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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 24 – 48 hours 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, and 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 expedited review.

IRB Compliance Statement

Aspire IRB is duly constituted and has written procedures in compliance with requirements defined in 21 CFR Parts 50 and 56, 312, 812, 45 CFR 46 and ICH Guidelines relating to Good Clinical Practice. Aspire IRB's mission is to ensure that research is conducted ethically according to the principles of the Belmont Report and in compliance with all federal and international (ICH) regulations, state laws and that the rights and welfare of human subjects are protected.

Also, in the event you would like to confirm our registration with the Office of Human Research Protection, our IORG number is: IORG0003876 and our IRB number is: IRB00004587.

Board Membership

A current IRB Board membership roster is updated as needed and maintained in our office at all times. A current roster is posted on our ASAP portal (located under the Library heading) and may be retrieved or sent out 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.
- Willingness to spend the time that is needed to adequately review the research.

- Understanding the concept of representing someone who cannot represent himself/herself.
- Possess good listening and verbal communication skills.
- Possess a basic understanding of scientific principles.
- Confidence to express self in a group setting and not intimidated by others.

An ad hoc consultant may be included if necessary due to 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.



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*). *There is only one opportunity for appeal.*

Criteria for IRB Submission

The submission must be complete in order to meet the submission deadlines. If a submission is determined to be incomplete you will be notified and the study will be moved to the appropriate agenda.

Following the meeting, necessary consent revisions will be made by our staff. Approval documents will be posted to ASAP and delivered promptly. In the event you have special instructions, this information should be imparted to the administrative staff at the time of study submission.

If the study protocol and/or informed consent are disapproved, either Aspire's QA Management or the designated Project Lead will contact the Sponsor/CRO/ Investigator to notify the relevant parties of the reasons for disapproval and suggestions for re-submission. Otherwise, approval documentation will be generated and posted in a timely manner, usually within 48 hours.

Administrative Amendments, Advertisements, and Additional Facilities, can often be reviewed using an expedited procedure. Our standard review of submissions that qualify for expedited review takes approximately 3-5 business 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), Package Insert (if applicable) or Device Description
- Informed Consent Document (unlocked electronic Word version)
- 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 every two years)
- Waiver/Deference of Review Form (if applicable)
- Cooperative Review Form (if applicable)
- Community Consultant Review Form (if applicable)



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In addition to the aforementioned 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.
- Conduct an annual on-site review of each research project approved by Aspire IRB.
- Verify that all approved PIs in Massachusetts have their appropriate licenses for research currently being conducted.

Full Board Review

IRB meetings are held each week on Tuesdays and Thursdays.

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:

- Approved
- Conditionally Approved
- Deferred
- Disapproved

Expedited Review

The IRB Chairperson, or one or more experienced reviewers among members of the IRB designated by the Chairperson, 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.

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



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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 \$5,000, and/or stock ownership or any equity interests exceeding \$5,000 or 5% or greater interest in any single entity connected to the research.

It is the responsibility of the Principal Investigator to 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.

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 and efforts. 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 of Aspire IRB.

In the event the study falls under the jurisdiction of another IRB, a Waiver/Deference of Review Form may be completed and signed by the facility Chairperson or other facility signatory. This Waiver places all review responsibilities with 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



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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 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 may only appeal one time.

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

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 must be approved by the IRB 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 removed from the study, the investigator must report discontinued subjects to the IRB and the reason for the discontinuance at the time of continuing review or within their Final Report.
- Any significant protocol deviations/violations that increase the risk to the study subject are to be reported on the form titled, *Unanticipated Problem Involving Risks to Subjects or Others Reporting Form*. The investigator's action plan for avoiding reoccurrence may be requested (see section titled, *Reporting Unanticipated Problems*)
- 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.
- Changes in the informed consent must be approved by the IRB prior to the use of any revised informed consent. The currently approved document is to be submitted to the IRB administrative staff in REDLINE form outlining all the changes.
- Any new information involving risks or benefits to the subjects that becomes



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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 participation in the study. A final report is to be completed for ending study participation.
- 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.
 - Final Completed Report Form

Informed Consent

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 in unlocked electronic Word form (via email or flash drive) must be provided.
- If there are any revisions to the informed consent requested by the IRB for approval, they will be made by our staff and you will receive a redline with all revisions with your approval. 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 an informed consent form is not available, one can be developed for an additional fee.
- If the informed consent form is not provided electronically, there will be an additional fee applied for formatting.

If you would like a copy of the Aspire IRB Informed Consent template, 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]. Aspire IRB requires that compensation to study subjects be distributed quarterly.

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



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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 only be required when the subject signs 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 and OHRP Subparts 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 as determined by the IRB.

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 persons or the PI or the IRB anticipates that the consent interviews will be conducted in a language other than English, it is the responsibility of the site to make the request and the IRB's responsibility to assure 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, ad hoc translation of the ICF is not a substitute 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. Aspire is able to facilitate the translation of consent documents through certified translators.

- 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.



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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 submitted for review and approval.

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 or 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 does not exercise undue influence and is not coercive. Furthermore, an advertisement should 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, the FDA believes that an advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.

PRESCREENING

Prescreening for a specific protocol to determine eligibility before study enrollment is acceptable if the study has been approved and the prescreening procedures are minimal in nature. The IRB is to be notified of the plans for prescreening and must approve the plan and document used for presentation and signature to study subjects.

Prescreening Plans for general purposes are also acceptable if the plan is well laid out and presented to the IRB for review. This plan is to include all procedures and must be submitted to the IRB for review and approval along with the consent document. All procedures are to be fully described in the prescreening consent document.

Changes to Previously Approved 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 the Principal Investigator and facility where research is being conducted.

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. A member of the IRB is notified if the request for review is urgent due to subject safety.

The following are examples of what Aspire IRB may consider 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)



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- A change in the Principal Investigator or site contact information

A qualified voting IRB member 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.

Submission for protocol amendments and/or revisions to an Informed Consent document that do not qualify for expedited review and must attend a fully convened meeting may be placed on the Tuesday or Thursday agenda. Submission for the Tuesday agenda must be received by our office by Friday at 2:00PM; submission for the Thursday agenda must be received at our office by Monday at 9:00AM.

For protocol amendments, a detailed list of all changes in the protocol or a redline copy of the protocol must be submitted with a rationale for the changes. For changes to an Informed Consent document, a redline of the previously approved Informed Consent with a rationale of the changes is required.

All submissions must be complete to meet the submission requirements. In the event the submission is not complete, the review may be placed on the next available agenda.

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 at 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.

Reporting Unanticipated Problems

An 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



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- The incident increases the risk to the study subject or to others
- The event is related to the study product and/or study participation (including wash-out periods). There is evidence that the event was caused by the study product and/or study participation (other than just occurring while on study)

Unanticipated problems can occur in many different ways and may include: serious adverse events, subject complaints, significant protocol deviations/ violations, reports of non-compliance and other reports.

Unanticipated Problem Involving Risks to Subjects or Others Reporting Form is to be used to report any issues that are related to the safety, rights and welfare of study subjects. It is required this form be completed and submitted within 10 calendar days from the date of discovery.

In the event you are required to submit safety information per sponsor instruction or your site's internal procedures, the form is still required to be completed. Please complete the form as far as it can be completed and submit with the annotation that the incident does not fit the reporting criteria and is being submitted for confirmation of receipt by the IRB.

This form is available on our website and can be forwarded to the IRB via ASAP.

IND Safety Reports

IND Safety Reports are not required to be submitted to Aspire IRB. Please refer to the section titled, ***Reporting of Unanticipated Problems***.

In the event you are required to submit this information per sponsor instruction or your site's internal procedures, the form is still required to be completed. Please complete the form as far as it can be completed and submit with the annotation that the incident does not fit the reporting criteria and is being submitted for confirmation of receipt by the IRB. Submission of safety documentation that does not require IRB review will incur a charge.

Protocol Deviations

Not all protocol deviations require submission to the IRB. Please refer to the section titled, ***Reporting of Unanticipated Problems***.

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.
- Aspire's QA Management and IRB Chairperson determine 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



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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, 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 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:

- OHRP Human Subject Assurance Training (*no charge*)
<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp?Submitted=True&UserType=Login>
- Clinical Research Training – National Institutes of Health (*no charge*)
<http://clinicalcenter.nih.gov/training/training/crt.html>
 - *You do not have to be an NIH Investigator to take this course.*

Additional Educational Resources are also available via:

- FDA Information Sheets
<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>
- CDER Guidance Documents
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/>

Medical Device Review

Aspire IRB has written guidelines for reviewing research involving medical devices. Medical Device studies fall under the IDE Regulations at 21 CFR 812.

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,



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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. The IRB is responsible for determining whether or not it agrees that the proposed use of the device in a study meets the criteria of non-significant risk.

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.

IDE Exempt Investigations All clinical investigations of devices must have an approved IDE or be exempt from the IDE regulations. Investigations that are exempted from IDE Regulations are described in 21 CFR 812.2(c).

For studies involving medical devices, Aspire IRB requires the submitting Sponsor/CRO/Investigator to submit the IDE number associated with the device in the study (for Significant Risk Devices) or the rationale for the proposed use of the device in the study to be considered Non-Significant Risk. In the event that the proposed use of the medical device meets the criteria for an exempted investigation, Aspire expects the Sponsor/CRO/Investigator to provide documentation of which exemption category this device satisfies. The submitting party will use the Initial Device Study Application when applying for review by Aspire IRB.

Special Considerations

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. Please note that when reviewing pediatric studies, the IRB may mandate the consent of two parents prior to enrolling a minor. Aspire IRB will document such determinations via the issued approval documentation.

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



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studies involving decisionally impaired persons. This may involve the addition of a signature line for a Legally Authorized Representative (LAR).

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 Employees. 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 stand-alone 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.

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



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Massachusetts in addition to "for cause" site visits/audits. There will be no charge for routine site visits.

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 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.

Holiday Observations

Aspire IRB will be closed on the following holidays:

- New Year's Day
- President's Day
- Memorial Day
- Independence Day
- Labor Day
- Thanksgiving Day
- The Day after Thanksgiving
- Christmas Eve
- Christmas Day

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