**RAP IRB Reliance Request Form  
UO to Serve as Reviewing IRB**

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| **Purpose:** For collaborative and multi-site research, a reliance arrangement may be established in which one IRB defers oversight to another. Submit this form to request that the UO IRB agree to serve as the IRB of record for the study providing oversight for collaborating researchers and any activities that occur at collaborating sites. |

**Instructions:** Use this form to request a reliance arrangement in which the University of Oregon IRB agrees to serve as the IRB of record.

**If you are** **requesting UO to be the lead institution**, attach this form and any solicited information with a New Study submission in the RAP. If your protocol has already been approved, submit this form with a Modification Submission in the RAP.

**General information for investigator’s reference (optional):**

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| Principal  Investigator (PI): |  | Faculty Advisor: |  |
| Study Title: |  | | |

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| 1. Funding | |
| * 1. If this research is funded (current or anticipated), is this reliance request being submitted to secure preliminary agreement for the UO IRB to be the IRB of record for a sponsored research application? | | |
| Yes  No  n/a | If “Yes”, briefly explain the sponsor requirements: | |
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| 1. Relying Site Information | | | | |
| * 1. Each site that will rely on the UO IRB review must be listed in the RAP as a “Participating Site”. Identify one principal investigator for each site. See our guidance on [creating a multi-site study](https://research.uoregon.edu/sites/default/files/2023-08/hrp-956_-_investigator_-_create_multi-site_irb_-_uo_reviewing_irb.pdf). Note whether the Participating Site PI has a conflict of interest. The PI must submit applicable [Human Subjects Conflict of Interest](https://research.uoregon.edu/sites/research1.uoregon.edu/files/2022-08/hrp-921_-_template_-_hs_coi_form_8.15.22.docx) (COI) forms ONLY for those individuals who answer “yes” to any question on their form. COI forms for these individuals should be uploaded to Question 2 of the Local Study Team Members section of the submission. | | | | |
|  | Name of Relying Institution/Organization | | Relying Site Principal Investigator | Does the Site PI have a conflict of interest? If yes, please upload the [COI form](https://research.uoregon.edu/sites/research1.uoregon.edu/files/2022-08/hrp-921_-_template_-_hs_coi_form_8.15.22.docx) to the RAP submission |
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| * 1. Each relying institution must complete a [Relying Site Survey](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/RAP%20Form%20-%20Relying%20Site%20Survey.docx). Is/Are Relying Site Survey/s attached? | | | | |
| Yes  No | | If “No”, briefly explain: | | |

| 1. Proposed Reliance Arrangement |
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| * 1. Provide justification for the request to have the UO IRB serve as the reviewing IRB (check all that apply) | |
|  | Majority of research activities will be performed at UO |
|  | Majority of research activities will be conducted or led by UO researchers |
|  | This is a collaborative study and all institutions are deferring to one approving IRB |
|  | This is a multi-site study (i.e., the same activities occur at each site) and all sites are deferring to one approving IRB |
|  | Other - Please provide details: |

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| * 1. Provide an overview of the research collaboration. Explain the following:      + - The role of each collaborator        - How the collaborators will [engage](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) in the research (e.g., consenting, interacting, analyzing identifiable data, etc.).        - The location of research activities; and        - What activities will occur at each respective site |

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| * 1. After reviewing the Principal Investigator Responsibilities for Multi-Site Research (see below), explain how the UO PI will oversee the conduct of the research for all sites. |

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| * 1. Describe where data collection activities will take place and how data will be stored, managed, and secured. |
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| 1. UO Principal Investigator Responsibilities  for Collaborative and Multi-Site Research |
| 1. As the overall PI for the study, the UO investigator is responsible for requesting the reliance arrangement for the UO IRB to serve as the IRB of record. This includes:    1. Requesting a pre-clearance letter of support from RCS prior to submitting for federal funding.    2. Facilitating execution of reliance arrangement in collaboration with RCS, the UO IRB, and relying sites. 2. The UO PI is responsible for securing IRB approval for the conduct of the research and maintaining current approval. This includes:    1. Submitting a protocol application and securing either an Exempt Determination from RCS or approval by the IRB prior to implementing human subject research activities.    2. Ensuring all sites are identified on the approved protocol and a Site Investigator is designated for each relying site. Ensuring executed reliance agreements are in place prior to a site engaging in human subject research activities.    3. Ensuring all research personnel engaged in the research at all sites are listed in the Research Personnel Form included in the IRB approved protocol. Ensuring all research personnel complete a Conflict of Interest forms and any forms identifying a conflict are included with the application for review by RCS and/or the IRB.    4. Developing a comprehensive Single IRB Plan included with the IRB protocol application.    5. Working with RCS during the review process to facilitate gathering information for all sites including basic contact information, local context surveys, and any other information required for review and approval of the protocol application.    6. Submitting and securing approval for any amendments to the research protocol and/or the reliance arrangement plan prior to implementing changes at any sites.    7. Submitting requests for continuing review or progress reports and ensuring continuous approval is secured while conducting human subject research activities. 3. The UO PI is responsible for overseeing the conduct of the research at all sites in compliance with the IRB approved protocol. This includes:    1. Fulfilling the obligations of the Principal Investigator Responsibilities as agreed to within the application submitted for protocol review to RCS and/or the UO IRB.    2. Ensuring all research personnel engaged in the research maintain current requisite training, are trained to conduct research according to the approved protocol and institutional policies.    3. Disseminating the currently approved protocol to all research sites and ensuring the currently approved protocol and materials, including the applicable consent and/or assent materials, are employed by the research team.    4. Implementing the reliance arrangement plan approved by the UO IRB.    5. Submitting reportable events that occur at any sites to the UO IRB and responding to any requirements resulting from the review of those event.    6. Providing and/or facilitating access to study records for all sites upon request from RCS, the UO IRB and/or regulatory agencies. | |