

August 1, 2011

Template 3

Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution/Organization A):

Federalwide Assurance # (FWA) / Expiration Date:

Name of IRB /IRB Registration #:

Name of Institution Relying on the Designated IRB (Institution B):

Federalwide Assurance # (FWA) / Expiration Date:

The Officials signing below agree that (name of Institution B) may rely on the designated IRB for initial review and continuing oversight of its human subjects research described below: *(check one)*

This agreement applies to all human subjects research covered by Institution B's FWA.

This agreement is limited to the following specific protocol(s):

Name of Research Project:

Name of Principal Investigator:

Sponsor or Funding Agency: _____

Award Number, if any: _____

Other

(describe): _____

[OPTION – Reference ATTACHMENT describing research or program if desired]

Institution A IRB will serve as the IRB of record for research covered under this agreement; it will conduct full review of research as specified above, consistent with the requirements of 45 C.F.R. 46 and 21 C.F.R. 50, 56, 312, and 812 as applicable. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations, the terms of its Office for Human Research Protections (OHRP)-approved FWA, and all other applicable laws and regulations related to the conduct of research covered under this agreement.

August 1, 2011

Other designated responsibilities are delineated in ATTACHMENT A.

This document must be kept on file by both parties and provided to OHRP/FDA upon request.

This Agreement is effective on the date that the last official signs and may be terminated by either party at any time. If the Agreement is terminated prior to the completion of the research, Institution B will need to obtain alternative IRB review.

Authorizing Officials

Signature _____ date _____
Reviewing Institution (Institution A)
Name:
Title:
Official's address:
Address continued:
Official's phone number:
Official's fax number:
Official's email address:

Signature _____ date _____
Relying Institution (Institution B)
Name:
Title:
Official's address:
Address continued:
Official's phone number:
Official's fax number:
Official's email address:

August 1, 2011

ATTACHMENT A

The responsibilities of (Reviewing) Institution A / Institution A IRB are:

1. Maintain a current FWA and accreditation [IF APPLICABLE] and notify Institution B should any lapse(s) occur;
2. Perform initial full Board review of [SPECIFY - protocols covered under this agreement] and make a final decision of approval or disapproval of the study in compliance with all applicable laws/regulations;
3. Conduct continuing review, Serious Adverse Event / Unanticipated Problems review, protocol amendment review, DSMB reports, and any other protocol related documents required by regulation or institutional policy in compliance with all applicable laws/regulations;
4. HIPAA – *[Content based on covered entity status, existence of Privacy Review Boards, and institutional officials' decision on responsibility for review of Research Authorization Forms and Request for Waiver of Authorization.]*
5. Make available to (Relying) Institution B the IRB membership roster and IRB SOPs; also, specific to the research covered under this agreement, any special arrangements to address local context issues as needed;
6. Provide the (Reviewing) Institution A IRB relevant minutes, outcome letters and other relevant documents to the investigator and/or institutional officials at (Relying) Institution B;
7. Comply with all reporting requirements, pursuant to 45 C.F.R. Part 46, including subsections 103 and 113 and 21 C.F.R. 56.108 regarding prompt reporting of unanticipated risks to subjects or others, any serious or continuing non-compliance with regulations or IRB requirements, and any suspension or termination of IRB approval; *[Specific reporting responsibilities to the IRB, appropriate institutional officials {A & B} and supporting department or agency head (or designee), OHRP/FDA, and other required entities will be dependent on institutional written procedures and mutual clarifications to avoid duplication. Other determining factors may include multisite research, whether a central IRB shares responsibilities with a local IRB (facilitated review), etc]*
8. Maintain an IRB membership in compliance with 45 C.F.R. 46 and 21 C.F.R. 56 and obtain additional expertise as needed;
9. Provide appropriate orientation and continuing education on topics related to human subjects protection for IRB Members;
10. Notify (Relying) Institution B immediately of if there is a suspension or restriction of (Reviewing) Institution's A IRB's authorization to review a study;
11. Notify (Relying) Institution B of any changes (Reviewing) Institution A policies or Institution A IRB SOPs that might affect the (Relying) Institution B's reliance on (Reviewing) Institution A's IRB reviews or performance of the research at the local institution.

The responsibilities of (Relying) Institution B and/or on-site Principal Investigator are:

August 1, 2011

1. Maintain a current FWA –[NOTE: The listing of Institution’s A IRB on the FWA for Institution B may or may not be required depending on various factors. Check current OHRP guidance relevant to the specific scenario.]- and accreditation [IF APPLICABLE] and notify Institution A should any lapse(s) occur;
2. Maintain a human subjects protection program compliant with 45 C.F.R. 46, 21 C.F.R. 50, and 21 C.F.R. 56 and have established procedures in place to ensure safe and appropriate performance of the research on site. Policies /SOPs should include, but not limited to:
 - a. Scope and authority of the Human Subject Protection Program;
 - b. Investigator and staff training in human subjects protection, Good Clinical Practice (GCP), and HIPAA as it relates to research;
 - c. Reporting/managing of adverse events, protocol violations, unanticipated problems, and non-compliance;
 - d. Document retention;
 - e. Research oversight and monitoring;
 - f. Managing and reporting conflict of interest;
 - g. Mechanism by which local study participants may report complaints about research;
3. Maintain records of IRB approval and ongoing IRB communications per local institutional policies;
4. Abide by all decisions of the (Reviewing) Institution A IRB relevant to the protocol(s) covered under this agreement;
5. Ensure that before implementing a change to the (Relying) Institution A IRB-approved protocol(s), the investigator will obtain IRB approval for the change (unless the change is designed to eliminate an apparent immediate hazard to subjects), pursuant to 45 C.F.R. 46.103 and 21 C.F.R. 56.108;
6. HIPAA – [*Content based on covered entity status, existence of Privacy Review Boards, and institutional officials’ decision on responsibility for review of Research Authorization Forms and Request for Waiver of Authorization.*]
7. Comply with all reporting requirements, pursuant to 45 C.F.R. Part 46, including subsections 103 and 113 and 21 C.F.R. 56.108 regarding prompt reporting of unanticipated risks to subjects or others, any serious or continuing non-compliance with regulations or IRB requirements, and any suspension or termination of IRB approval; [Specific reporting responsibilities to the IRB, appropriate institutional officials {A & B} and supporting department or agency head (or designee), OHRP/FDA, and other required entities will be dependent on institutional written procedures and mutual clarifications to avoid duplication. Other determining factors may include multisite research, whether a central IRB shares responsibilities with a local IRB (facilitated review), etc.]
8. Provide to the reviewing IRB, any local/institutional specific requirements -- such as required consent language – needed for initial and ongoing review.
9. Obtain and maintain other protocol specific approvals based on local institutional policies or other applicable regulations (e.g. radiation safety committee, Institute Biosafety Committee (IBC), Recombinant DNA Advisory Committee etc)

August 1, 2011

10. Notify the Institution A IRB immediately if there is ever a suspension or restriction from a federal or state regulatory agency or office of the local institution's authorization to conduct or review research;
11. Notify Institution A IRB immediately if there is a suspension or restriction of the local investigator's privileges to conduct human subjects research.
12. Maintain compliance with all applicable federal, state, local laws/regulations and sponsor and institutional requirements related to the conduct of human subjects research.