A multi-site study involves multiple institutions [engaged in research](http://orcr.arizona.edu/sites/orcr.arizona.edu/files/HRP-103%20v2014-01.pdf) (e.g., consenting, collecting data, or analyzing identifiable information). This appendix should be used when the UA IRB will review research activities for investigators or research staff not affiliated with the UA who are engaged in research. See HSPP guidance on *Single IRB Review* for more information about Single IRB research and requirements.

Note: This form should be completed with assistance from the Relying Institution’s IRB/Human Research Protection Program (HRPP).

Complete this form for each participating site (pSite) the UA IRB will oversee. If the site will obtain their own IRB approval, this appendix is not necessary.

|  |
| --- |
| Basic Information  |
| **Title of Study:** |       |
| **UA Principal Investigator Name:**  |       |
| **eDoc # (if federally funded)** |       |
| Section 1: Relying Institution General Information |
| Relying Institution Name:       |
| Relying Institution FWA#       |
| FWA expiration date:        |
| Is the Relying Institution AAHRPP accredited? [ ]  Yes [ ]  No |
| Relying Institution IRB Contact Information:Name:      Email:      Phone:       |
| Is the Relying Institution a participating member of [SMART IRB](https://smartirb.org/participating-institutions/) or [IRExchange](https://www.irbexchange.org/p/)? [ ]  Yes [ ]  No |
| Section 2: Relying Institution Engagement & Scope |
| Specify how the Relying Institution is engaged in this research project (check all that apply):

|  |
| --- |
| [ ]  The Relying Institution is the prime awardee of federal funds for this study. |
| [ ]  Site Principal Investigator (PI) and personnel are consenting participants.  |
| [ ]  Site PI and personnel are interacting with participants for research purposes. |
| [ ]  Site PI and personnel have access to identifying study information. |

Describe how recruitment and consent will occur at the Relying Institution:     *Note: Required consent form language from the Relying Institution cannot include HIPAA authorization language. The UA IRB will not act as the Privacy Board for Relying Institutions. HIPAA authorizations are required to be reviewed and approved by the Relying Institution’s IRB/HRPP/Research Compliance Office or Privacy Board.* |
| Describe any requirements specific to the Relying Institution on how data will be accessed and/or stored:      |
| **Are there any state or local laws that need to be considered that would impact this research protocol or informed consent document (wards of state, emancipated minors, etc.)?**      |
| Describe any state or local laws that need to be considered that would impact this research protocol or informed consent document (wards of state, emancipated minors, etc.):     *Please ensure that required language is included in the site-specific consent form(s).* |
| Please confirm all ancillary reviews at the Relying Institution have been obtained. Examples include site authorizations, scientific review committee, radiation/biosafety, travel authorization, etc.**[ ]**  No ancillary reviews required **[ ]**  Ancillary reviews required and completed |
| Describe how the research activities will be monitored and overseen, including a description of standards of professional conduct and practice that govern research at the Relying Institution:      |
| Describe the management of information (e.g., results, new information, unanticipated problems involving risk to subjects or others, or protocol modifications) among subjects at the Relying Institution:      |
| Are all procedures to be conducted by the participating site (pSite) already approved as part of the main study? [ ]  Yes [ ]  No If NO, specify what new procedures and/or materials need approval:      |
| Section 3: Relying Institution PersonnelList all personnel at the Relying Institution who will be engaged in the research.  |
| Name | Research Role | Consenting Individuals | Human Research Training Expiration Date |
|  |  | Choose an item. | Click or tap to enter a date. |
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| TO BE COMPLETED BY THE RELYING INSTITUTION:Describe any relevant investigations, audits, findings, or non-compliance determinations that have been made against study-related personnel listed above at the Relying Institution that would be relevant to the conduct of this study:        |
| Describe any local context information that is relevant to the conduct of this study:       |
| Did the Relying Institution determine there is a relevant individual or institutional financial Conflict of Interest (FCOI) for this protocol? [ ]  Yes [ ]  NoIf YES, provide a summary of the conflict and management plan or upload documentation to eIRB:      |
| Section 4: Signatures  |
| I attest that the information in this form is complete and accurate.Site PI Name:      Contact Phone Number & Email:      Site PI Signature:      Date:       |
| HRPP Contact Name:      HRPP Contact Title:      HRPP Contact Signature:      Date:       |

**Additional Items needed for review:**

* Refer to the *Single IRB Review* [HSPP guidance](https://research.arizona.edu/compliance/human-subjects-protection-program/guidance-researchers) for pSite requirements and information
* Word versions of applicable study materials: Consent Forms, Recruitment Materials, Data Collection materials, Participant Materials
* Documentation of reliance (as applicable; consult HSPP)
* Site PI CV or biosketch
* Copy of human subjects training certificates for site PI and all site personnel
* Any other site-specific requirements and/or approvals