

August 1, 2011

**Template 4**

**Memorandum of Understanding  
Between**

**[INSTITUTION X]**

**And**

**[INSTITUTION Y]**

This Memorandum of Understanding [MOU] is entered into by **[INSTITUTION X]** and **[INSTITUTION Y]** as of [DATE (Effective Date)], to specify the terms and conditions under which **[INSTITUTION X]**, through one of its duly-authorized Institutional Review Boards (IRBs), will serve as the IRB of Record, defined below, for research conducted at **[INSTITUTION Y]**.

The terms of this Agreement are applicable to the research program identified below conducted at **[INSTITUTION Y]**.

Name of Institution Providing IRB Review:  
Federalwide Assurance (FWA) # / (Expiration Date):  
Name of Institutional Review Board(s) (IRB):  
IRB Registration #(s):

Name of Institution Relying on the Designated Institutional Board (IRB):  
Federalwide Assurance (FWA) #/ (Expiration Date):

Research Program Covered Under This Agreement  
Name of Research Program or Network:  
Protocol Names, if available:  
Principal Investigator(s):  
Sponsor or Funding Agency:

[OPTION – Insert reference to any desired attachments – e.g. Research program description, other relevant agreements between entities, etc]

**I. Background**

[Describe rationale for the MOU – history between the institutions, investigator dual appointments, financial relationships, corporate management merger, collaborative research between the institutions, network affiliation, desire to streamline review etc.]

[SAMPLE LANGUAGE – at end of Background Description]

To facilitate the continued collaboration between **INSTITUTION X** and **INSTITUTION Y**, to clarify oversight responsibility for collaborative research, and to provide for the efficient review of collaborative protocols, **INSTITUTION Y** wishes to authorize the **INSTITUTION X** IRB to be the sole IRB for approval and continued oversight of research, as described above and [OPTION and/or in ATTACHMENTS \_ ]

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[With this Memorandum of Understanding, subject to the terms and conditions herein, the **INSTITUTION X IRB** will serve as the IRB of Record for the research program listed above and conducted at **INSTITUTION Y**.]

## **II. Definitions**

***IRB of Record*** An IRB that, on behalf of itself and its parent institution, assumes all of the legal and regulatory responsibilities conveyed upon an IRB, or upon an institution in connection with its operation of an IRB (IRB Responsibilities) by federal regulations for the protection of human subjects (45 CFR Part 46 and 21 CFR Parts 50 and 56). Unless otherwise provided in this MOU, the IRB of Record will assume all IRB responsibilities.

[Other definitions as desired by institutions entering into the MOU]

## **III. Exceptions / Conditions / Restrictions**

As of the effective date of this agreement, **INSTITUTION X IRB** shall serve as the IRB of Record for [insert program name] for **INSTITUTION Y**. Exceptions to this provision may be made on a case-by-case basis following mutual agreement in writing.

[SAMPLE LANGUAGE – example of restriction institutional officials may desire –  
The **INSTITUTION X IRB** may approve research as described in this agreement, but research may not begin until the principal investigator receives written approval from **INSTITUTION Y**. This condition is intended to enable both institutions to assure that their respective compliance obligations are satisfied. The **INSTITUTION X IRB** approval notice will include a statement that the research may not begin until the principal investigator receives written approval from **INSTITUTION Y**.]

## **IV. INSTITUTION X Responsibilities**

- A. Conduct initial and continuing IRB review, serious adverse event/unanticipated problems review, protocol amendments review, DSMB reports and review of other protocol related documents of the research program identified above in accord with the terms and conditions of its FWA and all other applicable laws, regulations, policies, and standard operating procedures (SOPs).
- B. Provide **Institution Y** officials / investigator with relevant IRB minutes, outcome letters and other relevant documents related to the review of the research;
- C. [If applicable, address Health Insurance Portability and Accountability Act (HIPAA) Authorization, Privacy Board, responsibility for Waiver or Alteration of Authorization etc as agreed upon between the institutions.]
- D. Notify the [Specify –Institutional Official(s) / Office(s) **Y**] of the following:

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- i. Any serious or continuing investigator non-compliance with IRB requirements or applicable law, regulation, and policy for the protection of human subjects;
  - ii. Any suspension or termination for cause of the IRB approved research;
  - iii. Any unanticipated problems involving risks to subjects or others related to the approved research which are reported to the **INSTITUTION X** IRB; and
  - iv. Additional concern(s) related to the conduct of the approved research that **INSTITUTION X** believes should be relayed, including but not limited to participant complaints associated with **INSTITUTION Y**'s role in the approved research.
- E. Maintain a current FWA and notify **INSTITUTION Y** of any changes in FWA status, Human Research Protection Program (HRPP) accreditation status [IF APPLICABLE], or policies or SOPs that might affect **INSTITUTION Y**'s reliance on **INSTITUTION X**'s IRB or performance of the research on site.

## V. **INSTITUTION Y** Responsibilities

- A. Provide relevant local expertise/input to any IRB inquiries, required consent template language, and any other local institutional requirements that must be fulfilled prior to submission to the reviewing IRB [SPECIFY PROCEDURES, TIMELINES IF DESIRED]
- B. [If applicable, address Health Insurance Portability and Accountability Act (HIPAA) Authorization, Privacy Board, responsibility for Waiver or Alteration of Authorization etc as agreed upon by the institutions.]
- C. Conduct research identified above in accord with the terms and conditions of its FWA and all other applicable laws, regulations, institutional/sponsor policies, standard operating procedures (SOPs), and **INSTITUTION X** IRB requirements.
- D. Obtain and maintain other protocol specific approvals based on local institutional policies or other applicable laws, regulations or requirements (e.g. radiation safety committee, Institute Biosafety Committee (IBC), Recombinant DNA Advisory Committee (RAC), etc.)
- E. **INSTITUTION Y** will promptly notify the **INSTITUTION X** IRB of:
- i. Unanticipated problems involving risks to subjects or others or serious or continuing non-compliance by **INSTITUTION Y** staff members (non-compliance includes non-compliance with

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**INSTITUTION X IRB** requirements or applicable law, regulation and policy for the protection of human subjects and patient confidentiality); and

- ii. Any additional concern(s) related to the conduct of the approved research that **INSTITUTION Y** or **INSTITUTION X** believe should be relayed, including but not limited to participant complaints associated with the approved research that are made to any offices or individuals of **INSTITUTION Y**.

F. **INSTITUTION Y** will assure that all personnel involved in the research complete appropriate human subjects protection education and training, consistent with applicable law, regulation, and policy for the protection of human subjects.

G. Maintain a current FWA and notify **INSTITUTION X** of any changes in FWA status, Human Research Protection Program (HRPP) accreditation status [IF APPLICABLE], or internal policies or SOPs that might affect **INSTITUTION X**'s willingness or ability to serve as IRB of Record for research covered under this agreement.

#### **VI. Reporting to Office for Human Research Protections (OHRP) / Food and Drug Administration (FDA) and Other Required Entities**

**(may OMIT Reporting under IV and V – if preference is to list all reporting here – OR delete IRB and Institutional reporting below – to avoid duplication)**

Federal regulations require written procedures for reporting the following:

- (1) Any unanticipated problems involving risks to subjects or others;
- (2) Any serious or continuing noncompliance with regulations or the determinations of the IRB; and
- (3) Any suspension or termination of IRB approval.

For research covered under this agreement, responsibilities for reporting to the IRB, institutional officials, department or agency head or designee, OHRP, and FDA are as follows:

**SPECIFY: [Responsibilities addressed here will be dependent on the institutions' policies and mutual clarifications to avoid duplication, the type of the research, whether a central IRB shares responsibilities with the a local site IRB (facilitated review), multisite collaborations, (local occurrence vs assessment of occurrences across sites that meets definition of unanticipated problems impacting study wide, etc)]**

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The chart example below is an optional format.

Event	Entity					
	IRB of Record	Institutional Officials		OHRP	FDA	Specify Dept./ Agency or Designee or Other Entity if applicable
		X	Y			
Unanticipated problems at a local site	*	*	*	*	*	*
Unanticipated problems study wide (if applicable)	*	*	*	*	*	*
Non-compliance with regulations or IRB requirements or determinations	*	*	*	*	*	*
Suspension or termination of IRB approval	----	*	*	*	*	*

\* Specify for each if applicable, the responsible party – individual(s) or office(s) – local principal investigator, lead principal investigator, institutional regulatory official or office, IRB, IRB administrator, central monitoring body etc

**VII. Record Retention and Access**

Each institution shall comply with applicable laws, regulations, and policies for research record retention. The following record access procedures will apply:

- A. The **INSTITUTION X** IRB of Record shall make available upon reasonable request from **INSTITUTION Y** relevant minutes of IRB meetings at which the covered research is discussed. **INSTITUTION X** agrees to provide the **INSTITUTION Y** access to **INSTITUTION X** IRB SOPs, IRB rosters, IRB training records, conflict of interest policies and other records as necessary to conduct audits and investigations of the IRB approval process whether for cause or on a routine basis, and as permitted by law. Any **INSTITUTION Y** representative afforded such access will be bound by applicable law, regulation and **INSTITUTION X** policy for the protection of confidential information.
- B. **INSTITUTION Y** will make available to **INSTITUTION X**, upon reasonable request, any records, including [SPECIFY – staff training records, policies/procedures on research oversight and monitoring, reporting of adverse events/ unanticipated problems, conflict of interest, mechanism by which local study participants report complaints, etc] as agreed upon and/or needed to conduct audits and investigations of the covered research, and as permitted by applicable law. Any **INSTITUTION X** representative afforded such access will be bound by applicable law, regulation and **INSTITUTION Y** policy for the protection of confidential information.

**VIII. Term and Termination**

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The initial term of this agreement shall commence on the Effective Date and shall continue for [SPECIFY #] years thereafter, unless otherwise terminated in writing by either party as provided herein.

- A. Either party may terminate the agreement upon [SPECIFY #] days written notice to the other party.
- B. In the event of a material breach of any of the terms of this agreement, any party may terminate the agreement upon filing written notice of any material breach of its terms with the other party, and affording the breaching party (SPECIFY #) business days to rectify the breach to the noticing party's satisfaction.
- C. In the event of any termination, the parties shall cooperate to minimize the disruption to ongoing research and to ensure the protection of all human subjects.
- D. This agreement may be modified, cancelled or renegotiated upon mutual consent, at any time, through an amendment signed by authorized representatives of the organizations.

**IX. Miscellaneous**

This MOU will be kept on file at **INSTITUTION X** and **INSTITUTION Y** [SPECIFY office / official if desired] along with all subsequent amendments to the original document. **INSTITUTION Y** will amend its FWA on file with OHRP to reflect delegation to the **INSTITUTION X** IRB of responsibility for the review, approval, and oversight of research as specified in this agreement. **[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.]** Any future changes to the responsibilities delegated under this MOU will also be communicated to OHRP.

**X. Signatures:**

**INSTITUTION X:**

Signature:  
Date:  
Name:  
Title:  
Address:  
Phone:  
Fax:  
Email address:

**INSTITUTION Y:**

Signature:  
Date:  
Name:  
Title:  
Address:  
Phone:  
Fax:  
Email address: