Sponsor/Investigator IRB Requirements and Guidebook

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Alpha IRB

Table of Contents

1. Introduction

This guidebook will provide a basic understanding to sponsors, investigators and their staff of what their role and responsibility will be while conducting human research studies. Alpha IRB's goal is to provide the information needed to protect the rights and welfare of every single research subject.

2. What Requires IRB Review

Regulations require IRB review and approval for ***research involving human subjects*** if it is funded or regulated by the federal government. Federal regulations define research as: "a systematic investigation designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(d)]

2.1. Definition of a Human Subject

Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project.

Under the federal regulations, human subjects are defined as: living individual(s) about whom an Investigator conducting research:

(1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

If an investigator is unclear about whether a planned activity is research involving human subjects, the investigator should contact Alpha IRB at: 949-542-3882 for assistance.

3. Responsibilities of Sponsor and/or Principal Investigator and their Research Staff

- Understand the ethical standards and regulatory requirements governing research activities with human subjects.
- It is the responsibility of the investigator to be cognizant of any local or State law(s) that may affect the conduct of human subject research in his/her state and apply these rules appropriately. The IRB may require that such knowledge and application be demonstrated before IRB approval is issued for studies involving certain populations and procedures.
- Inform research staff of the regulations governing research and the institutions research policies. The PI may delegate research responsibility to appropriately qualified persons; however, they must maintain oversight and retain ultimate responsibility for the conduct of the research study and of those to whom they delegate responsibility. The PI is responsible for maintaining a list of appropriately qualified persons to whom they have delegated trial-related duties.
- Ensure that all research activities have IRB approval and other approvals required by the institution before human subjects are involved.
- Implement the research activity as it was approved by the IRB.

- Obtain the informed consent of subjects before the subject is involved in the research and document consent as approved by the IRB.
- **Consent must be obtained using the most current IRB approved informed consent form(s) which will be "stamped" with the date of Alpha IRB approval and the Alpha IRB approval stamp.**  No other versions of the consent form(s) should be used with subjects.
- Maintain written records of IRB reviews and decisions and obtain and keep documented evidence of informed consent of the subjects or their legally authorized representative.
- Obtain IRB approval for any proposed change to the research protocol prior to its implementation.
- Comply with the IRB requirements for timely reporting of unanticipated problems involving risks to participants or others; including applicable serious adverse events, safety reports received from the Sponsor, or data safety and monitoring summary reports and significant protocol deviations.
- Obtain continuation approval from the IRB on the schedule prescribed by the IRB.
- Make provisions for the secured retention of complete research records and all research materials.
- Ensure the confidentiality and security of all information obtained from and about human subjects.
- Notify the IRB regarding the emergency use of an investigational drug or device within 5 working days of the administration of the test article.
- **Recruitment Bonuses** - Alpha IRB strongly recommends that the investigator carefully evaluate bonus payments offered by the sponsor for additional subject recruitment, beyond the original contractual agreement. Bonus payments or other incentives, such as medical equipment, may cause undue influence on the investigative staff, when the staff is recruiting study subjects. The IRB should be consulted on all bonus payments outside of the initial contract.
- **Referral Fees** - Alpha IRB does not allow payments to professionals in exchange for referrals of potential participants ("finder's fees").

3.1. Possible Actions if IRB Regulations are Not Followed

- Suspension of research project.
- Suspension of all of a Principal Investigator's research projects.
- Inability to use data or publish results.
- Notification of sponsors, regulatory agencies and funding agencies of non-compliance.
- Debarment by FDA from using investigational products.
- Inability to receive funding from federal grants.
- Additional monitoring and oversight by the IRB and/or third party monitoring of research activities.
- Termination of employment.
- Immediate shut-down of ALL research at an organization.

4. Submitting a Research Study

Alpha's Independent Review Board (IRB) meets twice a week on Monday and Wednesday for Full Board review. Submission materials must be received by 3:00 pm Pacific Time (PT) on the preceding Tuesday for Mondays meeting and the preceding Thursday for Wednesday's meeting. Submissions may be sent as hard-copy or electronically preferably entered online using **OASIS (**Online Access Study Information System).

To access **OASIS** go to: http://www.alphairb.com/

Click on  the link at the bottom right hand corner of the screen

to start submitting your study.

Remember, your Study Management Specialist is always available to assist you in navigating the system or answering any questions.

The review process will begin when Alpha IRB receives the complete submission. Incomplete submissions may not be placed on the agenda for the next meeting, so Sponsor/Investigators should review the IRB review process and the guidelines on the application forms for each type of submission. Submission forms are available on-line, via e-mail, or hard copy.

4.1. Basic components of an IRB submission - All Alpha IRB Forms are available on our website at: www.alphairb.com or via OASIS.

Submission Materials

- Sponsor/CRO Study Application (for Multi-center studies. Sites must also complete the Multi-Center Site Submission Form)
- Site Submission Form (for Single-Site studies)
- Research protocol - A detailed research protocol is required for IRB review of your research
- Investigator Brochure and/or Package Insert, Device Manual/Description (Required for FDA regulated products)
  - Alpha IRB is required to examine these items in order to adequately assess the risk/benefit ratio for subjects participating in the research
- Informed Consent Form(s) (Main, Genetic, Assent, Sub-Study, etc.)
- Proposed advertising and recruitment materials
  - Alpha IRB is required to review any advertisements (print, flyers, radio/TV ads, Internet postings, etc.) and written correspondence to subjects used for subject recruitment.
  - For radio and television advertisements, is recommended that scripts are created and submitted for IRB review prior to the taping in order to avoid re-taping because of inappropriate wording.

- The final version of all approved print, radio, web/internet, television ads must be submitted to Alpha IRB for verification. IRB staff will review the final copy of these advertisements to evaluate the relative size of type used and other visual effects and to ensure no additional changes have been made. When advertisements are to be taped for broadcast, the IRB staff will review the final audio/video file.
- In addition, Alpha IRB reviews all press releases intended to facilitate recruitment of subjects.
- If possible, include recruitment and study materials with your initial application. If the material is not ready at the time of initial application, submit the material when it is available and prior to use, but allow sufficient time for revisions prior to publication.
- Advertisements, press releases, etc., may qualify for expedited review.
- All recruitment materials must receive IRB approval before use.
- For further information regarding the recruitment of study subjects, please review the FDA Information Sheet entitled, "Recruiting Study Subjects - Guidance for Institutional Review Boards and Clinical Investigators."

- Surveys, Questionnaires, Patient Diaries, Subject Instructions and other written information to be provided to subjects
  - Alpha IRB is required to review all research instruments such as surveys and questionnaires. If the study uses an unmodified commercially available validated instrument which is used regularly in standard practice, it is not necessary to submit the instrument.
  - Alpha IRB reserves the right to determine whether a given document may require review in order for the IRB to fulfill its responsibilities. Please contact us if you have any questions regarding materials that require IRB review.
- Telephone / Web Screening Questionnaires
  - Alpha IRB requests that the following elements be present in a screening questionnaire:
    - The purpose of the screening questionnaire
    - The type of information that will be requested during the screening questionnaire
    - A statement indicating that participating in the questionnaire is voluntary and the prospective subject can refuse to answer any question or stop at any time
    - Notify the prospective subject who will have access to the information obtained during the screening questionnaire and what will be done with that information (i.e. will the information be destroyed, or, with the permission of the prospective subject, will the information be kept in a database and used to contact them about future studies.)
    - The prospective subject must be asked explicitly for their permission for the screener to ask the questions and the prospective subject must provide their permission to go forward with the screening questionnaire

** Copies of the approved recruitment and study material(s) will be issued to the site and/or sponsor.*

Approved material(s) may by "stamped" with the date of Alpha IRB approval and the Alpha IRB approval stamp; or in lieu of stamping the material, the approved material will include a version number and/or date which will be referenced on the IRB approval letter.

Generic Recruitment and Study Materials

- Generic materials are those that are not associated with a specific study and contain no study specific information.
- Approved generic materials will have an IRB approval period of one year. Each year, Alpha IRB will conduct an annual review of each generic material that was previously approved. Courtesy reminders of annual review will be sent to sites prior to the expiration date of the material. A site will need to identify if they plan to continue using the previously approved item(s). Any items that are not re-approved should no longer be used after their expiration.
- Standard review fees apply for each reapproved material.

5. Informed Consent

The outline for informed consent can be found in The Code of Federal Regulations 45 CFR 46.116(a) and 21 CFR Part 50.25(a).

5.1. Obtaining Informed Consent

- Provide subject with the IRB approved informed consent to read through in a quiet location. The IRB approved informed consent form will contain the date of Alpha IRB approval and the Alpha IRB approval stamp.
- Discuss study procedures thoroughly with subject.
- Ensure the subject understands by answering questions the subject may have.
- Encourage subject to discuss concerns with doctor, staff, family and friends.
- Obtain the voluntary agreement of the subject to participate in the study.
- Give the subject a copy of the signed informed consent and bill of rights (if applicable in your state) and encourage them to call if any further questions arise.

5.2. Ensuring Understanding

- Provide consent in a language that is understandable to the subject or his/her representative. For non-English speaking subjects, a member of the research team/non-family member interpreter must be available to interpret the initial and ongoing informed consent discussion for the subject.
- Provide non-English speaking subjects with a translated informed consent document that is certified as accurate (translated documents must receive IRB approval prior to use). *Please see the "Translation of Informed Consent Form and Study Materials" section of this guidebook for further details.*

- Give the person enough time to think about the research before consenting to research study participation.

5.3. Obtaining Voluntary Agreement to Participate

- Shall be obtained from the subject or the subject's legally authorized representative.
- Shall be obtained under circumstances that provide the subject with an opportunity to consider whether or not to participate and that minimize coercive influences.
- Coercive tactics such as inappropriate financial or other rewards cannot be used. Illiterate English-speaking subjects can "make their mark" on the informed consent document, as long as it is consistent with applicable state laws.
- If a subject withdraws prematurely from a clinical trial, although the subject is not obliged to give his or her reasons for withdrawing prematurely, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the subject's rights.

5.4. Waiving Informed Consent

In certain circumstances, the IRB may waive the requirement to obtain informed consent, or waive the requirement for the Investigator to obtain a signed consent form for some or all subjects, if the Board finds that the research meets specific criteria that is in accordance with provisions at 45 CFR 46.116(f), 45 CFR 46.117(c) , 21 CFR 50.23 or 24, 21 CFR 56.109(c).

6. Medical Device

6.1. Significant Risk and Non-Significant Risk Device Studies

What is a Significant Risk (SR) Device Study?

Under 21 CFR 812.3(m), an SR device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- 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
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

What is a Non-significant Risk (NSR) Device Study?

An NSR device study is one that does not meet the definition for an SR device study.

6.2. Device Study Submission

Provide the following:

- Device manual/description and **ONE** of the following:
  - **FDA Letter** granting the Investigational Device Exemption (IDE).
  - **Statement from sponsor** stating that the study is a non-significant risk device study. *A template letter is provided below.

  Or
  - Letter explaining why the investigation is **exempt**.

6.2.1. NON-SIGNIFICANT RISK STATEMENT (Template)

Date:

Protocol No:
Sponsor:
Investigator:
Site Name:

The investigational device, _____, we feel is a non-significant risk device based on the criteria listed below (§ 21 CFR 812.3(m)):

> It is **not** intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject;

Please provide an explanation of why this device meets this criterion:

> Is **not** purported or represented to be for use supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject;

Please provide an explanation of why this device meets this criterion:

> Is **not** for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject; or

Please provide an explanation of why this device meets this criterion:

> Does **not** otherwise present a potential for serious risk to the health, safety, or welfare of a subject

Please provide an explanation of why this device meets this criterion:

Sponsor Printed Name:_____ Date: _____

Sponsor Signature: _____

7. Submitting an Investigator's Site

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7.1. Basic components of an IRB submission - All Alpha IRB Forms are available on our website at: www.alphairb.com or via OASIS.

The following are a list of requirements for site submission.

- Completed Site Submission Form
- Investigator's Medical license(s)
- Investigator's Current Credentials (CV)
- FDA Audit Information (if applicable)
- Financial Disclosure information (if applicable)
- Additional Study Location Form (if the PI be conducting study related activity at other locations)

8. HIPAA – Health Insurance Portability and Accountability Act

Protected Health Information (PHI) is defined under HIPAA as individually identifiable health information. Identifiable refers to data explicitly linked to a particular individual as well with data that could enable individual identification.

Identifiers include but are not limited to: name, Social Security number, street address, birth date, telephone number, email, medical record number, health plan number, driver's license number, full face photography, etc.

8.1. Valid Authorizing Elements

- A description of the PHI being used.
- A statement of the purpose of the use of PHI.
- A list of those who can use the PHI.
- A list of those who can receive the PHI, including the possibility of re-disclosure.
- A statement that once PHI is disclosed by the recipient it may no longer be protected by the Privacy Rule.
- Information about the expiration of the authorization.
- Information about the right to revoke the authorization.

8.2. Authorization Under the Privacy Rule Regulations

Alpha IRB, as a central IRB, does not have authority to approve or disapprove authorization language under HIPAA regulations. This is a regulatory responsibility of any research site that are Covered Entities under 45 CFR 160 and 164. If Authorization is included in the consent document, Alpha IRB will review it for compliance with regulation as 21 CFR 50 and 56 and /or at 45 CFR 46. It is the responsibility of the Investigator to be aware of any state and local laws that raise the standard that HIPAA has set forth (for example, California requires the individual authorization be in 14 pt font, be separate from the consent document with its own signature lines and include a date or period in which it expires) . The sponsor should address their requirements regarding accessibility of data in their contract with each Covered Entity.

8.3. Waivers of Authorization

In the environment of research, it is essential to ensure the confidentiality of data and privacy of the individuals who have agreed to be the subjects of research. Since certain types of research require use and disclosure of PHI and since the nature of the research may preclude the obtaining of Authorization from the research subject to use or disclose such information, it may be necessary to proceed with such research without an Authorization.

A request for Waiver of Authorization must include enough information so the IRB can determine if the use, access to, or disclosure of identifiable health information meets the regulatory criteria for Waiver of Authorization and is the minimum necessary to accomplish the object of the research.

The following criteria must be satisfied to grant a waiver or partial waiver of authorization:

- The use or disclosure of protected health information involves no more than minimal risk to the individuals based on at least the presence of:
    - An adequate plan to protect PHI identifiers from improper use and disclosure
    - An adequate plan to destroy PHI identifiers at the earliest opportunity consistent with the research (unless there is a health or research justification, or it is required by law)

    - Adequate written assurances against re-disclosure of the PHI (except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by regulation)
- Practicability: The research could not practicably be conducted without the Partial Waiver/ Waiver
- Access: The research could not practicably be conducted without access to and use of the PHI

Investigators applying for Waiver of Authorization must submit:

- A completed Request for Waiver of Authorization Submission Form (for Full waivers) OR
- A completed Request for Partial Waiver of Authorization for Recruitment Form (for partial waivers related to screening and recruitment)
- Research protocol or activity plan (if not already submitted)

9. Conflicts of Interest

Alpha IRB is concerned about the potential for abuse when Investigators have a financial obligation or interest that may pose a conflict of interest. Alpha IRB requires that Investigators disclose all potential financial conflicts of interest and explain how the potential conflict of interest will be minimized or resolved. In these situations, the IRB may require additional actions such as: disclosure of conflicts in consent forms, limiting the role of the investigator by requiring a sub-investigator to conduct certain parts of the research like the informed consent process, or having the investigator recuse him/herself from the study entirely.

9.1. Financial interests that require disclosure include:

- Ownership interest, stock options, or other financial interest related to the research unless it meets four tests:
    - Does not exceed $5,000 when aggregated for the immediate family.
    - Publicly traded on a stock exchange
    - No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.
    - Does not exceed 5% interest in anyone single entity when aggregated for the immediate family.
- Compensation related to the research and/or institutional responsibilities unless it meets two tests:
    - Does not exceed $5,000 in the past year when aggregated for the immediate family.
    - No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, patent trademark, copyright or licensing agreement.
- A position in the sponsor company (executive, director, board member or employee) which is related to the research.

- Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to investigator's responsibilities for this study; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

A change in the conflict of interest status of the investigator, research staff, or an immediate family member that meets the above disclosure criteria must be reported to Alpha IRB.

Alpha IRB's Financial Disclosure Form is available on the Alpha IRB website at: www.alphairb.com or via OASIS.

10. Investigator and Research Staff Training

The Principal Investigator and all key research personnel must have appropriate training in conducting human subjects research. In addition, the IRB expects that the Investigator and staff will engage in continuing education devoted to the protection of research participants and ensure that the study staff is properly trained on human research participant protection.

Alpha IRB offers human research participant protection training to investigators and staff via the web based program, Collaborative Institutional Training Initiative (CITI). To register for the CITI course go to https://www.citiprogram.org click on "New Users" and then select Alpha IRB from the "Participating Institutions" dropdown list.

Other acceptable forms of training include:

- Attendance at seminars and conferences specific to human research participant protection, such as PRIMR, OHRP, etc.
- Completion of National Institutes of Health (NIH) Training: NIH Clinical center Clinical Research Training or NIH Office of Extramural Research Protecting Human Research Participants Training - https://phrp.nihtraining.com/users/login.php
- Completion of self-study or other training specific to human research participant protection , such as investigators meetings, CRO/SMO training
- Other online training specific to human research participant protection

Acceptable forms of training must be complete before full IRB Approval is granted. The investigator is also responsible for providing evidence of their qualifications through up-to date curriculum vitae or other relevant documentation.

11. Ethical Conduct

Alpha IRB expects that all research will be conducted in accordance with the principles of the Belmont Report.

12. Sponsor Monitoring of Investigative Sites

As sponsors routinely monitor investigative sites, they are in a unique position to uncover information to which the IRB may not otherwise be privy. Alpha IRB requests that the sponsor provide Alpha IRB with any information obtained as part of the study or for two (2) years after the study has closed that may affect the rights and welfare of participants, or their willingness to continue participation. Such information may be contained within a monitoring report, a Protocol Deviation Report Form (if applicable), an SAE/ Unanticipated Problem Report Form (if applicable), or may be summary of the sponsor's assessment. The Sponsor, CRO, or investigator must report this information to the IRB within ten (10) working days after the event has been identified. Alpha IRB will then work with the sponsor to rectify the situation. In addition, Alpha IRB may conduct its own monitoring visit to investigative sites. Alpha IRB selects sites to visit, based on certain criteria, such as the conduction of a high risk study, or the enrollment of a vulnerable population. Alpha IRB may also conduct a for-cause visit, or may randomly select a site to visit. Results of concern will be shared with the sponsor.

13. The Review Process

Under federal regulations, there are three possible IRB review procedures:

- **Full Committee Review** - *Most studies are reviewed by the full IRB.*
- **Expedited Review**
- **Review for Exemption Status**

13.1. Full Committee Review

Full committee review is the standard type of review described in the Federal regulations. It must be used for the initial review of all studies that are not eligible for expedited review or exemption status. Alpha IRB employ's a "primary reviewer system" which all IRB members receive basic information about the research application, but a "primary reviewer" with experience and/or expertise in the study area is assigned to conduct a thorough review of the IRB application and any accompanying documentation. The "primary reviewer" will then report his/her findings for discussion at a convened meeting of the full board.

Procedures and conditions for full committee review require that:

- The review must be conducted at a convened meeting of the IRB. A majority of IRB members (a quorum) must be present at the meeting
- At least one member whose primary concerns are in nonscientific areas must be present at the meeting (in addition, FDA policy requires that a physician be present).
- In order to approve research, the IRB must determine that all of the requirements specified in 45 CFR 46.111 (and if applicable, 21 CFR 56.111) are satisfied.
- A majority of the members present at the meeting must approve the research.
- IRB members who have a **conflict of interest** in a research project may provide information to the IRB, but cannot participate in the review. Members with a conflict do not count toward the quorum for that review.

- The IRB must notify investigators in writing of its decision to approve, modify or disapprove the research.
- IRBs must keep detailed documentation of meeting activities including attendance, voting on actions, the basis for the actions, and a written summary of the IRB discussion of controverted issues and their resolution.

13.2. Expedited Review

Alpha IRB may determine that your study qualifies for expedited review if the study meets criteria for Expedited Review.

Under an expedited review procedure, the review may be carried out by the IRB Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

Federal Regulations established the following 9 categories that IRBs may use to invoke the expedited review process. The research may not involve more than "minimal risk".

(1) Clinical studies on drugs or medical devices for which an investigational new drug (IND) or an investigational device exemption (IDE) application is NOT required. Similarly, a study with a cleared/approved medical device that is being used in accordance with its cleared/approved labeling.
(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
(3) Prospective collection of biological specimens for research purposes by noninvasive means.
(4) (Collection of data through noninvasive procedures routinely employed in clinical practice provided that:
    - The noninvasive procedure must not involve general anesthesia or sedation routinely employed in clinical practice or procedures involving x-rays or microwaves.
    - Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.
(5) Research involving data, documents, records, or specimens that:
    - Have been collected.
      or
    - Will be collected solely for non-research purposes (such as for medical treatment or diagnosis).
(6) Collection of data from voice, video, digital, or image recordings made for research purposes.
(7) Research on individual or group characteristics or behavior.
(8) Continuing review of research previously approved by the convened IRB where:

- The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; ***and,*** the research remains active only for long-term follow-up of subjects,
- ***Or where:*** No subjects have been enrolled and no additional risks have been identified.
- ***Or where:*** The remaining research activities are limited to data analysis.

(9) Continuing review of research not conducted under an investigational new drug (IND) application or investigational device exemption (IDE) and where categories two (2) through eight (8) do not apply.

13.3. Claim of Exemption

Federal regulations specifically define 8 categories of human subject's research that are exempt from the other provisions of the regulations. Federal Guidance indicates that applying exempt status to a project is a decision to be made by the IRB and that investigators cannot make this determination for themselves.

Research activities in which the only involvement of human subjects is in one or more of the categories listed below:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording), if at least one of the following criteria is met:

i. Information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; and

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. OR

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 ['HIPAA'], subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); OR

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(6) Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed, OR
ii. 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8):
1. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1) – (4), (a)(6), and (d) ;
ii. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §46.117; and
iii. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
ii. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data"* and makes the determination that the research to be conducted is within the scope of the broad consent; and
iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

NOTE:
A Claim of Exemption does not necessarily exempt Investigators from the requirement of gaining written informed consent from subjects. Most research requires the use an of informed consent form. For studies where there are no subject identifiers, i.e., anonymous data is collected; an information sheet or cover sheet is usually required.

13.4. Notification of Board Actions

Alpha IRB will communicate the results of the review directly to the responsible member of the clinical research team by e-mail, fax or phone within 24 hours of study review. Sponsor/Investigator is asked to respond to questions or requested revisions to a study or study material within 90 days of the review.

13.5. Determinations

Alpha IRB will make one of the following determinations as a result of its review of research submitted for initial review or for continuing review:

Approved:
The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IRB or Chairperson or designee and expire within one (1) year of the meeting date, but not later than the day preceding the date of review.

Approvals are always considered conditional. The conditions for continued approval, and the time frame (if any) within which they must be met will be clearly stated in the approval letter. If the conditions of the approval are not met, approval may be withdrawn. Investigators must receive their approval letter from the IRB before they initiated any procedures that are related to the protocol. The IRB expects the sponsors to use investigators who understand and adhere to the federal requirements regarding IRB review and approval.

It is the responsibility of the investigator to be cognizant of any local or State law(s) that may affect the conduct of human subject research in his/her State and apply these rules appropriately. The IRB may require that such knowledge and application be demonstrated before IRB approval is issued for studies involving certain populations and procedures.

After Initial Approval: When written approval is issued by Alpha IRB, investigator can initiate the study procedures. However, continued approval is always conditional. Standard conditions for continued approval are:

- Any changes in the research protocol, informed consent document, or subject information during the approval period must be submitted to the IRB for review and must not be initiated until approved by the IRB.
- All advertisements, letters and any other media for subject recruitment must be submitted and approved prior to use.
- Significant deviation from the research protocol and/or instances of non-compliance must be reported to the IRB as soon as possible, but no later than **ten (10) business days** from the date the site became aware of the event.
- All unanticipated problems that may involve risk to participants or others must be reported to the IRB as soon as possible, but no later than **ten (10) business days** from the date the site became aware of the event.
- A copy of the IRB approved informed consent document must be signed and dated by each subject or the subject's legal representative prior to initiation of ***any*** study

procedures. In addition, each subject must be given a copy of the signed consent form and subject's bill of rights (if applicable in your state).
- The investigator must cooperate with the IRB in its efforts to conduct continuing review.

The IRB may elect to place additional, specific conditions on the conduct of a study.

Approval with Changes:
The protocol or accompanying documents are approved with minor modifications required whereas the changes dictated to the investigator are considered to be approved, so long as additional changes are not requested.

Conditionally Approved:
Modification of, or addition to, a protocol or accompanying documents is required in which additional IRB review is also required. Changes will be voted upon during the IRB's meeting, as well as the terms of approval. The Investigator will be informed in writing of the required changes and requested information and must provide the IRB with the changes or information.

The Chairperson or his/her designee has the authority to review the information via expedited review unless the IRB requires that the material or information be reviewed by the full IRB, the primary reviewer or another individual delegated by the IRB to review the response. Upon satisfactory review, approval will be issued as of the date that the requested information or materials are approved. The expiration date will be based on the anniversary date on which the IRB, the primary reviewer, or individual delegated by the IRB to review the response, has reviewed the material or information and has given final approval. Subjects must not be recruited into the study until final approval has been issued.

Tabled:
Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Sponsor and/or Investigator.

Disapproval:
The proposal fails to meet one or more of the criteria used by the IRB for approval of research. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the IRB. Investigators have the right to discuss IRB requests for revision and decisions of disapproval directly with the Committee. The IRB, however, retains the final authority for approval of proposed research with human subjects.

The IRB review process allows Investigators various levels of appeal from the time a study receives initial review through approval or disapproval. Any and all IRB decisions are contingent upon the response of the Investigator. If the IRB finds that the negotiation is at an impasse, they may request an intramural and/or extramural independent consultant review. The IRBs wish to respect the Investigator's intellectual property, therefore, prior to assigning a consultant; Investigators are asked if there is anyone they would NOT like to review their study.

14. Investigator Responsibilities Once a Study is Approved

14.1. Record Keeping

The signed informed consent document is one of the most critical research records the investigator needs to obtain and keep. It provides verification that the research was explained to the subject and that the subject understood and voluntarily agreed to participate in the research study. Investigators are responsible for retaining signed consent documents, IRB correspondences, and research records for at least 3 years after the completion of the research activity.

14.2. Translation of Informed Consent Form and Study Materials

Informed consent must be presented in a language understandable to the subject. If the subject does not speak English, the informed consent form and all applicable study materials must be translated into a language they understand. Alpha IRB requires that translated documents be accompanied by a certificate which attests to accuracy of the translation(s). All revisions of the translated documents must also be accompanied by a certificate. Alpha IRB can arrange to have the documents translated into any language, or the site or Sponsor can facilitate the translation and submit the translated documents with a certification to Alpha IRB. Translated documents must receive IRB approval prior to use.

Translated materials will generally have the same version number and/or approval date as the previously issued English versions.

Alpha IRB does not require back-translation; however we can facilitate and provide back-translation of materials when requested.

14.3. Unanticipated Problems

Alpha IRB requires the reporting of any events determined by the Investigator and/or Sponsor to be unanticipated problems involving risk to participants or others. Alpha defines this as any problem, event, or new information that meets all of the following criteria:

1) The event is **unexpected** (in terms of nature, severity, or frequency) given:
    a. the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent documents; and
    b. the characteristics of the subject population being studied,
2) The event is **related or possibly related** to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research)
3) The event suggests that the research places participants or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

If the event (adverse or otherwise) does not meet all 3 of the above criteria, the event is not required to be reported to Alpha IRB. The Investigator must use his/her clinical judgment in

determining whether an event occurring at their site is a problem that meets all the above criteria.

For multicenter trials, Alpha IRB recognizes that the sponsor is in a better position to process and analyze adverse event information for the entire study and to assess whether an adverse event occurrence is an unanticipated problem involving risk to participants or others. Therefore, for the submission of multicenter trial reports such as IND Safety Reports, Medwatch Reports, CIOMS Reports, etc., Alpha IRB requires that the submission clearly indicate whether the event is considered to represent an unanticipated problem involving risk to participants or others and if so, what actions are being implemented in response. Multicenter reports where it is determined that the event does not represent an unanticipated problem involving risk to participants or others are not required to be submitted to Alpha IRB.

Events that meet all 3 of the above criteria need to be reported to Alpha IRB promptly, but no later than **ten (10) business days** from the date the site became aware of the event by completing either the "Serious Adverse Event / Unanticipated Problems Report Form" for events occurring at your site, OR the "IND Safety Report Form" for external events captured in multicenter trial reports. These forms are available on the Alpha IRB website at: www.alphairb.com or via OASIS.

For further information regarding the reporting guidelines for adverse events and unanticipated problems, please review the FDA Guidance Document entitled, "Adverse Event Reporting to IRBs — Improving Human Subject Protection," dated January 2009.

Possible examples of an unanticipated problem include, but are not limited to:

1) Serious adverse event that is both unexpected and related to the research
2) Serious Problem (local only) that results in:
3) Substantive harm or damage (or risk of substantive harm or damage)to the safety, rights, or welfare of research subjects, research staff, or others: or
4) Information that indicates a change to the risks or potential benefits of the research for example:
   - An interim analysis indicates that the participants have a lower rate of response to treatment than initially expected.
   - Safety monitoring indicates that a particular side effect is more severe or more frequent than initially expected.
   - A paper is published from another study that shows that an arm of the research study is of no therapeutic value.
5) A breach of confidentiality.
6) Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
7) Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
8) Incarceration of a participant in a protocol not approved to enroll prisoners.
9) Event that requires prompt reporting to the sponsor.
10) Complaint from a participant when the complaint indicates unexpected risk or cannot be resolved by the research team.

11) Protocol violation (which an accidental or unintentional change to the IRB-approved protocol) caused harm to participants or others or indicates that the participants or others are at an increased risk of harm.
12) Sponsor-imposed suspension for risk.

14.4. Amendments and Other Changes to Research

- All amendments, including changes to consent forms, changes in protocol study personnel, and planned deviations in the protocol must be reported to Alpha IRB.
- All modifications/changes to currently approved research are required to have IRB review and approval prior to implementation.
- An amendment may require full IRB review if the modification is significant, or affects the risks and benefits to subjects in the research. Changes in the risks or benefits to subjects may require modifications to the consent form and re-consenting of subjects.
- Minor changes in previously approved research during the period for which approval is authorized, those which do not adversely affect the rights and welfare of study subjects or do not involve increased risk or significant changes in study procedures, may receive an expedited review. If appropriate, the Chairperson or designee will review the changes to determine if they qualify for expedited review.
- Amendments and other changes to research include, but are not limited to, consent forms, protocols, Investigator Brochures, study instruments, recruitment and advertising tools/materials, protocol study personnel changes, planned protocol deviations, adding an additional study location, a change in the primary study location and/or additional study location (phone number change, site name change), changes in conflict of interest status, changes in planned enrollment of vulnerable populations, etc.
- The IRB may only approve modifications submitted during a current approval period to the end of that period. For example, if the new, renewal, or continuing approval is issued on January 1, it will have an expiration date December 31. If an addendum is approved during this time, the approval still lasts only until December 31. Please reference all modifications and addendums, as applicable, in the renewal application for the IRB consideration during the continuing review.
- Applicable changes that do not qualify for expedited review will be reviewed by the IRB at the next available meeting.
- For study changes, please include a cover letter explaining the requested modifications, and any modified items such as consent forms, protocols, Investigator Brochures, study instruments, recruitment tools, etc. Revisions to protocols, Investigator's Brochures, Package Inserts and Device Manuals should be submitted along with a redlined/tracked changes version (preferable) or a summary of changes. Revised consent forms and study/recruitment materials should be submitted with the changes tracked/redlined.
- For site information changes (site name change, address change/removal, subject compensation change, phone number for subject use change), please complete the "Site Information Change Submission Form." The form is available on the Alpha IRB website at: www.alphairb.com or via OASIS.

- Principal Investigator Changes - When changing Investigators, please complete the "Change of Principal Investigator Form" and submit along with the new PI's CV and any applicable licenses and attachments. The form is available on the Alpha IRB website at: www.alphairb.com or via OASIS. Principal Investigator changes may qualify for expedited review, if deemed appropriate.

14.5. Protocol Deviations

Protocol Deviations are defined as any departure or change from the protocol that is unanticipated and happens without any prior agreement.

Alpha IRB requires that all significant protocol deviations be reported. Significant deviations are considered to be protocol deviations that, in the opinion of the investigator:

- adversely affect the safety, rights or welfare of subjects or others
- adversely affect the integrity of the study data

Deviations that have occurred repetitively or might occur again may also qualify as significant deviations and should be reported to Alpha IRB (if it is anticipated that this violation will occur again, an amendment to the protocol should be considered).

Significant protocol deviations need to be reported to Alpha IRB promptly, but no later than **ten (10) business days** from the date the site became aware of the event.

Non-significant protocol deviations do not need to be reported to the IRB unless the protocol or sponsor requires the Investigator to do so.

14.6. Planned Protocol Deviations

A planned protocol deviation is a prospective, intentional departure or change from the Alpha IRB approved protocol. A planned deviation typically involves an individual subject, or may involve a small group of subjects, and is not a permanent revision to the protocol. In general, all planned protocol deviations must be submitted to the IRB for review and approval prior to implementation; except where necessary to eliminate apparent immediate hazards to the human subjects. [45 CFR § 46.103(b)(4); 21 CFR § 56.108(a)(4); ICH 3.3.7].

However, if the research is a clinical investigation of a **device**, and the research is not federally funded, and the research is not conducted under an FWA, then only planned protocol deviations that may *adversely affect the rights, safety or welfare of subjects or the integrity of the research data* should be submitted to the IRB for review and approval prior to implementation; except where necessary to eliminate apparent immediate hazards to the human subjects. [45 CFR § 46.103(b)(4); 21 CFR § 56.108(a)(4); ICH 3.3.7; 21 CFR 812.150(a)(4)].

You may submit planned protocol deviations using the "Protocol Deviation Report Form" available on the Alpha IRB website at www.alphairb.com or via OASIS. Planned protocol deviation submissions should be submitted as far in advance as possible and must be accompanied by written documentation of Sponsor approval.

The investigator has ultimate responsibility for obtaining prior IRB approval for planned

protocol deviations. Repeated failure to obtain prospective IRB approval for planned protocol deviations may be viewed as continuing non-compliance.

14.7. Continuing Review

Reports must be submitted by the investigator and/or study sponsor at intervals determined by the IRB. The expiration date and the date that an interim report is due, if required, will be stated in the study approval letter. Reminders will be sent to the Investigator and to the Sponsor prior to the due date.

The Federal regulations do not allow an IRB to approve a study for more than one year. For multi-year research, the Principal Investigator is responsible for submitting a renewal application prior to the expiration of the current IRB approval.

If the **approval expires** prior to submission of the renewal application, the investigator is required to cease all research activities including recruitment, screening enrollment, subject contact and data collection until the renewal is approved by the IRB. For therapeutic studies where subject safety is a concern, there is some flexibility towards the continued treatment for currently enrolled subjects and the IRB should be consulted and provided with additional information. However, no new subjects may be contacted, recruited, or enrolled until the Investigator obtains current IRB approval.

The information within the IRB renewal application should incorporate all of the addenda, data and safety monitoring board reports (DSMB) and research modifications submitted to and approved by the IRB during the previous approval period.

Continuing review and approval is necessary if recruitment of subject's stops but previously enrolled subjects continue to participate in the research or the study is in data analysis.

Research subject to the Common Rule

Continuing review of research may not be required for research studies approved on or after January 21, 2019 which are **not** FDA-regulated but are subject to the Common Rule in the following circumstances:

- Research eligible for expedited review;
- Research reviewed by the IRB in accordance with limited IRB review (applicable to exempt research);
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, **or**
    b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

Please note - The IRB may determine that continuing review is still required for any research protocol that falls within the above criteria.

14.8. Continuing Investigator and Research Staff Training

All investigators and members of their research teams should meet continuing education requirements at least every two years after Initial IRB approval for as long as they are involved in human subjects research. Acceptable training includes:

- Attendance at seminars and conferences specific to human research participant protection, such as PRIMR, OHRP, etc.
- Completion of the CITI Program refresher modules - https://www.citiprogram.org/
- Completion of National Institutes of Health (NIH) Training: NIH Clinical center Clinical Research or NIH Office of Extramural Research Protecting Human Research Participants Training - https://phrp.nihtraining.com/users/login.php
- Other online training specific to human research participant protection
- Completion of self-study or other training specific to human research participant protection

Other training may be acceptable. In these cases, the researcher should check with the Alpha IRB Office for a determination.

Investigators should submit evidence of continuing education at the time of continuing review. This can be achieved via the investigator's Site Continuing Review Report, an updated curriculum vitae or other relevant documentation. Continuing review approval may not be granted for investigators who do not submit satisfactory evidence meeting continuing education requirements.

The PI is responsible for ensuring the research staff and key personnel are appropriately trained, are aware of their obligations with regard to human research participant protection regulations and can perform their assigned duties.

14.9. Monitoring Reports

As sponsors routinely monitor investigative sites, they are in a unique position to uncover information to which the IRB may not otherwise have privy. The Investigator should request that the sponsor provide any information that may affect the rights and welfare of participants, or their willingness to continue participation. Such information may be contained within a monitoring report, a Protocol Deviation Report Form (if applicable), an SAE/ Unanticipated Problem Report Form (if applicable), or may be summary of the sponsor's assessment. The Investigator will then notify the IRB of these findings.

14.10. Research Data Retention for FDA-Regulated Research

For FDA-regulated trials, the Investigator is advised to observe the following with regard to data retention when participants withdraw from a clinical trial:

- When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.
- The Investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal

from the interventional portion of the study. Under this circumstance, the discussion with the subject distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.

- The Investigator must obtain the subject's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB must approve the consent document.
- If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the Investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, a Investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

Please also refer to FDA's Guidance for Sponsors, Clinical Investigators, and IRBs Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials for additional information.

14.11. Study Completion/Termination

In order to formally complete a study file, the IRB requires that Investigators officially notify the IRB when a study is terminated or completed by submitting a Close-Out Report to Alpha IRB. A Close-Out Report may be submitted when:

- All subjects have finished their final visits and follow-up, or
- for DHHS-supported protocols, when all subjects have finished their final visits and follow-up and all data analysis at the site been completed.

14.12. REPORTS OR COMPLAINTS FROM EMPLOYEES, STAFF AND SUBJECTS

Alpha IRB encourages sponsors, investigators and research staff to contact us with any feedback, suggestions, or concerns related to the protection of human subjects or IRB processes. You may contact Alpha IRB at 949-542-3882 or email at: info@alphairb.com.

15. Additional Information

Statement of Compliance

Alpha Independent Review Board (Alpha IRB) operates in compliance with applicable laws and regulations including, but not limited to, federal regulations at 45 CFR 46 and 21 CFR 50 and 56, that pertain to human subject protection, as well as other pertinent regulations and guidelines, such as the Good Clinical Practice (GCP) Guideline (E6) of the International Conference on Harmonization, as applicable. Alpha IRB is registered with OHRP/FDA; our registration number is IRB00006205, or you may refer to OHRP's Web site at http://www.hhs.gov/ohrp/. Alpha IRB is also fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Alpha IRB consists of members of the clinical and scientific communities, non-scientists, as well as members of the community as required by Federal regulations to assure a fair and thorough review process.

Resource List

- Food and Drug Administration – www.fda.gov
- United States Department of Health & Human Services – www.hhs.gov
- Clinicaltrials.gov – www.clinicaltrials.gov
- The World Medical Association – www.wma.net
- Frontiers in Bioscience – www.bioscience.org
- ACRP – www.acrpnet.org
- CITI Collaborative Institutional Training Initiative – www.citiprogram.org
- Medical Device Link – www.devicelink.com
- Association for the Accreditation of Human Research Protection Programs - www.aahrpp.org