A multi-site study is a study that 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 (Reviewing IRB) for an investigator or research staff not affiliated with the UA who is engaged in research (Relying IRB). See HSPP Guidance, [*Single IRB Review*](https://research.arizona.edu/sites/default/files/Single%20IRB%20Review%20v2022-08.pdf), for more information about Single IRB research and requirements.

This form should be completed with assistance from the Relying Site’s local IRB/HRPP/Research Compliance Office. They will also be able to provide their local submission requirements for when another IRB will serve as the single IRB of record. Most IRBs require a local submission to initiate the local context review process.

* Single IRB: An IRB either assumes (Reviewing IRB) or gives up (Relying IRB) its oversight of the research activity to another equally qualified IRB. sIRB is designed to reduce duplication and increase efficiency by designating a sIRB review when more than one site is involved in a research project.
* Reviewing IRB: The IRB that is providing IRB oversight for all sites engaged. Also called IRB of record.
* Relying Institution: The Institution that gives up (i.e., defers, cedes) their IRB oversight to and relies on the Reviewing IRB to provide proper oversight of their researchers on the project.

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

|  |
| --- |
| Basic Information  |
| **Title of Study:** |  |
| **Short Title:** |       |
| **UA Principal Investigator Name:**  |       |
| **eDOC# if Federally Funded** |       |
| Section 1: Relying Institution General Information |
| Name of Relying Institution:      |
| Relying Institution’s IRB Contact Information:Name:      Email:      Phone:       |
| Is the Relying Institution willing to rely on the University of Arizona IRB’s Minimal Risk or Exempt determination for this project, if applicable?\* [ ]  Yes [ ]  No\*Consult the Relying Institution’s IRB for assistance with answering this question. If No, and the project is eligible for a Minimal Risk or Exempt determination, a separate IRB approval for each site will be needed from each site.  |
| Is the Relying Institution a participating member of [SMART IRB](https://smartirb.org/participating-institutions/) or [IRExchange](https://www.irbexchange.org/p/)? [ ]  Yes [ ]  No |
| Will the University of Arizona be the coordinating center?\* [ ]  Yes [ ]  No\*When the UA is the coordinating center, investigators must submit this Appendix and all recruitment, data collection and consent documents, for EACH site that the UA is requested to be the IRB of record; copies of IRB deferral to the UA; and any other site-specific requirements to be reviewed by the UA IRB. |
| Section 2: Relying Institution Engagement & Scope |
| Specify how the Replying Institution is Engaged in this research project (check all that apply):

|  |  |
| --- | --- |
| [ ]  | The Relying Institution receives part of federal funds from this study |
| [ ]  | Site 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:      |
| **Describe any state, local, or federal regulatory requirements that apply to the conduct of this study at the Relying Institution. Please describe steps that must be taken to adhere to these requirements. This could include, for example, age of majority, legally authorized representatives, children/adults with impaired decision-making capabilities, confidentiality of specific health information, emancipated minors, wards of the state, embryonic stem cells, etc.:**      |
| Are any of the applicable state, local, or federal requirements identified above associated with specific required consent form language? [ ]  Yes [ ]  NoIf YES, please ensure this language is included and identified in the site-specific consent form provided for local review. |
| 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 conducted by the site already IRB approved as part of the main study? [ ]  Yes [ ]  No If not, specify what new procedures and/or materials need approval at this time:      |
| Section 3: Relying Institution Personnel List 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 relevant 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 (COI) for this protocol? [ ]  Yes [ ]  NoIf YES, provide a summary of the conflict and management plan or attached documentation:      If YES, provide an institutional Conflict of Interest point of contact for questions related to the Relying Institution’s COI management plan (this should be someone in the office/entity who prepared the management plan): Name:      Email:      Phone:       |

**Additional Items needed for review:**

* [Refer to Single IRB guidance](https://research.arizona.edu/sites/default/files/Single%20IRB%20Review%20v2022-08.pdf) for P-site requirements and information.
* Word Versions of applicable subject materials: Consents, PHI Authorization Form(s), Recruitment Materials, Data Collection materials, additional Participant Materials.
* Documentation of reliance (as applicable; consult HSPP).
* Site PI CV.
* Copy of Human Subjects Training certificates for Site PI and all site personnel.
* Any other site-specific requirements and/or approvals.