



Investigator Manual

Version date: April 1, 2010

Dear Principal Investigator:

Aspire Independent Review Board (Aspire IRB) is dedicated to the ethical protection of human subjects in research. Aspire IRB shall provide efficient and quality ethical review services to the research community. Our company shall approve and monitor research study protocols that include but are not limited to drugs, biologics, devices and behavioral research. It is also our goal to oversee early drug development with the use of human subjects.

Aspire IRB's business philosophy is to build lasting relationships with business partners who have a dedication to research integrity and the ethical protection of human subjects. We are committed to timely and efficient service with an emphasis on communication and teamwork between our staff and business associates.

This manual has been written to assist you in utilizing the services of Aspire IRB and to inform you of the requirements of doing business with our company. It is necessary that you read all of the information provided to you in this manual. We also recommend that all members of your study staff read and understand the information in this manual.

We are here to assist you with your study from start to finish. If at any time you need additional assistance or information in this manual is not clear, please do not hesitate to contact a member of our qualified staff.

Sincerely,

The Staff of Aspire IRB

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Please visit our web site at www.aspire-irb.com for the following:

Meeting Schedule

Fee Schedule Requests

Submission Forms

BOARD MEMBERSHIP

A current IRB Board membership roster is updated as needed and maintained in our office at all times. A current roster will be sent out with all new study approval notifications and upon request.

The IRB will consist of at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area and at least one member who is non-affiliated with Aspire IRB.

Aspire IRB practices diversity and non-discrimination in terms of race, gender and cultural differences in its membership.

Aspire IRB has an experienced and seasoned Board. Qualities of an Aspire IRB Board member include:

- Concern for the good and welfare of participants who volunteer for the purpose of research.
- Willing to spend the time that is needed to adequately review the research.
- Understand the concept of representing someone who cannot represent himself/herself.
- Experienced working professional in some field required for scientific and non-scientific members.
- Possess good listening and verbal communication skills.
- Basic understanding of scientific principles.
- Confident to express self in a group setting and not intimidated by others.
- Personal or professional experience working with one or more of the following groups:
 - Children, elderly, minorities, cognitively impaired, physically challenged, and non-English speaking individuals.

An ad hoc consultant may be included if necessary because of the special knowledge or experience they possess or by virtue of their expertise. An ad hoc consultant in attendance will not be permitted to vote or be counted toward the quorum.

INVESTIGATOR RESPONSIBILITIES

As a Principal Investigator (PI) conducting research projects with Aspire IRB, you must agree to conduct responsible research in accordance with all applicable regulations and requirements of Aspire IRB as follows:

- Amendments or changes in the protocol. Approval must be obtained from the Board prior to initiation unless to eliminate immediate hazards to the subjects. Sponsor closure of the study will be considered a change in the research activity; if subjects are taken off the study, the investigator must report discontinued subjects to the IRB and the reason for the discontinuance.
- Any significant protocol deviations / violations. The investigator's action plan for avoiding reoccurrence may be requested.
- FDA 483, Warning Letters and/or other audit correspondence and the Principal Investigator's written response to the findings and corrective action (if applicable).
- Any other audit report by a regulatory agency and/or Sponsor or IRB.
- Any unanticipated problems involving risks to the subject or others, injuries to subjects, unexpected adverse events / reactions whether or not thought to be related to the study.
- Changes in the informed consent. Approval must be granted by the Board prior to the use of any revised informed consent.
- Serious adverse and unanticipated reactions, including but not limited to death, pregnancy, congenital anomaly, overdose, malignancy, or hospitalization or prolongation of current hospitalization. Aspire IRB may also ask for any communications from the Sponsor concerning these reports.
- Safety Alerts, IND Safety Reports, MedWatch Reports, DSMB reports, Sponsor interim and annual reports.
- Any new information involving risks or benefits to the subjects that becomes available. The investigator's plan of action to be taken to notify subjects of the new information may be requested.
- Enrollment changes (increases in enrollment, suspensions / re-openings, etc). Investigator must submit dates of these actions.

- Notification of the Investigator's decision not to conduct the study, or to withdraw from the conduct of the study.
- Interim, annual and final reports (if applicable). These reports should be submitted 30 days prior to the expiration of IRB approval using the IRB Status Report Form.
 - These reports will include at a minimum:
 - Completed IRB Status Report Form and Attachments.
 - Any new information since the IRB's last review.

CONFLICT OF INTEREST

It is the policy of Aspire IRB that IRB Board members may not participate in the initial or continuing review of any research study in which a member has a conflicting interest, except to provide information as requested by the IRB. The IRB Board member shall abstain from deliberation and voting on any research review that the member has a conflict of interest.

At the beginning of each Board meeting, members will be asked if they have any conflict of interest for any of the agenda items. If it has been determined that any Board member has a conflict of interest on an agenda item, they will be asked to leave the room during the deliberation and voting on that item.

FINANCIAL DISCLOSURE

The PI, the study staff, or family members of either party must disclose any financial arrangements they might have that could potentially pose a conflict of interest, not including payment for the conduct of the clinical research. Examples include but are not limited to speaking fees or consultation fees exceeding \$25,000, and stock ownership or any equity interests exceeding \$50,000.

The FDA's Financial Interest Disclosure form can be found at:

<http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>

It is the responsibility of the Principal Investigator to revise the Financial Interest Disclosure form and inform the IRB of any changes to disclosable financial arrangements.

The American Medical Association Code of Ethics, Section 6.03 states that it is unethical for physicians to offer or accept payment for referrals of patients to research studies. In accordance with the AMA, Aspire IRB does not support physicians accepting payment for referrals of patients to research studies.

INVESTIGATOR NON-COMPLIANCE

Aspire IRB follows written procedures for suspension and termination of approval of research that is not being conducted in accordance with federal regulations, Aspire IRB's policy, or has been associated with unexpected serious harm to subjects.

- The IRB identifies a significant problem that has been associated with a subject safety concern or non-compliance with Aspire IRB policy or federal regulations that would justify possible suspension or termination of study approval.
- The Chief Operating Officer in consult with the QA & Compliance Manager and IRB Chairman determines if further attempts should be made to obtain compliance before placing the problem on an IRB meeting agenda. These individuals will also determine whether immediate suspension of enrollment is merited to protect the rights and welfare of subjects.
- The convened IRB decides whether a suspension or termination of approval is warranted.
- A decision of suspension or termination of approval requires that the IRB notify the PI in writing, explaining the reasons for the action, and if appropriate, what measures need to be taken in order to lift suspension or avoid termination.
- The PI will be sent a letter detailing the IRB's determination, length of suspension or termination of IRB approval, any additional requirements, sanctions or restrictions and a request for a response in writing.
- The statement will include a deadline (not to exceed 30 days) for complying with the IRB's requests. If the corrective action is completed within the specified time, the suspension or termination process ends.

- If the corrective action is not completed or the PI fails to respond within the specified time, then the study file will go to the IRB meeting for a vote of action.
- The Food and Drug Administration (FDA) and/or Office of Human Research Protection (OHRP) will be notified of any determination to suspend or terminate approval in addition to the Sponsor and other parties.
- The research is sent to a fully convened IRB meeting for review prior to reinstatement.

INVESTIGATOR AND STAFF TRAINING AND EDUCATION

Please be advised that Aspire IRB requires that the PI receive ongoing training and education in the area of human subject protection/Good Clinical Practice (GCP) at least every two years. This includes training on federal regulations in human subject protection/GCP, reporting serious adverse events, ethical principles in conducting research involving human subjects and other topics related to GCP.

Aspire IRB believes that ongoing training and education for the PI and key research staff is important to ensure that research studies are conducted in accordance with applicable federal regulations/GCP and that the PI and the research staff have a solid understanding of their respective responsibilities.

To assist you, Aspire IRB recommends visiting the following web sites that offer online training for clinical investigators:

1. OHRP Human Subject Assurance Training

<http://137.187.172.153/cbts/assurance/login.asp> (No charge)

2. Clinical Research Training – National Institutes of Health

http://www.nihtraining.com/crtpub_508/index.html (No charge).

You do not have to be an NIH Investigator to take this course.
Additional educational resources are located on these web sites:

FDA information sheets www.fda.gov/oc/ohrt/irbs/

CDER Guidance Documents www.fda.gov/cder/guidance/index.htm and <http://www.gpoaccess.gov/cfr/about.html> for the Code of Federal Regulations and to obtain copies.

CENTRAL IRB SERVICES

Aspire IRB provides central IRB services and is able to handle an unlimited amount of sites. Standard turnaround time for documents is 3-5 business days following Board approval.

Criteria for reviewing PIs who are part of a multicenter submission and using Aspire IRB as their central IRB:

- Protocol is submitted by the Sponsor or Contract Research Organization (CRO) as a multicenter study.
- Protocol, Informed Consent, Investigator's Brochure/Package Insert (if applicable) are reviewed by a fully convened IRB unless eligible for expedited review.
- PIs that are part of a multicenter study are reviewed individually and if qualified may be approved via expedite review.

IRB REVIEW

Aspire IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by federal regulations.

The PI and/or Sponsor have the right to appeal the IRB's decision. (See *IRB Appeal Process*)

Full Board Review

Any research involving human subjects that does not qualify for an exemption or expedited review must be reviewed and approved by a full Board at a convened IRB meeting. The review will result in one of the following actions:

- Approval without stipulation
- Approval with modifications
- Deferral of approval until further information is provided
- Disapproval

Continuing Review

Aspire IRB performs continuing review of previously approved research at intervals appropriate to the degree of risk and the vulnerability of the study subject population, but not less than once per year.

Not less than once per year means that the research must be reviewed on or before the expiration date of the last IRB approval, even though the research activity may not begin until a later date.

A Research Status Report Form is a written summary submitted by the PI regarding the status of the clinical trial. Continuing review must occur within 12 months from the time of initial approval. Aspire IRB may limit approval if warranted to a shorter period, as specified when the study was approved or at renewal time.

Aspire IRB sends a Research Status Report Form to the PI approximately sixty days prior to expiration of the study. *Continuing review is the responsibility of the PI.* The Research Status Report Form must be received by the IRB office by the designated due date in order for the IRB to have sufficient time to perform its review prior to the expiration date.

Failure to meet the continuing review due date may result in a warning notice being sent to the PI and/or Sponsor/CRO, stating that approval of the research will expire unless the report is received and reviewed prior to the expiration date.

Expedited Review

The IRB Chairperson, or one or more experienced reviewers designated by the Chairperson among members of the IRB, is authorized to perform expedited review of certain kinds of research involving no more than minimal risk.

Aspire IRB may use expedited review for the review of minor changes in previously approved research during the period for which approval is authorized.

The purpose of this policy is to allow the IRB to use the expedited review procedure for certain kinds of research that are in accordance with the Federal Register's published list of eligible research categories and the Code of Federal Regulations.

Study Closure

A written notification that all research activities at the approved research facility or facilities have been completed is required. Once the IRB has received a Final/Study Completed Report or Research Status Report indicating study closure, a letter of confirmation is issued to the PI informing them that their records will be maintained for no less than a period of three years.

IRB Appeal Process

A PI and/or sponsor wishing to appeal Aspire IRB's decision shall submit a written statement describing in detail the basis for the appeal and addressing all the concerns raised by the IRB in its review.

The information is submitted to the IRB and a determination is made within 30 days upon review. The decision of the Board is considered to be final.

- The PI, sponsor, and all applicable Federal agencies are notified by certified mail and/or courier of the final decision.
- A copy of the appeal request and the IRB decision is maintained in the study record.

CRITERIA FOR IRB SUBMISSION

IRB meetings are held each week on Tuesdays and Thursdays. All study materials must be received by our office on the Monday a week prior to the meeting date to be guaranteed review. The submission must be complete in order to meet the Monday deadline. If a submission is received on Monday and determined to be incomplete and will not meet the deadline, you will be notified. For complete submissions that meet the deadline, standard turn around is 7-10 days for full committee review.

Following the meeting, necessary consent revisions will be made by our staff. Approval documents will be mailed promptly. If the study protocol and/or informed consent are disapproved, either the Project Lead or QA and Regulatory Compliance Manager will contact the PI. The PI will be informed of the reasons for disapproval and suggestions for re-submission. Otherwise, approval documentation will be generated and mailed in a timely manner.

Administrative Amendments, Advertisements, Additional Facilities, and Sub-Investigators can often be reviewed using an expedited procedure. Our standard review of submissions that qualify for expedited review takes approximately 3-5 days.

The following items must be received to complete a full review of a study:

- Initial Study Application or Initial Device Study Application
- Protocol
- Investigator's Brochure(s) or Package Insert (if applicable)
- Informed Consent Document (Electronic version)

- Form FDA 1572 (or 1572 Equivalent for non-IND studies, including the location(s) where the study will be conducted, name and address of Principal Investigator and all Sub-Investigators)
- Curriculum Vitae for PI (signed and dated within 2 years)
- Current Medical License for PI only (if applicable)
- Site Information Form (one per site required per calendar year)
- Waiver/Deference of Review Form (if applicable)
- Cooperative Review Form (if applicable)
- Community Consultant Review Form (if applicable)

In addition to the above standard requirements, Aspire IRB must perform the following for investigational sites located in the state of Massachusetts:

- Conduct an on-site review within (30) days of the study start date when the PI has not previously been approved by Aspire IRB for a research project.
- Conduct an annual on-site review of each research project approved by Aspire IRB.
- Verify that all approved PI's in Massachusetts have or have applied for their appropriate licenses for research currently being conducted by each investigator.

INFORMED CONSENT FORM (ICF)

For studies that are subject to the requirements of the FDA and OHRP regulations, the informed consent documents should meet the necessary requirements of these regulatory agencies. IRBs have the final authority for ensuring the adequacy of the information in the informed consent document.

Aspire IRB follows the procedures listed below for informed consent submissions:

- All Informed consent document(s) are entered into our computer upon receipt. A copy of the informed consent form on diskette (MS Word) or e-mail must be provided.

- If there are any revisions to the informed consent requested by the IRB Board for approval, they will be made by our staff the day following the meeting.
- Our office will generate customized informed consent documents for each investigator. In addition, since all informed consents are maintained in our computer, our office will generate revisions.
- If a sample informed consent form is not available, one can be developed for an additional fee.
- If the sample informed consent form is not provided on a diskette or sent via e-mail, there will be an additional informed consent fee applied for additional formatting.

If you would like a copy of the Aspire IRB template informed consent, please contact the IRB office.

Financial Incentives

Financial incentives are often used when health benefits to subjects are remote or non-existent. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the proposed method of timing of disbursement to assure that neither are coercive nor present undue influence [21 CFR 50.20].

Witness Signature

FDA does not require the signature of a witness when the subject reads and is capable of understanding the ICF, as outlined in 21 CFR 50.27(b)(1). When the subject lacks the capacity to read and understand the consent document and the information provided, the signature of a witness is required, 21 CFR 50.27(b)(2). The intended purpose is to have the witness present during the entire consent interview and to attest to the accuracy of the presentation and the apparent understanding of the subject.

If the intent of the regulation were only to attest to the validity of the subject's signature, witnessing would also be required when the subject reads the ICF.

Pediatric Assent

Aspire IRB will take additional steps towards safeguarding and protecting the well being of children participating in human research.

Children are a vulnerable research population and require special ethical and regulatory consideration by the IRB. This complies with the FDA Interim Rule, the Children's Health Act of 2000 and 45 CFR 46 Subpart D.

The IRB determines what the assent process should involve and how the child's assent (or dissent) will be documented. It is the investigator's responsibility to explain the assent process and obtain the permission of the parents or legal guardian.

If you would like a copy of the Aspire IRB template assent document, please contact the IRB office.

TRANSLATION SERVICES

To meet the federal requirements of 21 CFR 50.20 and 45 CFR 46.116, the ICF should be in a language understandable to the subject (or authorized representative). When the consent interview is conducted in English, the ICF should be in English. When the study subject population includes non-English speaking people or the PI or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated ICF to be prepared and assure that the translation is accurate.

As required by 21 CFR 50.27, a copy of the ICF must be given to each subject. In the case of non-English speaking subjects, this would be the translated ICF. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the ICF should not be substituted for a written translation.

It is Aspire IRB's policy that the ICF must be in a language understandable to the subject. Non-English speaking study subjects must be provided an IRB-approved certified translation of the ICF in the subject's primary language.

- There will be an administrative review charge for the approval of ICFs submitted that are translated into a foreign language by a certified translator. A cover letter verifying the translation, which includes a copy of the name and certification of the translator, is required.
- If a translation of the ICF is requested, we will provide that service for the cost of the translator plus a processing fee.

REPORTING SERIOUS ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Unanticipated Problems

Unanticipated Problem is an unforeseeable event where the nature, frequency of occurrence or severity of the event is not consistent with information presented in the protocol, Investigator Brochure or ICF, such that the PI would not have had advance knowledge that it would occur.

Unanticipated problems can occur in many different ways and therefore Aspire IRB may receive them as serious adverse events, subject complaints, significant protocol deviations/violations and other reports.

Adverse Event Reporting

All serious adverse events must be reported to the IRB in accordance with the Code of Federal Regulations. The manner and speed with which an adverse event must be reported is based on the ICH Guideline for GCP; definition of seriousness of the adverse event; whether the adverse event was unexpected; and whether the adverse event is related to the study drug.

SERIOUS ADVERSE EVENTS OCCURRING AT YOUR SITE MUST BE REPORTED TO THE IRB IMMEDIATELY IF FATAL AND OTHERS WITHIN FIVE CALENDAR DAYS FROM THE DATE OF DISCOVERY.

Once you have identified a serious adverse event that is harmful to subject participation, increases the risks of harm in the research or has an unfavorable impact on the risk/benefit ratio, please download our [Serious Adverse Event/Device Effect Report Form](#) from the Aspire IRB website.

The completed form can be returned via email or printed and faxed to (619) 469-4108.

IND Safety Reports

IND Safety Reports submitted to Aspire IRB will be reviewed and documentation acknowledging this review will be forwarded to the submitting party.

In the event of a multicenter study, the CRO/Sponsor is required to submit the IND Safety Report on behalf of their investigators. Once received, Aspire IRB will review and provide documentation acknowledging this review to the submitting party (CRO/Sponsor). In order to avoid duplication of review, investigators on multicenter studies should not submit IND Safety Reports. It is the responsibility of the CRO/Sponsor to provide confirmation of the review of the IND Safety Report to the individual sites.

Protocol Deviations

Significant protocol deviations/violations are defined as any change from the approved protocol that affects the scientific design or integrity of the study and/or the rights and welfare of participating study subjects. These deviations/violations are to be reported to the IRB within 10 calendar days from the date of discovery. Protocol deviations/violations that only affect the administrative aspects of the study are not considered significant and, therefore, are not required to be reported to the IRB.

MEDICAL DEVICE REVIEW

Aspire IRB has written guidelines for compliance with 21 CFR Part 812 when determining the level of risk for device studies. Aspire IRB has the responsibility of determining whether a device poses a significant risk or non-significant risk and whether a study utilizing the device poses a minimal or more than minimal risk.

Medical Device is defined, in part, as any health care product that does not achieve its primary intended purpose by chemical action or by being metabolized. Examples of medical devices include, among other things, wheelchairs, surgical lasers, vascular grafts, and diagnostic aids such as reagents and test kits for medical conditions. (Refer to the Appendix for FDA Classification of Medical Devices).

Significant Risk Device (SR) is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; or (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; or (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to a subject.

Non-significant Risk Device (NSR) is an investigational device that does not meet the definition for significant risk. An IDE is not required provided that (1) the device is not a banned device and the sponsor follows 21 CFR 812.2(b) or (2) the FDA notifies the sponsor that an IDE is required.

Investigational Device Exemptions (IDE) is an application to the FDA, requesting approval to utilize a significant risk device in a clinical investigation in accordance with 21 CFR 812.

Pre-market Approval Application (PMA) is the FDA process to evaluate the safety and effectiveness of some Class III devices that are subject to pre-market approval requirements in accordance with 21 CFR Part 814. Examples of Class III devices that require PMA include: replacement heart valves; silicone gel filled breast implants and implanted cerebella stimulators. An approved PMA is a license granted to the applicant to market a particular medical device.

Class III devices that are substantially equivalent to devices legally marketed before May 28 1976 may be marketed through the 510K processes.

510(k) or Pre-market Notification (PMN) is a marketing application submitted to the FDA to demonstrate that a medical device is as safe and effective or substantially equivalent to a legally marketed device that was or is currently on the U.S. market and does not require pre-market approval.

The sponsor or investigator submits to Aspire IRB all the necessary information on the Initial Device Application.

SPECIAL CONSIDERATIONS FOR VULNERABLE POPULATIONS

Aspire IRB will take additional steps towards safeguarding and protecting the well being of vulnerable populations participating in human research.

Children

Aspire IRB follows applicable Federal Regulations when reviewing pediatric studies to safeguard and protect minors participating in human research. The special vulnerability of children as research subjects requires special ethical and regulatory consideration by the IRB.

Decisionally Impaired Persons

Aspire IRB shall determine that adequate consideration has been given to the manner in which subjects are selected and assure that adequate provisions have been made for monitoring of the informed consent process for clinical studies involving decisionally impaired persons.

Pregnant Women and/or Fetuses

Aspire IRB shall determine that adequate consideration has been given to the manner in which subjects are selected and assure that adequate provisions have been made for monitoring of the informed consent process for clinical studies involving pregnant women and/or fetuses.

In addition to the vulnerable categories stated above, Aspire IRB also considers the following populations to be vulnerable: Terminally ill individuals, Traumatized or Comatose individuals, Educationally and Economically Disadvantaged individuals, and Students and Employee Volunteers. Aspire IRB shall determine that adequate consideration has been given to the manner in which subjects are selected and assure that adequate provisions have been made for monitoring of the informed consent process for clinical studies involving these populations.

Health Insurance Portability and Accountability Act (HIPAA)

Aspire IRB will review research materials to determine how the privacy and confidentiality of subjects' personal health information is protected in accordance with applicable laws and regulations. The burden of HIPAA compliance rests with the covered entity.

Researchers who are covered entities and do not wish to request a waiver, may satisfy the HIPAA requirement for authorization by choosing one of the following alternative methods:

- Obtain a HIPAA compliant signed authorization from the research participant using a standalone document that the covered entity has created; or
- Incorporate the HIPAA language into the ICF and submit to Aspire IRB for review in accordance with applicable laws; or
- Attach an addendum that contains the HIPAA language to the ICF and submit to Aspire IRB for review in accordance with applicable laws.

If you would like a copy of the Aspire IRB HIPAA template document or if you would like Aspire IRB to serve as your privacy Board, please contact the IRB office.

CHANGES TO PREVIOUSLY REVIEWED RESEARCH

Aspire IRB requires investigators to report any changes in research activity. This includes, but is not limited to, Protocol Amendments, updated Investigator Drug Brochures, recruitment materials, and changes in research staff and/or facilities.

The change must be submitted in writing by electronic submission, facsimile or by mail to the Aspire IRB office. The submitted change is reviewed by a member of the IRB staff for adherence to Aspire IRB policy and regulatory compliance. The IRB Chairman is notified if the request for review is urgent due to subject safety.

The following are examples of what may be considered by Aspire IRB to be a minor change:

- Recruitment materials
- A change in grammar or wording that improves the clarity of a statement but does not change the intended meaning
- Correction of typographical error(s)
- A change in sub investigators or site contact information.

A qualified voting IRB member with signature authority is authorized to approve these changes by an expedited procedure.

A change that is determined to involve more than a minor change may not be eligible for expedited review. These changes will be sent to a fully convened IRB meeting for discussion and voting determination.

COOPERATIVE REVIEW & WAIVER/DEFERENCE OF REVIEW

Aspire IRB will have a written agreement that describes the respective responsibilities of Aspire and any institution that chooses joint or cooperative review of its research studies. The purpose is to avoid duplication of research review. The policy is in accordance with the FDA and Department of Health and Human Services (HHS) regulations.

The respective review responsibilities for each institution will be described and agreed to in writing on the Cooperative Review Agreement form. The delegating institution remains responsible for ensuring that research conducted is in full accordance with the determinations Aspire IRB.

NON-LOCAL REVIEW

Regulations require that the IRB be sufficiently qualified through the diversity of members, including consideration of race, gender, and cultural backgrounds and sensitivity to issues such as community attitudes, to promote respect for its counsel and ability to ascertain the acceptability of the research in terms of regulations, applicable laws and standards of professional conduct and practice.

This responsibility exists regardless of geographic location of the IRB relative to the research facility conducting research.

A written agreement between the PI and Aspire IRB verifies that Aspire IRB has the authority to oversee the study. This agreement is established when:

- The PI completes and signs the Aspire Initial Study Application as part of consideration for review of research being conducted.
- If there is a change in PI, a new investigator agreement, attached to the Initial Study Application, is required.

Aspire IRB informs the principal investigator in writing of their responsibility for oversight and continuing review of research.

Adequate knowledge of community attitudes, information on conditions surrounding the conduct of the research and the continuing status of the research for each location is met by one or more of the following:

- The PI completes the Aspire IRB Site Information Form for each performance site, including additions.
- The PI is responsible for providing updates to the Site Information Form. The IRB will maintain copies of the Site Information Form in the study file.

- As part of the continuing review process, the IRB will determine whether the site has submitted any changes to their Site Information Form and verify that it is current.

The IRB may ask the name and contact information of a layperson in the community who is not affiliated with the organization. This person may be contacted for confirmation and additional questions about community attitudes and local context. This information may be requested at any time during the review process if the IRB feels that there is a need.

IRB SITE VISITS

Aspire IRB may make site visits to the performance site or arrange for an outside agency to make the visit. If travel is not feasible, consultation via telephone conferencing or other technologies that allow real time conversational interaction between the remote community representative and the IRB Board members is permitted at a convened IRB meeting.

Aspire IRB is authorized to make periodic site visits to research facilities to obtain additional knowledge of community attitudes, conditions surrounding the conduct of the research and to ensure that risks to subjects are minimized according to 21 CFR 56.111.

Please note that Aspire IRB will charge for site visits required by the state of Massachusetts in addition to "for cause" site visits/audits. There will be no charge for routine site visits.

SUBJECT RECRUITMENT GUIDELINES

FDA considers direct advertising for study subjects to be the start of the informed consent and subject selection process. Advertisements should be reviewed and approved by the IRB as part of the package for initial review. However, when the PI decides at a later date to advertise for subjects, the advertising may be considered an amendment to the ongoing study.

When such advertisements are easily compared to the approved consent document, the IRB Chairman, or other designated IRB member, may review and approve by expedited means, as provided by 21 CFR 56.110(b)(2). When the IRB reviewer has doubts other complicating issues are involved, the advertising should be reviewed at a convened meeting of the IRB. FDA expects IRBs to review the advertising to assure that it is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol.

Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational.

Advertisements should not promise “free medical treatment,” when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisements may state that subjects will be compensated or reimbursed, but should not emphasize the payment or the amount to be paid, by such means as larger or bolder type.

Generally, FDA believes that an advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.

HOLIDAY OBSERVATIONS

Aspire IRB will be closed on the following holidays:

New Years Day

Martin Luther King, Jr. Day

President’s Day

Memorial Day

Independence Day

Labor Day

Thanksgiving Day

The Day after Thanksgiving

Christmas Eve

Christmas Day