

August 22, 2011

## Template Outline

### **Reliance Agreement /IRB Authorization Agreement / Memorandum of Understanding**

(Content bullet suggestions below major headings are from Toolkit Sample Templates and review of publicly available on-line information from academic centers.)

#### **I. Objectives and/or Background**

Reduce and eliminate redundant reviews, promote collaborative research, streamline IRB submissions across multi-organization system, decrease cost and time to overall approval and study implementation

Organizational relationships, investigator dual appointment, network affiliation

#### **II. Definitions**

If needed for clarification and determined by entering organizations e.g., "IRB of Record", "facilitated review"

#### **III. Research Covered**

Specific protocols or program unless identified on cover page of the agreement

And / or

Specific categories or other requirements/ exclusions

e.g., expedited review, phase, IND/non-IND, collaborative effort among more than one participating organization

#### **IV. Communication**

(May not be applicable if covered under other sections)

May address utilization of central coordinating center for communicating IRB submissions, IRB review determinations to sites, investigators, utilization of common IT platform, etc

#### **V. Designating Reviewing Institution/IRB and Participation Options**

(Scenario of several organizations entering into ongoing agreement to designate a "central" IRB based on established criteria and/or rotate "central" IRB designation within their group)

Specify criteria and procedure for determining reviewing organization IRB – e.g. primary research recipient award, organization with projected

August 22, 2011

highest enrollment, required IRB expertise, organizational affiliation of lead PI, fixed rotation schedule across participating organizations

Participation options – specify if organizations (reviewing or relying) may decline to participate on a case-by-case basis, if program includes “facilitated review” as an option or requirement as part of the agreement

## **VI. Regulatory Compliance and Other Requirements**

(Or may be incorporated/referenced in sections VII - X below)

General statements referencing applicable federal regulations (e.g. 45 C.F.R. 46, 21 C.F.R. 50, 56, 312, and 812 as applicable, Health Insurance Portability and Accountability Act {HIPAA}), state and local regulations, institutional policies and institutional committee requirements, e.g. radiation safety, Institutional Biosafety Committee, sponsor requirements

### **Minimum requirements for establishment / maintenance of SOPs/policies to include but not limited to:**

- a. Scope and authority of the Human Research Protection Program (HRPP);
- b. Investigator and staff training in human subjects protection, Good Clinical Practice (GCP), Conflict of Interest (COI) and HIPAA as it relates to research;
- c. Reporting/managing of adverse events, protocol violations, unanticipated problems, non-compliance, and suspension/termination of IRB approval of research
- d. Document retention;
- e. Research oversight and monitoring;
- f. Managing and reporting conflict of interest;
- g. Mechanism by which study participants may report complaints about research;

## **VII. Responsibilities of the Reviewing Institution / IRB**

(See Sample Templates for more sample text)

Scope of IRB review – initial submission, continuing reviews, adverse events/unanticipated problems, amendments, DSMB reports

Documentation and communication of review and decisions

Reporting responsibilities (institutional officials, OHRP, FDA, department or agency head, and other required entities) – “what” and “to whom” of Serious Adverse Events / Unanticipated Problems, serious or continuing noncompliance, suspensions and terminations of IRB approval

August 22, 2011

If applicable, address HIPAA Authorization, Privacy Board, responsibility for Waiver or Alteration of Authorization etc as agreed upon between the organizations

**VIII. Responsibilities of the Relying Institution / HRPP**  
(See Sample Templates for more sample text)

Responsibilities for facilitated review (if applicable)

Identification of local contact person who has authority / responsibility to respond to questions and provide relevant information re local context issues (May specify someone other than PI if desired)

Ensure local investigator and staff are appropriately qualified and meet the institution's standards for eligibility to conduct research.

Ensure that local institutional committee reviews and approvals are in place before research commences at the institution. (e.g., radiation safety, bio-safety, conflict of interest, etc)

Monitor compliance with the terms and conditions of the IRB's approval of research being conducted at the local institution as well as compliance with all applicable laws, regulations, and policies.

Reporting responsibilities (IRB, institutional officials, OHRP, FDA, department or agency head, and other required entities)- "what" and "to whom" of Serious Adverse Events / Unanticipated Problems, serious or continuing noncompliance, suspensions and terminations of IRB approval

If applicable, address HIPAA Authorization, Privacy Board, responsibility for Waiver or Alteration of Authorization etc as agreed upon between the organizations

**IX. Responsibilities of Both Reviewing Institution / IRB and the Relying Institution / HRPP**

Maintenance of active FWA and reporting to other organizations in this agreement should lapses occur

Maintenance of HRPP accreditation and reporting to other organizations in this agreement should lapses occur - IF applicable

August 22, 2011

Subject to applicable law, provision of access to information necessary to execute responsibilities to: (1) support human subject protections review; (2) maintain compliance with IRB and organizational requirements; and (3) satisfy regulatory oversight agencies and accrediting bodies

Compliance with applicable laws, regulations, and policies for research record retention

**X. Responsibilities of the Principal Investigator**  
(specific to structure / scenario)

May address responsibilities of "Lead PI"

Specify need to submit letter of intent to rely on IRB of another organization, protocol submission and reporting, request for facilitated review if applicable

**XI. Agreement Term, Modification, Termination**

Effective date of agreement, expiration

Renewal/extension of agreement

Procedures for modification/amendment

Procedures for termination – conditions, notification, option to correct deficiencies cited for termination

Cooperation across organizations to minimize disruption of research and the protection of human subjects in the event of termination

**XII. Miscellaneous**

Retention of this agreement on file and made available upon request to OHRP / FDA

Amendment of FWA **IF** applicable

Other as determined by the organizations