**RAP Form
Potential Relying Site
Point of Contact Survey**

**Instructions:** Use this form to when requesting reliance arrangement in which the University of Oregon IRB agrees to serve as the IRB of record. This form must be completed by the relying IRB. The University of Oregon Principal Investigator must submit this form along with the [IRB Reliance Request Form – UO to Serve as Reviewing IRB](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/RAP%20Form%20-%20Reliance%20Request%20-%20UO%20Reviewing%20IRB.docx) with either a New Study submission or a Modification submission in the RAP, along with all other solicited materials. [[1]](#endnote-1)

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. Relying IRB Information
 |
| Name and title of person completing this form: |       |
| Name of Relying Institution: |       | Federal Wide Assurance (FWA) #: |       |
| Provide any other Names the Site is Known by: |       |
| IRB Contact Name: |       | IRB Contact Phone: |       |
| Local PI Name: |       | Local PI Email: |       |
| Local Protocol Title: |       |
| * 1. Has the institution’s FWA been extended to non-federally funded research?
 |
| [ ]  Yes [ ]  No |  |
| * 1. Identify any affiliations this site has relevant to this study, such as a university, clinic, or hospital. Note: This information is collected to allow us to confirm that all sites engaged in the research are covered by a reliance arrangement and to identify relationships between institutions.
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|       |
| * 1. If any of the sites identified in question 2 are within a network or system, do they have a separate FWA?
 |
| [ ]  Yes [ ]  No | If “Yes”, identify the sites with separate FWAs below. |
|       |
| * 1. Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subjects research proposed at the site?
 |
| [ ]  Yes [ ]  No | If “Yes”, explain any investigations, audits or findings that may be relevant below. |
|  |
| * 1. Does the institution have a post approval monitoring program or other regulatory oversight for ongoing research?
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| [ ]  Yes [ ]  No | If “Yes”, does the post approval monitoring program or other regulatory oversight monitor studies that have been deferred to an external IRB?[ ]  Yes [ ]  No |
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| 1. Local Context Information
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| * 1. Are there any state laws that the Reviewing IRB will need to consider when reviewing this study?
 |
| [ ]  Yes [ ]  No | If “Yes”, describe the relevant state laws and provide a link to any key documents (e.g., institutional policy for applying state law or link to the statute) below. |
|       |
| * 1. Are there any community or cultural differences for the local population of subjects that require consideration?
 |
| [ ]  Yes [ ]  No | If “Yes”, describe the relevant information below. |
|       |
| * 1. Is 18 the age of majority for the state in which your site is located?
 |
| [ ]  Yes [ ]  No | If “No”, identify the age of majority below. |
|       |
| * 1. Does the institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects (e.g., the institution does NOT consider this “Preparatory to Research” activities)?
 |
| [ ]  Yes [ ]  No [ ]  Not applicable – the HIPAA Privacy Rule does not apply to this study or institution. |

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| 1. Site Policies
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| * 1. Does the site have a posted policy for the following? *NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.*
 |
| [ ]  | Age of Assent Policy |
| If selected, provide a link (URL) to the policy or paste the policy here |
| [ ]  | Consent Process for those with Impaired Decision-Making Capacity |
| If selected, provide a link (URL) to the policy or paste the policy here |
| [ ]  | Use of short forms for non-English speaking individuals |
| If selected, provide a link (URL) to the policy or paste the policy here |
| [ ]  | Translation of consent forms for non-English speaking individuals |
| If selected, provide a link (URL) to the policy or paste the policy here |
| * 1. Provide any institutionally-required consent form language for compensation in the event of research- related injury:
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|       |
| * 1. Provide any institutionally-required consent form language for pregnancy testing in minors:
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|       |
| * 1. Provide any institutionally-required consent form language for genetic testing:
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|       |
| * 1. Provide any other consent form language required by site policy or state law:
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|       |

1. Information for this form was obtained from the *Potential Relying Site SMART IRB Point of Contact Survey* as part of SMART IRB, which is funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-01S1. [↑](#endnote-ref-1)