

August 1, 2011

## Template 2

### Institutional Review Board Authorization Agreement between

\_\_\_\_\_

**and**

\_\_\_\_\_

Pursuant to 45 C.F.R. 46.114, the \_\_\_\_\_ and \_\_\_\_\_ are entering into this agreement for \_\_\_\_\_ to conduct Institutional Board Review (IRB) review of the research protocol or activities identified below.

**Name of Institution/IRB Providing IRB Review (Institution A):**

Federalwide Assurance (FWA) # \_\_\_\_\_ Expiration date \_\_\_\_\_  
IRB Registration # \_\_\_\_\_

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

\_\_\_\_\_

FWA # \_\_\_\_\_ Expiration date \_\_\_\_\_

Institution B will rely on the designated \_\_\_\_\_ IRB for review and continuing oversight of its human subjects research described below. This agreement is limited to the following specific protocol(s) or research activity:

Name of Research Project/Activity:

Protocol Number(s):

Name of Principal Investigator (**Institution B**):

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The extent to which **Institution B** may rely upon the review by the **Institution A** IRB is limited to [as specified above AND / OR as further described per ATTACHMENT A - protocol / the study summary.] **Institution A** IRB 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 and will conduct research in accord with the terms and conditions of its OHRP-approved FWA and all other applicable laws, regulations, and policies. **Institution A's** IRB will be listed on the OHRP-approved FWA for **Institution B**. [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.]

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The **Institution A** IRB retains responsibility for compliance with regulatory requirements under 45 C.F.R. Part 46 related to the administration and operation of the IRB. These include, for example, following written procedures and maintaining records in accord with 45 C.F.R. parts 46.103 and 115, respectively. **Institution B** agrees that the **Institution A** IRB may suspend or terminate approval of research that is not conducted in accordance with the **Institution A** IRB's requirements or that is associated with unexpected serious harm to subjects pursuant to 45 C.F.R. 46.113.

**Institution B** will ensure that before implementing a change to **Institution A** IRB-approved protocol, its investigator will obtain **Institution A** 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. **Institution B** retains responsibility, pursuant to 45 C.F.R. Part 46, including subsections 103 and 113 and in accordance with written procedures, to promptly report to the **Institution A** IRB, appropriate institutional officials, and supporting department or agency head (or designee) and OHRP any unanticipated risks to subjects or others, any serious or continuing noncompliance with 45 C.F.R. Part 46 or the IRB's requirements or determinations, and any suspension or termination of IRB approval. [NOTE: Institutions A & B should clarify and edit this section based on each institution's internal written procedures for reporting to OHRP and other entities to clearly designate responsibilities under this Agreement. In the setting of multisite studies, a lead institution or lead principal investigator (via a central coordinating center) may be responsible for reporting of an adverse event or series of adverse events at other sites that meet the criteria of unanticipated problems. ]

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.

This Agreement will be kept on file at both institutions and will be available to OHRP upon request.

Authorizing Officials

X \_\_\_\_\_  
Name  
Title  
Official's address  
Address continued  
Official's phone number  
Official's fax number  
Official's e-mail address

\_\_\_\_\_  
Date

X \_\_\_\_\_  
Name  
Title  
Official's address  
Address continued  
Official's phone number  
Official's fax number  
Official's e-mail address

\_\_\_\_\_  
Date