If you withdraw before the study is completed, you will be compensated for your participation up to that time."

WITHDRAWAL PROCEDURES:

If appropriate to the study, include this section and statements like the following:
"You may withdraw from the study at any time."
“If you wish to withdraw, please notify the study staff immediately. We will discuss with you the procedures to be followed if you wish to withdraw. If you withdraw, it will not interfere with the future care you receive at any AOMA Institutions."

INvoluntary termination:

If appropriate to the study, include this section and add some or all of the following statements.
“Your participation in this research study may be ended without your consent. Possible reasons for termination from the study include not following study procedures as instructed, an event making your continued participation unsafe, or if the study has been ended. There may be other reasons that end your participation without your consent. If you are taken out of the study before the study is completed, and if you are being compensated for participating in the study, you will be compensated for your participation up to that time."

Alternatives to participation:

- For treatment studies in which other therapy is available to the subject, include the following: “If you decide not to join this study, there are other treatments available. You do not need to participate in this study to receive treatment for your condition. Other treatments available include (describe alternative treatments). If you do not join, your care at any AOMA Institution will not be affected.”
- For non-treatment studies include the following: “You do not have to join this study. If you do not join, your care at any AOMA Institution will not be affected.”

If you are physically injured by being in the study:

If the study is commercially funded, include a description of what coverage is available to the subject in case of injury and how to obtain further information about this coverage. The study sponsor will provide the specific language for this section. (In this case, you may request revision of the paragraph headed “What Happens If You Get Injured or Need Emergency Care?” in section 6.7.13 This request will have to be approved by the legal department.)

If the study is NOT funded, or if indemnification coverage is not provided by a sponsor, the standard wording on the back of this form is sufficient and a separate section need not be included in the consent form.
QUESTIONS YOU MAY HAVE ABOUT THE RESEARCH STUDY:

This consent form explains the research study. Please read it carefully. Ask questions about anything you do not understand. If you do not have questions now, you may ask later. During the study, you will be told any new facts that could affect whether you want to stay in the study. If the study relates to a health problem you have, we will explain what other treatment could be given outside the research. You should understand those options before you sign this form. If you have questions, you should call the principal investigator, ________________, at _____________.

PRIVACY INFORMATION:

We will keep the study information private to the extent possible by law. However, state law requires us to report certain contagious diseases or if we find information about child abuse. Also, under certain conditions, people responsible for making sure that the research is done properly may review your study records. This might include people from any AOMA Institutions, the National Institutes of Health, the Food and Drug Administration, The Office for Human Research Protections, or the sponsoring company. All of these people are also required to keep your identity confidential. Otherwise, the information that identifies you will not be given out to people who are not working on the study, unless you give permission.

IN CASE OF INJURY:

If you believe that you have a medical problem related to your participation in this study, or have questions about your medical care, please contact ____________MD.

If you are injured as a result of being in the study, or think you have not been treated fairly, please contact Dr. ___________ at (512)_____________. The services at any of the AOMA Institutions will be open to you in case of any such injury. However, none of the AOMA Institutions or the Federal Government has a program to pay you if you are hurt or have other bad results.

You will be responsible for payment of any treatment or hospitalization you require if you are injured as a result of being in the study. At your request your insurance company will be billed for payment of any treatment or hospitalization. It is up to you to check with your insurance company before you start this study to find out what your insurance company will pay for.

By signing this consent form, you have not waived any of the legal rights which you otherwise would have as a subject in a research study.

QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT:

If you have any questions about your rights as a subject in a research project, you should contact Raja Mandyam, Chair of IRB, at 512-492-3036 or rmandyam@aoma.edu to receive help or advice.

JOINING OF YOUR OWN FREE WILL (Volunteering for the study):
You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.

DEFINITION OF AOMA GRADUATE SCHOOL OF INTEGRATIVE MEDICINE INSTITUTIONS:

NOT VALID WITHOUT THE IRB STAMP OF CERTIFICATION

AOMA Institutions includes the AOMA South Clinic and Campus, the AOMA North Clinic, and externship affiliates with whom research may be conducted. (Fill in the name of the externship site if study is performed off campus.)
WHAT YOUR SIGNATURE MEANS:

Your signature below means that you understand the information given to you about the study and in this consent form. If you sign the form, it means that you agree to join the study.

WE WILL GIVE YOU A COPY OF THIS CONSENT FORM.

Do not sign after the expiration date of:____________

FOR ADULTS AND CHILDREN CAPABLE OF GIVING CONSENT:

Subject's Signature:_________________________ Date

FOR ADULTS NOT CAPABLE OF GIVING CONSENT:

Signature of Surrogate/Guardian/Health Care Agent for Subject Date

Relationship of Surrogate to Subject: ________________________________

FOR CHILDREN NOT CAPABLE OF GIVING CONSENT:

Signature of Parent:_________________________ Date

Signature of Parent #2 (where applicable) : ___________________________ Date

Signature of Legal Guardian (where applicable)________________________ Date

SIGNATURE(S):

Signature of Person Obtaining Consent Date
(Investigator or IRB-Approved Designee)

Witness to Consent Procedures Date
(Optional unless IRB or Sponsor required)

NOTE: A COPY OF THE SIGNED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR
AND A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PATIENT’S RECORD

FOR OFFICE USE ONLY:

STUDY APPROVED FOR ENROLLMENT OF:
___ Adults Only ___ Adults and Children ___ Children Only
# Appendices

## 7.1 Recommended Terms for Use in Consent Forms

To facilitate understanding of consent forms by the subject, it is recommended that the language used is at a reading level of a 12-year-old (8th-grade reading level). The following lay terms, definitions, and suggestions are recommended to help investigators in this process. (Note to Investigators: Choose the wording that makes sense in your study.)

<table>
<thead>
<tr>
<th>Term</th>
<th>Lay Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal; abdomen</td>
<td>Area around stomach; part of the body cavity that holds the stomach, intestines, liver, and other organs; midsection; belly; tummy; stomach area</td>
</tr>
<tr>
<td>acute</td>
<td>new; recent; sudden; short-lasting</td>
</tr>
<tr>
<td>adjuvant</td>
<td>additional treatment; treatment that goes along with main treatment to make it work better; treatment to prevent your cancer from coming back</td>
</tr>
<tr>
<td>adverse effect</td>
<td>side effect; bad effect</td>
</tr>
<tr>
<td>agitation</td>
<td>Upset</td>
</tr>
<tr>
<td>allergic reaction</td>
<td>allergy to the medication that can cause swelling, rash, itching, trouble breathing</td>
</tr>
<tr>
<td>ambulate (-ation, -ory)</td>
<td>walk; able to walk; ability to walk</td>
</tr>
<tr>
<td>ameliorate</td>
<td>make smaller or less, reduce</td>
</tr>
<tr>
<td>analgesia</td>
<td>pain relief</td>
</tr>
<tr>
<td>anaphylactic reaction</td>
<td>a severe and sometimes dangerous allergic reaction which may cause swelling, skin rash, itching, problem breathing, and/or lower blood pressure</td>
</tr>
<tr>
<td>anemia</td>
<td>low red blood cell count that may make a person tire easily and short of breath</td>
</tr>
<tr>
<td>anesthetic (local)</td>
<td>a drug used to decrease pain by numbing an area of the body, without putting you to sleep</td>
</tr>
<tr>
<td>anesthetic (general)</td>
<td>a drug used to decrease or eliminate pain by putting you to sleep</td>
</tr>
<tr>
<td>anonymous</td>
<td>We don’t ask your name; without identifying you</td>
</tr>
<tr>
<td>anorexia</td>
<td>no appetite; not feeling hungry</td>
</tr>
<tr>
<td>antibody</td>
<td>substance produced by your body to protect against infection/disease</td>
</tr>
<tr>
<td>arrhythmia</td>
<td>abnormal heartbeat</td>
</tr>
<tr>
<td>aspiration</td>
<td>remove fluid with a tube or needle</td>
</tr>
<tr>
<td>asymptomatic</td>
<td>without symptoms; having no symptoms</td>
</tr>
<tr>
<td>barrier method</td>
<td>a type of birth control such as diaphragm, condom, cervical cap, or sponge</td>
</tr>
<tr>
<td><strong>benign</strong></td>
<td>not cancer, harmless</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>bolus</strong></td>
<td>a dose of medicine given over a short period of time</td>
</tr>
<tr>
<td><strong>bradycardia</strong></td>
<td>slow heartbeat</td>
</tr>
<tr>
<td><strong>carcinogenic</strong></td>
<td>can cause cancer</td>
</tr>
<tr>
<td><strong>carcinoma</strong></td>
<td>a type of cancer</td>
</tr>
<tr>
<td><strong>cardiac</strong></td>
<td>Heart</td>
</tr>
<tr>
<td><strong>catheter</strong></td>
<td>a tube placed in the body for removing or putting fluids into the body; a tube that moves liquids in or out of the blood; a plastic tube placed in a vein or under the skin for withdrawing or putting fluids into the body</td>
</tr>
<tr>
<td><strong>central nervous system</strong></td>
<td>the brain and spinal cord</td>
</tr>
<tr>
<td><strong>central venous catheter</strong></td>
<td>a plastic tube inserted in a vein under the skin of the chest for removing or putting fluids into the body</td>
</tr>
<tr>
<td><strong>cerebral</strong></td>
<td>the brain; of the brain</td>
</tr>
<tr>
<td><strong>cessation</strong></td>
<td>Stopping</td>
</tr>
<tr>
<td><strong>CHD</strong></td>
<td>coronary heart disease; heart disease</td>
</tr>
<tr>
<td><strong>chemotherapy</strong></td>
<td>drug treatment of a disease, usually cancer</td>
</tr>
<tr>
<td><strong>chronic</strong></td>
<td>continuing for a long time; long-term condition</td>
</tr>
<tr>
<td><strong>clinical status</strong></td>
<td>current state of health</td>
</tr>
<tr>
<td><strong>clinical trial</strong></td>
<td>an experiment with human subjects</td>
</tr>
<tr>
<td><strong>confidential</strong></td>
<td>secret; private</td>
</tr>
<tr>
<td><strong>congenital</strong></td>
<td>problem that you are born with</td>
</tr>
<tr>
<td><strong>conjunctivitis</strong></td>
<td>red, itchy eyes; eye infection</td>
</tr>
<tr>
<td><strong>consequences</strong></td>
<td>result or effects</td>
</tr>
<tr>
<td><strong>controlled trial</strong></td>
<td>study to compare a new/experimental treatment with the best available treatment we have now</td>
</tr>
<tr>
<td><strong>conventional therapy</strong></td>
<td>standard treatment</td>
</tr>
<tr>
<td><strong>coronary</strong></td>
<td>the blood vessels that are connected to the heart</td>
</tr>
<tr>
<td><strong>CT (CAT) scan</strong></td>
<td>computerized series of x-rays</td>
</tr>
<tr>
<td><strong>cutaneous</strong></td>
<td>relating to the skin</td>
</tr>
<tr>
<td><strong>culture</strong></td>
<td>take a sample of blood, fluid, or tissue to see if bacteria or viruses can be found in it</td>
</tr>
<tr>
<td><strong>dehydration</strong></td>
<td>not enough fluids</td>
</tr>
<tr>
<td><strong>dermatologic</strong></td>
<td>pertaining to the skin</td>
</tr>
<tr>
<td><strong>diastolic</strong></td>
<td>the lower number in a blood pressure reading</td>
</tr>
<tr>
<td><strong>dilation</strong></td>
<td>expansion or stretching</td>
</tr>
<tr>
<td><strong>discomfort</strong></td>
<td>pain; uncomfortable feeling</td>
</tr>
<tr>
<td><strong>disseminated</strong></td>
<td>widely spread</td>
</tr>
<tr>
<td><strong>distal</strong></td>
<td>toward the end; away from the center of the body</td>
</tr>
<tr>
<td><strong>distend</strong></td>
<td>stretch, expand, bloat</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td><strong>diuretic</strong></td>
<td>water pill; medicine that makes you urinate</td>
</tr>
<tr>
<td><strong>double-blind</strong></td>
<td>neither the subject nor physician can know what is being given</td>
</tr>
<tr>
<td><strong>dysfunction</strong></td>
<td>doesn’t work properly</td>
</tr>
<tr>
<td><strong>dysplasia</strong></td>
<td>abnormal cells</td>
</tr>
<tr>
<td><strong>echocardiogram</strong></td>
<td>sound wave test of the heart</td>
</tr>
<tr>
<td><strong>edema</strong></td>
<td>fluid in the tissues; puffiness; swelling</td>
</tr>
<tr>
<td><strong>efficacy</strong></td>
<td>how well it works</td>
</tr>
<tr>
<td><strong>electrocardiogram, EKG</strong></td>
<td>heart test; tracing of heartbeat or heart rhythm</td>
</tr>
<tr>
<td><strong>emesis</strong></td>
<td>Vomiting</td>
</tr>
<tr>
<td><strong>endoscopic</strong></td>
<td>examination of the inside of the body with a lighted tube</td>
</tr>
<tr>
<td><strong>epidural</strong></td>
<td>a type of local anesthesia to decrease or eliminate pain</td>
</tr>
<tr>
<td><strong>eradicate</strong></td>
<td>get rid of</td>
</tr>
<tr>
<td><strong>erythrocyte</strong></td>
<td>a type of red blood cell</td>
</tr>
<tr>
<td><strong>FDA</strong></td>
<td>Food and Drug Administration; the branch of the government that approves new drugs</td>
</tr>
<tr>
<td><strong>fibrillation</strong></td>
<td>irregular heartbeat</td>
</tr>
<tr>
<td><strong>fibrous</strong></td>
<td>like scar tissue</td>
</tr>
<tr>
<td><strong>gastrointestinal</strong></td>
<td>stomach and intestines</td>
</tr>
<tr>
<td><strong>granulocyte</strong></td>
<td>a type of white blood cell</td>
</tr>
<tr>
<td><strong>hematocrit</strong></td>
<td>number of red blood cells</td>
</tr>
<tr>
<td><strong>hematoma</strong></td>
<td>bruise; black-and-blue mark</td>
</tr>
<tr>
<td><strong>Holter monitor</strong></td>
<td>portable machine for recording heartbeats</td>
</tr>
<tr>
<td><strong>hormonal therapy</strong></td>
<td>treatment with hormones</td>
</tr>
<tr>
<td><strong>hypertension</strong></td>
<td>high blood pressure</td>
</tr>
<tr>
<td><strong>hypotension</strong></td>
<td>low blood pressure</td>
</tr>
<tr>
<td><strong>hypoxia</strong></td>
<td>low oxygen level in the blood</td>
</tr>
<tr>
<td><strong>immunosuppressive</strong></td>
<td>a drug or therapy that reduces the body’s ability to fight infection; helps prevent rejection of a transplanted organ;</td>
</tr>
<tr>
<td><strong>incidence</strong></td>
<td>number of times it happens</td>
</tr>
<tr>
<td><strong>infarct</strong></td>
<td>death of tissue due to loss of blood flow</td>
</tr>
<tr>
<td><strong>inflammation</strong></td>
<td>swelling which is usually painful, red and warm</td>
</tr>
<tr>
<td><strong>infusion</strong></td>
<td>putting a substance into the body, usually into the blood</td>
</tr>
<tr>
<td><strong>intravenous</strong></td>
<td>putting it into the vein</td>
</tr>
<tr>
<td><strong>intubate</strong></td>
<td>the placement of a tube into the airway to help person breathe</td>
</tr>
<tr>
<td><strong>ischemia</strong></td>
<td>low oxygen in a tissue, usually because of decreased blood flow</td>
</tr>
<tr>
<td><strong>lactating</strong></td>
<td>producing milk</td>
</tr>
<tr>
<td>Medical Term</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>laparotomy</td>
<td>a procedure where a small cut is made in the stomach area, so a physician can look at the organs</td>
</tr>
<tr>
<td>lethargy</td>
<td>lack of energy; sluggish</td>
</tr>
<tr>
<td>lumen</td>
<td>inside a blood vessel</td>
</tr>
<tr>
<td>lymphocyte</td>
<td>a type of white blood cell important for defense against infections</td>
</tr>
<tr>
<td>malaise</td>
<td>feeling bad; a feeling of bodily discomfort; feeling sick; not feeling well</td>
</tr>
<tr>
<td>malignancy</td>
<td>cancer which usually spreads and may be fatal if not successfully treated</td>
</tr>
<tr>
<td>bone marrow suppression</td>
<td>decreased growth of the blood cells</td>
</tr>
<tr>
<td>metastasis</td>
<td>spread of cancer cells from one part of the body to another</td>
</tr>
<tr>
<td>monoclonal antibody</td>
<td>a type of antibody made outside your body to protect against your particular disease</td>
</tr>
<tr>
<td>morbidity</td>
<td>sickness; illness</td>
</tr>
<tr>
<td>mortality</td>
<td>Death</td>
</tr>
<tr>
<td>motility</td>
<td>the ability to move</td>
</tr>
<tr>
<td>MRI</td>
<td>pictures of the body created using magnetic rather than x-ray energy</td>
</tr>
<tr>
<td>murine</td>
<td>obtained from mice</td>
</tr>
<tr>
<td>myalgia</td>
<td>muscle aches</td>
</tr>
<tr>
<td>myocardial infarction</td>
<td>heart attack</td>
</tr>
<tr>
<td>nasogastric tube</td>
<td>a tube from the nose to the stomach</td>
</tr>
<tr>
<td>necrosis</td>
<td>death of tissue</td>
</tr>
<tr>
<td>neoplasia</td>
<td>new growth of cells that may be cancerous or non-cancerous</td>
</tr>
<tr>
<td>neural</td>
<td>brain or nerves</td>
</tr>
<tr>
<td>neutropenia</td>
<td>decrease in a type of white blood cells</td>
</tr>
<tr>
<td>non-invasive</td>
<td>not breaking, cutting, or entering the skin</td>
</tr>
<tr>
<td>obviate</td>
<td>to prevent or eliminate</td>
</tr>
<tr>
<td>occlusion</td>
<td>closing; obstruction; blockage</td>
</tr>
<tr>
<td>occult blood test</td>
<td>testing a stool sample for small amounts of blood that you can’t see</td>
</tr>
<tr>
<td>oncology</td>
<td>the study of tumors or cancer</td>
</tr>
<tr>
<td>ophthalmic</td>
<td>pertaining to the eye</td>
</tr>
<tr>
<td>orthopedic</td>
<td>pertaining to bones</td>
</tr>
<tr>
<td>osteoporosis</td>
<td>bone disorder resulting in thinning of bones causing them to break easily</td>
</tr>
<tr>
<td>ovaries</td>
<td>female sex glands that release the egg cells</td>
</tr>
<tr>
<td>pancytopenia</td>
<td>low number of all the blood cells</td>
</tr>
<tr>
<td>paralysis</td>
<td>permanent or temporally loss of sensation or voluntary motion</td>
</tr>
<tr>
<td><strong>Short Definition</strong></td>
<td><strong>Long Definition</strong></td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>paresthesia</td>
<td>numbness, prickling, or tingling feeling</td>
</tr>
<tr>
<td>percutaneous</td>
<td>through the skin</td>
</tr>
<tr>
<td>perforation</td>
<td>puncture, tear, or hole</td>
</tr>
<tr>
<td>phlebitis</td>
<td>irritation or inflammation of a vein</td>
</tr>
<tr>
<td>placebo</td>
<td>a pill or fluid with no medicine in it</td>
</tr>
<tr>
<td>platelets</td>
<td>blood cells that help the blood clot normally</td>
</tr>
<tr>
<td>post-</td>
<td>After</td>
</tr>
<tr>
<td>prenatal</td>
<td>before birth</td>
</tr>
<tr>
<td>probability</td>
<td>Chance</td>
</tr>
<tr>
<td>prognosis</td>
<td>outlook, probable outcomes</td>
</tr>
<tr>
<td>prophylaxis</td>
<td>a drug given to prevent disease or infection</td>
</tr>
<tr>
<td>prosthesis</td>
<td>artificial body parts, such as arms, legs, hips</td>
</tr>
<tr>
<td>proximal</td>
<td>closer to the center of the body; nearby</td>
</tr>
<tr>
<td>pruritus</td>
<td>Itching</td>
</tr>
<tr>
<td>psychosis</td>
<td>serious mental disorder</td>
</tr>
<tr>
<td>pulmonary</td>
<td>pertaining to the lungs</td>
</tr>
<tr>
<td>QID</td>
<td>four times a day</td>
</tr>
<tr>
<td>radiotherapy</td>
<td>treatment with radiation</td>
</tr>
<tr>
<td>randomly assigned</td>
<td>similar to the toss of a coin; assignment to a treatment group by chance; drawing/pulling a number from a hat</td>
</tr>
<tr>
<td>recur</td>
<td>happen again or come back</td>
</tr>
<tr>
<td>refractory</td>
<td>not responding to treatment</td>
</tr>
<tr>
<td>regimen</td>
<td>pattern of giving treatment; schedule of when you will get medicine</td>
</tr>
<tr>
<td>relapse</td>
<td>return or reappearance of a disease</td>
</tr>
<tr>
<td>remission</td>
<td>disappearance of evidence of cancer or other disease</td>
</tr>
<tr>
<td>renal</td>
<td>Kidney</td>
</tr>
<tr>
<td>resect</td>
<td>remove or cut out surgically</td>
</tr>
<tr>
<td>respiratory failure</td>
<td>lung failure; stop breathing</td>
</tr>
<tr>
<td>somnolence</td>
<td>Sleepy</td>
</tr>
<tr>
<td>staging</td>
<td>figure out the extent of the disease</td>
</tr>
<tr>
<td>stenosis</td>
<td>narrowing of a duct, tube, or blood vessel</td>
</tr>
<tr>
<td>stratify</td>
<td>arrange in groups by age, sex, etc., for analysis</td>
</tr>
<tr>
<td>subcutaneous</td>
<td>under the skin</td>
</tr>
<tr>
<td>subsequent</td>
<td>another, next</td>
</tr>
<tr>
<td>supine</td>
<td>lying on the back</td>
</tr>
<tr>
<td>symptomatic</td>
<td>having symptoms</td>
</tr>
<tr>
<td>syndrome</td>
<td>a condition with a certain set of symptoms</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>--------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>systolic</td>
<td>the top number in blood pressure</td>
</tr>
<tr>
<td>tachycardia</td>
<td>fast heartbeat</td>
</tr>
<tr>
<td>taper</td>
<td>decrease; reduce</td>
</tr>
<tr>
<td>therapy</td>
<td>Treatment</td>
</tr>
<tr>
<td>thrombosis</td>
<td>a blood clot in a blood vessel</td>
</tr>
<tr>
<td>tinnitus</td>
<td>ringing in the ears</td>
</tr>
<tr>
<td>titration</td>
<td>gradual increase or decrease of a drug dose until finding the dose that works best</td>
</tr>
<tr>
<td>topical</td>
<td>put on the skin, like a cream or lotion</td>
</tr>
<tr>
<td>toxicity</td>
<td>harm; problem; poisoning; unwanted side effect</td>
</tr>
<tr>
<td>transdermal</td>
<td>through the skin</td>
</tr>
<tr>
<td>transient</td>
<td>short-term; brief</td>
</tr>
<tr>
<td>trauma</td>
<td>injury; wound</td>
</tr>
<tr>
<td>trial</td>
<td>Study</td>
</tr>
<tr>
<td>uptake</td>
<td>taking a substance into the body and the cells</td>
</tr>
<tr>
<td>uremia</td>
<td>kidney failure</td>
</tr>
<tr>
<td>vertigo</td>
<td>dizziness; lightheadedness</td>
</tr>
<tr>
<td>varices</td>
<td>enlarged veins, usually in the legs or lining of the tube connecting the mouth to the stomach</td>
</tr>
<tr>
<td>vasodilation</td>
<td>widening of the blood vessels</td>
</tr>
<tr>
<td>vasospasm</td>
<td>narrowing of blood vessels due to a spasm of the vessel walls</td>
</tr>
<tr>
<td>vehicle preparation</td>
<td>a cream or liquid used to deliver medicine to you</td>
</tr>
<tr>
<td>venipuncture</td>
<td>place a needle in a vein to take blood</td>
</tr>
<tr>
<td>via</td>
<td>By</td>
</tr>
<tr>
<td>waive</td>
<td>give up; do without</td>
</tr>
</tbody>
</table>
What Is HIPAA?

The Health Insurance Portability and Accountability Act (HIPAA) is a complex regulation that affects many researchers at AOMA. HIPAA is designed to protect the use and disclosure of individually identifiable health information (also defined as Protected Health Information or PHI). PHI is defined as any of the 18 HIPAA recognized identifiers (see below) in combination with health information.

HIPAA recognized identifiers:

1. Names
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, ZIP Code, and their equivalent geocodes
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including fingerprints and voice prints
17. Full-face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code

It is important that you understand that you could face criminal and/or civil liabilities for non-compliance. Please use the templates for HIPAA Authorization and Appendix A below for your research. [Note: Information in the Authorization should NOT conflict with the consent form.]

AUTHORIZATION TO CREATE, ACCESS, USE, AND SHARE (DISCLOSE) HEALTH INFORMATION FOR RESEARCH

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Title:</td>
<td></td>
</tr>
</tbody>
</table>

By law, researchers must protect the privacy of health information about you. In this form the word “you” means both the person who takes part in the research and the person who gives permission for another person to be in the research. Researchers may use, create, or share your health information for research only if you let them. This form describes what researchers will do with your information. Please read it carefully. If you agree with it, please sign your name at the bottom. You will get a copy of this form after you have signed it.

If you sign this form, information will be shared with the people who conduct the research. In this form, all these people together are called “researchers.” Their names will appear on the research consent form that you sign.

The researchers will use the health information only for the purposes named in this form.

1. **What “health information” includes**
   - All information about you that is collected during the research study. This might include the results of tests or exams that become part of the study records; diaries and questionnaires that you might be asked to fill out as part of the study, and other records from the study.
   - All health information in your medical records that is needed for this research study. These might include the results of physical exams, blood tests, x-rays, diagnostic and medical procedures, and your medical history.

2. **What the researchers may do with health information**
   The researchers may use and create health information about you for the study. They may also share your health information with certain people and groups. These may include:
   - The sponsor of the study [____], and its representatives
Government agencies, review boards, and others who watch over the safety, effectiveness, and conduct of the research. Other researchers when a review board approves the sharing of the health information.

• Your health insurer if they are paying for care provided as part of the research study.
• Others, if the law requires.

3. **Removing your name from health information**
The researchers may remove your name (and other information that could identify you) from your health information. No one would know the information was yours. If your name is removed, the information may be used, created, and shared by the researchers and sponsor as the law allows. (This includes other research purposes.) This form would no longer limit the way the researchers use, create, and share the information.

3. **How the researchers protect health information**
The researchers [and sponsor] will follow the limits in this form. If they publish the research, they will not identify you unless you allow it in writing. These limitations continue even if you take back this permission.

4. **After the researchers learn health information**
The limits in this form come from a federal law called the Health Insurance Portability and Accountability Act. This law applies to your doctors and other health care providers.

Once the researchers get your health information, this law may no longer apply. But other privacy protections will still apply.

6. **Storing your health information**
Your health information may be added to a database or data repository. This permission will end when the database or data repository is destroyed.

7. **Please note**
You do not have to sign this permission ("authorization") form. If you do not, you may not be allowed to join the study. You may change your mind and take back your permission at any time. To take back your permission, write to:

If you do this, you may no longer be allowed to be in the study. The researchers will keep any information in the study record they already collected. **Your authorization will expire when the goals of the study have been met.**

[Insert the highlighted text only if applicable. For example, a double-blinded randomized trial. Otherwise delete the template language.]

During the study, you will not be allowed to see your health information that the researchers may place in your medical record. After the study is finished, you may see this information.

8. **Your signature**
If I have not already received a copy of the Privacy Notice, I may request one. If I have any questions or concerns about my privacy rights, I should contact the AOMA IRB at 512-492-3036.

I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed. I agree to the use, creation, and sharing of my health information for purposes of this research study.

____________________       __________________
Signature of research subject or subject’s legal representative    Date

__________________________       __________________________
Printed name of research subject or subject’s legal representative       Representative’s relationship to subject
APPENDIX A: For the use or creation of PHI in research

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Title:</td>
<td></td>
</tr>
</tbody>
</table>

SECTION 1: Type and Source of Protected Health Information

1. HIPAA-recognized identifiers for PHI:
   - Names
   - All geographic subdivisions smaller than a State, including street address, city, county, precinct, ZIP Code, and their equivalent geocodes
   - All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death
   - Telephone numbers
   - Fax numbers
   - Electronic mail addresses
   - Social Security numbers
   - Medical records numbers
   - Health plan beneficiary numbers
   - Account numbers
   - Certificate or license numbers
   - Vehicle identifiers and serial numbers, including license plate numbers
   - Device identifiers and/or serial numbers
   - Web Universal Resource Locators (URLs)
   - Internet Protocol (IP) address numbers
   - Biometric identifiers including fingerprints and voice prints
   - Full-face photographic images and any comparable images
   - Health plan beneficiary number
   - Any other unique identifying number, characteristic, or code
   - Other, specify [ ]

2. Name of entity providing PHI:
   [ ]

3. Describe how the PHI will be used and how access to PHI will further the research aims.
   [ ]

SECTION II: Consent/Authorization
Select options 1, 2, or 3 as appropriate.

1. [ ] Written consent/authorization will be obtained (please attach authorization document)

2. [ ] PHI will be accessed for activities preparatory to research. The following representations are true about my study:
A. The use or disclosure of the PHI being sought is solely for the purposes of designing the study or for assessing the feasibility of conducting the study, and

B. The PHI will not be removed from the covered entity

Describe how the PHI will be used in preparation for research

3. I am requesting a waiver of authorization for access to medical records. Waivers of consent and authorization are governed by HIPAA, the “Common Rule” (45 CFR 46) and the Washington State Health Care Information Act (RCW 60.02). Respond to each of the following and explain how your study is designed to address each of these concerns.

A. The access of PHI without authorization/consent present no more than minimal risk to the subjects and their privacy because:

Explain:

B. The waiver will not adversely affect the rights and welfare of the subject because:

Explain:

C. The research could not practicably be conducted without the waiver because:

Explain:

D. Access and use of the PHI is necessary to conduct this research because:

Explain:

E. The risks to the subjects and their privacy are reasonable in relation to the anticipated benefits of this research because:

Explain:

F. I have taken the following steps to protect the privacy and confidentiality of the data and to protect identifiers from improper use or disclosure:

Explain:

G. I plan to destroy identifiers at the earliest opportunity, no later than:

Explain:

H. I will not destroy the identifiers for the following scientific or health-related reasons:

Explain:

SECTION III: Data Security and Data Use

1. Describe data security measures in place to protect PHI. Include security related to electronic security (password protection, virus software, etc.), physical security measures (locks, surveillance, etc.) and data-handling techniques (coded data, identifier destruction date, etc), as applicable.

2. Attach any data use agreements, or business associate agreements related to the access and use of the PHI described in this Human Subject Application and Appendices.
By checking this box, I am providing assurance that the information is essential to the research, and access to the information will be limited to the greatest extent possible, allowable under the Privacy Regulations.
APPLICATION NUMBER: __________________

Email: aoma-irb@aoma.edu
Office Use Only

APPLICATION CHECKLIST FOR A NEW HUMAN SUBJECTS RESEARCH PROJECT

ALL NEW APPLICATIONS MUST INCLUDE A COPY OF EACH OF THE FOLLOWING:

☐ New IRB Research Application Submission Form including Abstract (Study Rationale) and Synopsis
☐ Consent Form – if required
☐ Results of scientific review, if required
☐ Complete grant application, if funding will be from any external agency
☐ Advertisements, brochures, radio scripts, etc., if planned

If study will use any SUBSTANCE, or BIOLOGIC agent that is not FDA-approved or is FDA-approved but not for the use, dosage, route of administration of this study, please include:
☐ Background information for food supplements
☐ Source material for any acupuncture protocols

If study will use a DEVICE that is not FDA-approved, please attach:
☐ Copy of the signed Investigator Agreement for protocols with an IDE, and one of the following:
☐ FDA letter approving the Investigational Device Exemption (IDE); OR
☐ Letter from Sponsor or manufacturer stating non-significant risk

In order to approve research involving human subjects, the IRB must determine that the research design is sound and minimizes risks to subjects, that informed consent will be obtained if required from the subject or their legally authorized representative, that adequate monitoring of subjects will be performed to ensure safety, that vulnerable subject populations receive additional protections, and that subject confidentiality is protected.

I. PROJECT

A. Title:

II. INVESTIGATOR INFORMATION

A. Principal Investigator
AOMA IRB

1. Name:
2. Office Address:
3. City:
4. State:
5. Country:
6. ZIP Code:
7. Phone:
8. Pager:
9. FAX:
10. E-mail:
11. Principal Investigator Title:
12. Principal Investigator Signature: ____________________________

B. Investigators and Co-Investigators

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Department</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

E-mail address for recipient of regulatory documents:

A. Co-Investigator(s) on this project with signature(s) which attest to their having read the protocol and agreeing to serve as co-investigator(s):

B. Human Subjects Compliance Training

1. List all personnel involved in this research study who have completed Human Subjects Compliance Training: (all personnel will complete NIH-PHP or equivalent)
2. List the consent designee(s) other than co-investigator(s):

III. INSTITUTIONAL SCIENTIFIC REVIEW AND APPROVAL

A. Research Department: __________________________________________________________

B. Director of Research/Designee Signature: ________________________________

(print name) : __________________________________________

C. Indicate level of review conducted:
1. [ ] Full SRC committee review
2. [ ] DAOM Program Review
3. [ ] SRC Waiver
AOMA IRB

IV. STUDY-SPECIFIC INFORMATION

A. Indicate where this study will be conducted: (check all that apply)
   1. ☐ AOMA Clinic
   2. ☐ AOMA Academic Department
   3. ☐ Community Clinic
   4. ☐ Other:

B. Subject enrollment:
   Number of subjects to be enrolled at AOMA’s site(s):
   1. First year: __
   2. Total study: __

C. Total number of subjects to be enrolled at all sites:
   1. First Year: __
   2. Total study: __

   a. Subject population(s) to be enrolled:
      1. Age range: _____
      2. ☐ Males
      3. ☐ Females
      4. ☐ Children (<18 years old) (complete Form F)
      5. ☐ Adults
      6. ☐ Inpatients
      7. ☑ Outpatients

D. If any subjects from the following categories are planned, please check.
   1. ☐ Staff/employees
   2. ☐ Nursing home or assisted living residents
   3. ☐ Terminally ill
   4. ☐ Pregnant women
   5. ☐ Children
   6. ☐ AOMA students
   7. ☐ Poor/uninsured
   8. ☐ Limited or non-reader
   9. ☐ Institutionalized
   10. ☐ Handicapped
   11. ☐ Mentally disabled
   12. ☐ Prisoner
   13. ☐ Fetuses or fetal tissue
   14. ☐ Cognitively impaired (including comatose)
   15. ☐ Non-English speakers
   16. ☐ Emergency Department patients

E. Is this research funded entirely, or in part?  Yes ☐  No ☐

   IF Yes, Source of funding/Sponsor Name: ______
   Grant number/Sponsor Number: ______
   IF Yes, pending? _____ Yes ☐  No ☐
F. Will Chinese medicinals be given to subjects? Yes ☐ No ☐  
   Substance Name(s): _____  
   **IF Yes,** describe methods used to assure proper identification of plant species.

G. Will medical devices, including acupuncture needles, be used in the study? Yes ☐ No ☐  
   **IF Yes,** is the device FDA-approved? Yes ☐ No ☐  
   If an approved IDE device, provide IDE#:  
   **IF No,** is an IDE# required? Yes ☐ No ☐  
   Has the device been ruled by the FDA as a "non-significant risk" device? Yes ☐ No ☐

H. Will samples be tested in a laboratory/facility without CLIA (Clinical Laboratory Improvement Amendments) certification? Yes ☐ No ☐ N/A ☐

I. Do any of the participating faculty (or their immediate family, staff, or students) have a financial interest (royalty, equity, or consulting) in the sponsor and/or products used in this project? Yes ☐ No ☐  
   **IF Yes,** submit a written statement of disclosure to the designated official for review of conflict of interest at the investigator’s institution of primary appointment.

V. ABSTRACT AND SYNOPSIS

A. **Abstract:** Please provide no more than a one-page study abstract briefly stating the problem, present knowledge relevant to it, the research hypotheses, and the goals of the proposed study as related to ________________.

B. **Synopsis:** Please provide a brief synopsis of the study design, study population, significant interventions, and length of study.

VI. PROTOCOL

A. Please submit the protocol in the AOMA-IRB format (Form A) - or sponsor's protocol.  

   **Form A: REQUIRED - AOMA-IRB Protocol Format.** Please use the section Headings to write the Protocol, inserting the appropriate material in each. If not applicable, please leave Heading in and insert:

   1. Protocol Title:  
      Protocol Version and Date of Version:

   2. Study Summary:

   3. Study Procedures:
Study design, including the sequence and timing of study procedures. Distinguish procedures that are experimental from those which are part of routine care.

A. Study duration and number of study visits required of research subjects
B. Blinding including justification for blinding or not blinding the trial, if applicable
C. Justification on why subjects will not receive standard care or will have current therapy stopped
D. Justification for inclusion of a placebo or non-treatment group
E. Definition of treatment failure or subject removal criteria
F. Description of what happens to subjects with therapy when study ends or if a subject’s participation in the study is ended prematurely

4. Study Subjects:
   a. The subject population, including how subjects will be identified and recruited
   b. Inclusion criteria
   c. Exclusion criteria
      1. If research involves study of existing samples/records, describe how authorization to access samples/records will be obtained

5. Chinese Medicinals/Substance/Devices:
   a. The rationale for choosing the Chinese Medicinal, substance doses, or for choosing the device to be used
   b. Justification and safety information if FDA-approved Chinese Medicinals will be administered for non-FDA-approved indications, or if doses or routes of administration or subject populations are changed
   c. Justification and safety information if non-FDA-approved Chinese Medicinals without an IND# will be administered

6. Study Statistics:

7. Human Biological Samples:
   If collected, provide information to address all of the following points:
   a. Will samples from living individuals be studied?
   b. Will new samples be obtained and/or will pre-existing samples be studied?
   c. Will identifiers or codes be retained that could link the identity of the subject to the sample?
   d. Describe procedures to protect against unauthorized use and loss of confidentiality of the samples or inadvertent release of confidential information
   e. Describe the plans to contact subjects or to access their medical records
f. Will specimens be collected for “banking” and future research?

g. Describe procedures for obtaining consent for future studies of existing samples

h. If genetic testing will be conducted, describe plans for contact of relatives of an existing proband and include any proposed written contact letter or materials

i. Describe plans for disclosure of test information including to whom information will be disclosed and by whom

j. Describe how genetic counseling will be provided prior to and following disclosure

8. Risks:
   a. Medical and environment risks, listing all procedures, their major and minor risks, and expected frequency

   b. Steps taken to minimize the risks

   c. Safety monitoring plan including plans for a Data Safety Monitoring Board (DSMB)

   d. For DSMBs, describe details on its operation, including membership and reporting procedures

   e. Plan for reporting adverse events

   f. Legal risks such as the risks that would be associated with breach of confidentiality

   g. Financial risks to the subjects

9. Confidentiality:
   a. Description of the procedures to be used to protect confidentiality of data collected and stored for research purposes. If sensitive information (illicit drug use, illegal activity, etc.) will be collected, indicate whether a Certificate of Confidentiality would be obtained (See the JCCI/JHBM Guidelines for information on how to obtain a Certificate).

   b. Benefits

   c. Description of the probable benefits
      i. Individual subject
      ii. Society

10. Compensation
    a. Details:
11. **Costs**
   a. **Detail costs of study procedure(s) or Chinese Medicinal(s) or substance(s) to subjects, and identify who will pay for them.**

12. **Consent**
   a. **Identify Type of Consent**
      i. ☐ Written informed consent form(s) to be signed by all subjects (complete Form B and C for each consent form)
      ii. ☐ Oral consent (complete Form D and attach a copy of the proposed consent script to be read to subjects)
      iii. ☐ Waiver of the requirement to obtain prospective informed consent from subjects (Complete Form E and provide a justification in concert with the requirements)
      iv. ☐ Waiver of the requirement for written informed consent for a project involving research in an emergency situation. SUCH WAIVERS MAY BE GRANTED ONLY IN STRICTLY DEFINED CIRCUMSTANCES. (Please provide a justification in concert with the seven points required, justifying a waiver of consent in this research area, see 45 CFR 46 Section 46.10)
   b. **Payment for study subjects**
   c. **Persons conducting the informed consent discussion with the subject**
   d. **Where and when will consent be obtained?**
   e. **Time allotted for obtaining consent**
   f. **Reading level of consent form (indicate software program used to determine)**
   g. **Describe how comprehension of the consent information will be assessed**
   h. **Describe how capacity for consent will be determined if some or all subjects are cognitively impaired or have language/hearing impairment. Describe the procedure for identifying legal representatives for those unable to consent**

13. **Consent Form including all of the following applicable paragraph headings:**
   a. **Purpose***
   b. **Procedures***
   c. **Withdrawal Procedures**
   d. **Subject Termination**
   e. **Risks/Discomforts***
   f. **Pregnancy Risks**
   g. **Benefits***
   h. **Costs**
   i. **Compensation**
   j. **Alternatives***
*Required elements
References
AOMA IRB

Form B
Verify that the informed consent document contains each of the eight required elements (45 CFR 46.116):

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>REQUIRED ELEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. A description of any reasonably foreseeable risks or discomforts to the subject.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. A description of any benefits to the subject or others which may reasonably be expected from the research.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. A statement of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subjects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8. A statement that the participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.</td>
</tr>
</tbody>
</table>
When appropriate, which of the following additional elements are provided in the consent form?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>ADDITIONAL ELEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>☒</td>
<td>1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐</td>
<td>2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐</td>
<td>3. Any additional costs to the subject that may result from participation in the research.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐</td>
<td>4. The consequences of a subject’s decision to withdraw from the research and the procedures for orderly termination of participation by the subject.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐</td>
<td>5. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>☐</td>
<td>6. The approximate number of subjects involved in the study.</td>
</tr>
</tbody>
</table>
An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Considering the above, please justify the request for the use of oral consent.
Form E: Waiver of Informed Consent (45 CFR 46.116)

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects
3. The research could not practicably be carried out without the waiver or alteration
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Considering the above, please provide a justification for the waiver of informed consent addressing (1) thru (4) above.
Form F: Research on Children (45 CFR 46.404-407)

If children will be involved in the research, indicate which category applies and justify:

**45 CFR 46.404** Research not involving greater-than-minimal risk. “Minimal risk” means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1. Yes [ ] No [ ] Is the risk minimal?
2. Yes [ ] No [ ] NA [ ] Are adequate provisions made for soliciting assent of the children and the permission of their parents or guardians?

Justification:

**45 CFR 46.405** Research involving greater-than-minimal risk but presenting the prospect of direct benefit to the individual subjects.

1. Yes [ ] No [ ] Is the risk greater than minimal risk?
2. Yes [ ] No [ ] Is there a prospect of benefit to the participants?
   
   IF yes, describe:
   
   3. Yes [ ] No [ ] Are risks justified by anticipated benefit to subjects?
4. Yes [ ] No [ ] NA [ ] Is the relation of the anticipated benefit to the risk at least as favorable to the subjects as that presented by available alternative approaches?
   
   IF yes, explain:
5. Yes [ ] No [ ] NA [ ] Are adequate provisions made for soliciting the assent of the children and permission of their parents or guardians?

Justification:

**45 CFR 46.406** Research involving greater-than-minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.

1. Yes [ ] No [ ] Does the risk represent a minor increase over minimal risk?
2. Yes [ ] No [ ] Does the intervention or procedure present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations?
3. Yes [ ] No [ ] Is the intervention or procedure likely to yield generalizable knowledge that is of vital importance for the understanding or amelioration of the subjects’ disorder or condition?
4. Yes [ ] No [ ] Are adequate provisions made for soliciting assent of the children and permission of their parents or guardians?

Justification:

**45 CFR 46.407** Research not otherwise approvable (under 45 CFR 46.404-406) which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. NOTE: Research in this category must be approved by the Secretary of DHHS who has delegated this responsibility to OHRP.

1. Yes [ ] No [ ] Does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children?
CONSENT FORM
“Study Title”

Name            Position            Department            Telephone

We are inviting you to participate in a research study. The purpose of this consent form is to give you information to help you decide whether or not to participate in the study. You may ask questions about the purpose and the possible risks and benefits of the research. You may also be curious about our expectations as researchers and your rights as a volunteer. We encourage you to ask additional questions about the research or this form if the information provided is unclear or insufficient. You can decide if you want to be in the study or not once we have answered all your questions. This process is called “informed consent”. We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

STUDY PROCEDURES

BENEFITS

RISKS

ALTERNATIVES TO TAKING PART IN THIS STUDY

COSTS/COMPENSATION

WITHDRAWAL PROCEDURES

IN VOLUNTARY TERMINATION

If you have any questions regarding your rights as a research subject, you may contact IRB of AOMA

Printed name of researcher          Signature of researcher          Date
Subject’s statement
This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I may call AOMA IRB. I will receive a copy of this consent form.

Printed name of subject          Signature of subject          Date
8.3 Waiver of Authorization or Altered Authorization

IRB Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule

Application

This application is to request the following:

1. ☐ Waiver of authorization (for all uses of PHI)
2. ☐ Partial waiver of authorization (for some uses of PHI, describe the parts of the protocol for which you are requesting a waiver)
3. ☐ Altered authorization (Attach 2 copies of your altered authorization form for proposed use with subjects)

PROJECT
  A. Title:

INVESTIGATOR INFORMATION
  i. Principal Investigator

1. Name:
2. Office Address:
3. City:
4. State:
5. Country:
6. ZIP Code:
7. Phone:
8. Pager:
9. FAX:
10. E-mail:
11. Principal Investigator Title:
12. Principal Investigator Signature: ________________________________
AOMA IRB

Investigators and Co-Investigators

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Department</th>
<th>Telephone</th>
</tr>
</thead>
</table>

1. E-mail address for recipient of regulatory documents:
2. Co-Investigator(s) on this project with signature(s) which attest to their having read the protocol and agreeing to serve as co-investigator(s):
3. Human Subjects Compliance Training
   a. List all personnel involved in this research study who have completed Human Subjects Compliance Training:
   b. List the consent designee(s) other than co-investigator(s):

INSTITUTIONAL SCIENTIFIC REVIEW AND APPROVAL

1. Research Department: ________________________________

2. Director of Research/Designee Signature: __________________
   (print name): ____________________________

   3. Indicate level of review conducted:
      a. Full SRC committee review
      b. DAOM Program Review
      c. SRC Waiver

STUDY-SPECIFIC INFORMATION

A. Indicate where this study will be conducted: (check all that apply)
   - AOMA Clinic
   - AOMA Academic Department
   - Community Clinic
   - Other:

B. Subject enrollment:
   Number of subjects to be enrolled at AOMA’s site(s):
   First year: _____ Total study: _____
   Total number of subjects to be enrolled at all sites:
   First Year: _____ Total study:

C. Subject population(s) to be enrolled:
   Age range:
   - Males
   - Females
   - Children (<18 years old) (complete Form F)
   - Adults
   - Inpatients
   - Outpatients
If any subjects from the following categories are planned, please check:

- Staff/employees
- Nursing home or assisted living residents
- Terminally ill
  - Pregnant women
  - Children
  - AOMA students
  - Poor/uninsured
  - Limited or non-reader
  - Institutionalized
  - Handicapped
  - Mentally disabled
  - Prisoner
  - Fetuses or fetal tissue
  - Cognitively impaired (including comatose)
  - Non-English speakers
  - Emergency Department patients

D. Specify which, if any, of the following identifiers will be associated with the health information you propose to collect:

1. Name
2. Address
3. Telephone number
4. Fax number
5. E-mail address
6. Medical record numbers
7. Social Security numbers
8. Account numbers
9. Health plan beneficiary numbers
10. Vehicle identifiers and serial numbers
11. Certificate/License numbers
12. Device identifiers and serial numbers
13. Biometric identifiers (fingerprints and voice prints)
14. Internet Protocol (IP) address numbers
15. Any geographic subdivisions smaller than a state (specify which of the following identifiers you will use: county, city, parish, or ZIP Code)
16. Any elements of dates (specify which of the following identifiers you will use: birth date, admission date, discharge date, date of death, age over 89)
17. Full face photographic images and comparable images
18. Specify other unique identifying number, characteristic, or code:

E. What is the source of the PHI? List all sources from which you plan to obtain PHI for the study

1. Clinic paper records
2. A departmental database
AOMA IRB

3. ☐ your own database
4. ☐ other, please list:

F. List, if any, the individuals or groups outside AOMA's Covered Departments to whom you will disclose the PHI (e.g., research collaborators from other institutions or a research sponsor). If PHI will NOT be released outside Covered Departments in this study, please make a statement to that effect. Note: The Privacy Rule requires researchers to keep a detailed accounting of releases of PHI outside the Covered Departments. This accounting must be made available upon request to the individual who is the subject of the PHI. If you can share health information that is de-identified, or that is a limited data set under a data use agreement with the collaborators or sponsor, you will not need to keep an accounting.

G. Describe your plan to protect PHI from unauthorized use or disclosure. Specify the measures that will be implemented by your research group to safeguard the PHI from unauthorized use or disclosure for both paper and electronic forms of PHI. (Examples include locking up your research files while they are unsupervised, using screensavers, shredding excess copies of paper documents, protections for codes that link patients to their data, and security measures to protect storage and transmission of electronic data.) If PHI is to be disclosed outside the Covered Departments, describe the plans of any research collaborators to protect the PHI you will share with them.

H. Describe your plan for destroying the identifiers at or before the conclusion of the study, or provide a justification for long-term or permanent retention of the identifiers. Specify which identifiers and information will be destroyed. If long-term retention is requested, such as maintenance of a database, specify the security measures you will use.

I. Explain why the study cannot be conducted without the waiver of or altered authorization. In order for an IRB to grant a waiver of authorization or altered authorization, the research cannot practically be conducted without it. Criteria the IRB considers in determining whether a waiver of or altered authorization should be granted include: the number of research subjects proposed, difficulties of obtaining individual authorization, time constraints, time since last contact with the research subjects, and need to have historical controls. Other criteria may apply.

J. Researcher Assurances.
As Principal Investigator of the research described above, I make the following assurances to the IRB regarding the use and disclosure of PHI:
“The investigators and research staff who use and disclose PHI in connection with this research will not reuse the PHI or disclose it to any person or entity other than those authorized to receive it, except: 1) as required by law, 2) for authorized oversight of the research, or 3) in connection with other research for which the HIPAA Privacy Rule permits the PHI to be used or disclosed.”

________________________________________  _______________________
Signature of Principal Investigator  Date
AOMA IRB

Print Name of Principal Investigator

______________________________________________________________

Study Title

_____________________________________

IRB Protocol Number (if assigned)
AOMA IRB

8.4 Exemption Determination Application

AOMA Institutional Review Board
4701 West Gate Blvd., Austin TX 78745
aoma-irb@aoma.edu

Exemption Determination Application

<table>
<thead>
<tr>
<th>IRB Use Only – Do Not Write or Mark in This Box</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Application No:____________________________</td>
</tr>
<tr>
<td>□ Certified Exempt under 45 CFR 46.101(b)…</td>
</tr>
<tr>
<td>□ 1 □ 2 □ 3 □ 4 □ 5 □ 6</td>
</tr>
<tr>
<td>□ Exemption or approval not required due to: ___</td>
</tr>
<tr>
<td>□ Research may not be certified as exempt due to: ____ Must be re-submitted on Non-Exempt Application</td>
</tr>
<tr>
<td>Signature: ___________________________Print Name: ___________________________Date: ___________________________</td>
</tr>
</tbody>
</table>

NOTE: EXEMPTION CERTIFICATION IS NOT APPROVAL. THE STUDY MATERIALS SHOULD NOT INCLUDE THE STATEMENT THAT AOMA IRB HAS REVIEWED AND APPROVED THE STUDY FOR HUMAN SUBJECT PARTICIPATION.

Instructions:

• AOMA IRB will determine whether or not your research qualifies for exemption. Do NOT begin data collection prior to IRB determination.
• All materials must be typed; handwritten materials will be returned.
• DO NOT leave a question blank.
• If AOMA IRB determines that a study meets the criteria for exemption research, the regulatory requirements for informed consent do not apply. However, research that is exempt from federal regulations is not exempt from ethical standards as outlined in the Belmont Report. This means, for example, that if potential subjects will be interviewed in a study that qualifies for exemption, they must be fully informed and free to choose whether to participate.
AOMA researchers (faculty and staff) conducting research which involves any external institution need to receive approval from their institutional IRB.

1. Principal Investigator (PI) Contact Information: (PI must be AOMA faculty or staff, and will be the study supervisor at AOMA. Students, post-doctoral researchers, and visiting faculty may not serve as PI, but may be listed as co-investigators in Section 4. All correspondence will be directed to the PI listed below.)

   Last Name: ______ First Name: ______ AOMA ID #: ______
   Department: ______ Position: ______ Campus: ______
   Address/Mail Code: ______ Phone: ______ E-mail: ______

2. Study Title: __________________________________________

SECTION 1. IRB REVIEW DETERMINATION

Answer the questions below:

1. ☐ Yes ☐ No Is the data being obtained about living individuals, directly or indirectly?

2. ☐ Yes ☐ No Is the data collected through intervention or interactions with individuals, including by internet or email?

3. ☐ Yes ☐ No Does the data contain identifiable private information?

If you answer “NO” to all the above questions, your research does not involve human participants and IRB review is not required.

If you answer “YES” to one or more of the above questions, your research involves human participants and you need to complete question 4 below.

4. ☐ Yes ☐ No Is the study a systematic investigation, including research development, testing and evaluation, and designed to develop or contribute to generalized knowledge?

If you answer “NO” to the above question, your study is not research and IRB review is not required. However, your study may qualify for non-regulatory review.
If you answer “YES” to the above question, your study is research and you need to complete sections 2 and 3 (‘screening questions’ and ‘exemption categories and determinations’).
SECTION 2. SCREENING QUESTIONS

Federal regulations specify that certain types of research pose low risk to participants, and therefore MAY qualify for EXEMPTION under federal regulations. To determine if your study is exempt, answer the following screening questions.

1.  □ Yes □ No  Will participants be asked to report their own or others' sexual experiences, alcohol or drug use, and will their identities be known to you?

2.  □ Yes □ No  Are the participants' data directly or indirectly identifiable, and could these data place subjects at risk for criminal or civil liability, or might they be damaging to subjects' financial standing, employability or reputation?

3.  □ Yes □ No  Are any participants confined in a correctional or detention facility?

4.  □ Yes □ No  Are participants involved who may not be legally/mentally/cognitively competent?

5.  □ Yes □ No  Are personal records (medical, academic, etc.) used with identifiers and without written consent?

6.  □ Yes □ No  Will alcohol or drugs be administered?

7.  □ Yes □ No  Will blood/body fluids be drawn?

8.  □ Yes □ No  Will specimens obtained from an autopsy be used?

9.  □ Yes □ No  Will you be using pregnant women by design?

10. □ Yes □ No  Are live fetuses participants in this research?

If you answer “YES” to any of the above questions, then your research is NOT exempt and you need to fill out the non-exempt application.

If you answer “NO” to all the above questions, your research might be exempt if it fits into one of the 6 exemption categories in Section 3.
SECTION 3. EXEMPTION CATEGORIES AND DETERMINATIONS

EXCEPTIONS: The exemption categories listed below do not apply when the research includes the following:

- Prisoners
- Survey or interview techniques which include minors as participants (this applies to exemption category #2 only)
- Observation of minors where the investigator participates in the activities being observed (this applies to exemption category #2 only)
- Food and Drug Administration (FDA)-regulated research (this applies to exemption categories 1-5 and includes projects for which the data will be submitted to or held for inspection by the FDA, or research for which the investigator gathers data on participants who serve as controls for participants who receive FDA-regulated drugs or medical devices, other than in the course of medical practice.)

Research activities are exempt from the federal regulation 45 CFR 46.101(b) for the protection of human participants when the ONLY involvement of human participants falls within one or more of the categories below. Check the appropriate categories that apply to your research study:

1.☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   a. research on regular and special educational instructional strategies, or
   b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2.☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
   a. information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
   b. any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability; or
   c. be damaging to the participants' financial standing, employability, or reputation.

   PLEASE NOTE: According to 45 CFR 46.401(b), this exemption does NOT apply to survey or interview procedures when the participants are children.

3.☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2) of this section, if:
   a. the human participants are elected or appointed public officials or candidates for public office; or
   b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. □ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the participants. **PLEASE NOTE:** According to the Office for Human Research Protections (OHRP), “to qualify for this exemption the data, documents, records, or specimens must be in existence before the project begins. The principle behind this policy is that the rights of individuals should be respected; participants must consent to participation in research.”

5. □ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   a. public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
   c. possible changes in or alternatives to those programs or procedures;
   d. possible changes in methods or levels of payment for benefits or services under those programs.

6. □ Taste and food-quality evaluation and consumer-acceptance studies:
   a. if wholesome foods without additives are consumed, **or**
   b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If you mark one or more of the six exemption categories above, complete the remainder of the application and submit to AOMA IRB. AOMA IRB will determine whether or not your research qualifies for exemption. Do **NOT** begin data collection without exemption certification from IRB.

**Justification of Exemption Category**

You must justify how your study qualifies for exemption by addressing the **critical elements** of the exemption category you choose. The critical elements for each category are:

**Category 1:** Specify whether 1(a) or 1(b) applies and briefly explain.

**Category 2:** Assure that condition 2(a) will be met and briefly explain how; and assure that condition 2(b) applies; and attach a copy of test/survey/interview questions or items.
**Category 3:** Explain why conditions 2(a) and 2(b) cannot be met; and attach a copy of test/survey/interview questions or items; and either assure and briefly explain that condition 3(b) applies, or explain subject’s public office and how it precludes anonymity (i.e., 3(a)).

**Category 4:** Briefly explain the nature of the existing data/documents and briefly explain either their public availability or the procedures to ensure anonymity and confidentiality.

**Category 5:** Briefly explain method by which the project is reviewed and approved by a federal department/agency head; and identify and describe which of the 5(a) – 5(d) categories apply.

**Category 6:** Assure that condition 6(a) will be met; and assure via documentation regarding approved safety levels that condition 6(b) will be met.
Human Participants Training: AOMA IRB requires the PI and encourages all staff involved in this research to complete NIH training in the ethical use of human participants in research. Re-training is required every five years. For NIH training options, visit the NIH website at https://phrp.nihtraining.com. If you have any further questions, contact the IRB coordinator at rmandyam@aoma.edu **Attach documentation of training for PI.** The PI is ultimately responsible to adequately train all staff listed on the application in the protection of human participants in research.

1. Human Participant Training Record (NIH-AOMA) of Principal Investigator:
   Date of Completion: Certificate #:  

2. Co-Investigator(s) (Co-PIs) Contact Information and Role in study: (Include all persons who will be directly responsible for the study management, data collection, consent process, data analysis, transcription, participant recruitment, or follow up. NOTE: If necessary, attach a list of additional Co-PI’s.)

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>E-mail</th>
<th>Role in the study</th>
<th>PHRP-Confirmed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Estimated Study Start Date: ______ Duration of the Study: ______

4. ☐ Yes ☐ No  Is this research supported in whole or in part by a grant or contract?

   Funding Agency(s), Foundation, or Business: ____________

   PI on Grant/Contract: OGRD #: ____________

5. ☐ Yes ☐ No  Does the research require another IRB’s review (US and International)?
   If yes, complete below.

   Name of the IRB: ______ FWA # or equivalent #: ______
   (NOTE: PI is responsible for securing approval and forwarding the documentation of approval to AOMA IRB.)
6. □ Yes □ No Does the PI, Co-PI, or any other person responsible for the design, conduct, or reporting of this research have an economic interest in or act as an officer or director of any outside entity whose financial interest would reasonably appear to be affected by the results of the study? If yes, complete below:

Name of the person with potential conflict of interest (COI): _____

Explain the potential financial conflict of interest: _____

Explain how the potential conflict of interest will be managed? _____

7. □ Yes □ No Is the proposed research study conducted at an outside (non-AOMA) facility or entity (such as hospitals, clinics, schools, school districts, factories, offices, etc.)? If yes, complete below.

The researcher has an obligation to ensure that the outside entity is aware of the proposed research study and has no objections (i.e., agrees to participate). By signing this application, the researcher indicates they will comply with this requirement.

Name (s) of the facility or entity: _____

SECTION 5. STUDY-SPECIFIC QUESTIONS

Provide below brief details of the proposed research. Use lay language and avoid technical terms.

1. Intent of the research study (hypothesis or research question of the study):

2. Participants (describe your inclusion criteria and methods of recruiting):

3. Procedures (describe your data collection methods, etc.):

4. Data confidentiality and security during collection, analysis, and storage:

5. Risks (describe any potential risks to participants--physical, psychological, social, legal, or other):

6. Benefits (describe any benefits to the participants and society): _____
Indicate that you have read and will comply with each statement.

1. □ I certify that the information provided in this application, and in all attachments, is complete and correct.

2. □ I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants, the conduct of this study, and the ethical performance of this research.

3. □ I agree to comply with all AOMA policies and procedures, the terms of its Federalwide Assurance, and all applicable federal, state, and local laws regarding the protection of human participants in research.

4. □ I certify that:
   • the study will be performed by qualified personnel according to the AOMA IRB-approved application
   • the equipment, facilities, and procedures to be used in this research meet recognized standards for safety
   • unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the AOMA IRB (aoma-irb@aoma.edu) and to my Departmental Chair/Director/Dean
   • student and co-investigators on this study have received adequate training and are knowledgeable about the regulations and policies governing this research
   • I agree to ensure adequate supervision of all research study personnel and to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.

5. □ I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.

PI Name: ____________________________
Signature: ____________________________ Date: ____________________________

How to Submit:
1. By email. You must attach the application and supporting materials (survey questions, interview guide, etc.) to an email sent to aoma-irb@aoma.edu.
2. A hard copy of the application and supporting materials (survey questions interview guide, etc.) may be sent to the Office of IRB, in Building D Room 3 D10. The
application must bear the PI's physical signature. Hard copies must be single-sided and must not be stapled or folded.

Please allow up to 10 business days for the IRB to complete exemption determination.
8.5 Notification of Research Project Termination

AOMA Institutional Review Board
4701 West Gate Blvd., Austin TX 78745
aoma-irb@aoma.edu

Notification of Research Project Termination Form

RPN NO: PRINCIPAL INVESTIGATOR:

TITLE:

DATE OF TERMINATION:

NUMBER OF SUBJECTS ENROLLED/STUDIED:

a) Since date of last annual renewal:
   Males: Females:

b) For the total Study:
   Males: Females:

ANY UNTOWARD REACTIONS, SIDE EFFECTS, OR ADVERSE EVENTS: YES NO
IF YES, describe in detail below:

SUMMARY OF CONCLUSIONS OF THE STUDY:

Signature of Principal Investigator Date
AOMA IRB

8.6 Request for Amendment or Withdrawal of Proposal

Request for Amendment or Withdrawal of Proposal/Project
AOMA Institutional Review Board

FOR IRB USE ONLY
For Expedited & Full Board Review Protocols

_____ Approved
_____ Disapproved

Comments/Recommendation:
Signature: Date:

IRB # 002-14
PRINCIPAL INVESTIGATOR’s Name: Dr. Xiao Tian Shen
Research Project Title:
Principal Investigator’s Email address: xshen@aoma.edu

TYPE OF AMENDMENT REQUEST (Check all that apply.)

NOTE: Be sure to attach the new consent form and/or any revised documents, as applicable, with changes highlighted or electronically shaded.

___ Protocol change or amendment
___ Change to Data Collection Tools or Procedure
___ Subject selection Criteria Change
___ Subject Recruitment Methods Change
___ Editorial/Administrative/Personnel Changes
___ Withdrawal
___ Other Change (Specify)

SUMMARY: (Provide brief description of changes and rationale)

Instructions for Submission of Amendment Request: You can send this as a signed hardcopy to Office of IRB, AOMA, Building D, AOMA Graduate School of Integrative Medicine, 4701 West Gate Blvd., Austin TX 78745

I am the Principle Investigator (PI)
AOMA IRB

________________________________________
(Please Sign, Scan, and Email to IRB Chair: aoma-irb@aoma.edu)
Signature of PI ______________________________ Date: __________