**RAP Application  
Initial Review**

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| **Purpose:** This is a supplemental application form to be included with your electronic application submitted through the Research Administration Portal (RAP) system when applying for an **Initial Review** by the Institutional Review Board (IRB) of proposed human subjects research.  The IRB serves to protect the rights and welfare of human subjects in research in accordance with federal, state, and institutional regulations and policy. This application initiates IRB review of the proposed research.  **No human subject research activities may occur until IRB approval is issued.** |

**Instructions:** Complete the form below and upload to the Basic Study Info page of the New Study submission activity in the IRB Module of the RAP. Upload all applicable research materials (e.g., research plan, attachments, consent form, surveys, interview guides, etc.) as prompted throughout this application and within the electronic application pages in the RAP. NOTE: Incomplete or unreadable applications will extend the IRB review process.

For more information about protocol submission and to find forms and other documents referenced below, see our [Human Subjects Applications, Forms, and Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-applications-forms-guidance) webpage. Please reference the [Attachment Guidance](https://research.uoregon.edu/sites/default/files/2021-01/RAP%20Guidance%20-%20Attachments.pdf) for where to upload documents in the RAP Smartform.

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

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

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| 1. Research Request | | | | |
| * 1. Select one of the following: | | | | |
| **Initial Review of Newly Proposed Research** | | | | |
| **Initial Review for Expired Research** – For review of research that was previously approved by the IRB that has now expired. Answer the questions below: | | | | |
|  | * + 1. State reason for lapse in approval: | | | |
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|  | * + 1. Describe the plan to prevent future lapses in approval: | | | |
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|  | * + 1. If the study is sponsored or funded, has the sponsor/funding agency been notified of the lapse in approval? | | | |
|  | | Yes  No | | N/A (no sponsor involved/not required) |
| If “No”, explain: | | |  | |
|  | * + 1. Has any human subject research activity been conducted after the IRB approved expiration date? | | | |
| * Once there is a lapse in IRB approval of research, investigators must stop all human subject research activities, including intervening or interacting with subjects and obtaining or analyzing identifiable private information about human subjects. | | | | |
|  | | Yes  No | | If “Yes”, submit a [**Reportable New Information**](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/report-new-information-event-reporting) report in the RAP describing the number of subjects enrolled, the research interventions/activities conducted and/or the data analyzed: |

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| 1. Developing Materials for Submission | | | | |
| * 1. Identify additional application forms to include with your submission. | | | | |
| * Check all that apply, and upload completed forms in the **IRB Module of the RAP** system as noted in the “Where to Upload” column. | | | | |
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| **Check all that apply to your protocol** | | **Topical Guidance** | **Applicable Forms** | **Where to Upload in the RAP** |
|  | Funded or Sponsored | * [Funded and Sponsored Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/funded-sponsored-research) | * Funding and Sponsorship Form | Study Funding Sources, Question 1 |
|  | Collaborative research with organizations external to the UO | * [Collaboration in Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/collaborations-reliance-arrangements) | * Reliance Request Form UO as Reviewing IRB * Relying Site Point of Contact Survey | Basic Study  Information Last Question |
|  | Collaborative research with individuals external to the UO with no other affiliation | * [Collaboration in Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/collaborations-reliance-arrangements) | * Individual Investigator Agreement * External Research Personnel Form | Local Study Team Information  Question 3 |
| * 1. Develop a Research Plan and Identify Protocol Materials for Submission | | | | |
| * The list below are key considerations for which the IRB will need specific information to evaluate your proposed research. Use this list to (1) develop your **Research Plan** document and (2) identify other materials to upload into the RAP to complete your submission.   1. Develop your Research Plan:   + Start with the [Research Plan Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/research-plan) for the core content of your **Research Plan** document.   + Then, identify any **supplemental content** to include within your **Research Plan** document by reviewing the **topical guidance** noted for any Key Considerations on the list below that apply to your research.   1. Develop any **supplemental forms and/or materials noted for submission** as noted for any applicable Key Considerations (e.g., appendices to the Research Plan, consent forms, etc.)   2. Upload all protocol materials through the **IRB Module of the RAP.**   + Upload your **Research Plan** (including Appendices) into the **Basic Information page (Question 8) of the RAP**.   + Upload all other materials as noted in the column “**Where to Upload”** into the RAP * *Other tips.*   + See the [RCS Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-research-guidance-library) Library for other topical guidance that may be relevant to your research design.   + NOTE: Grant, thesis, dissertation, or course work proposals may NOT be submitted in lieu of the Research Plan. | | | | |
| **Key Considerations**  **(Check all that apply to your protocol)** | | **Topical Guidance**  **for Research Plan Content**  **& Other Resources** | **Supporting Materials to Develop & Submit** | **Where to Upload**  **in the RAP Submission System** |
|  | Drugs and Other Substances | n/a | * Drugs and Other Substances (fka, Appendix A) | Drugs Question 4 |
|  | Investigational Device(s) | n/a | * Investigational Devices (fka, Appendix B) | Devices Question 3 |
|  | Ionizing Radiation | * [Using Radiology Devices in Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/using-radiology-devices-research) | * Ionizing Radiation (fka, Appendix C) | Local Site Documents Question 3 |
|  | HIPAA (Protected Health Information) | * [HIPAA and Human Subjects Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/hipaa-human-subjects-research) | * HIPAA (fka, Appendix D) * Submit HIPAA Authorization Form | Local Site Documents Question 3 |
|  | Genetic Information/Tests | * [Research Involving DNA](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/oregon-genetic-privacy-law) | * Genetic Information/Tests (fka, Appendix E) | Local Site Documents Question 3 |
|  | Clinical Trials | * [Clinical Trials](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/clinical-trials) | n/a | n/a |
|  | Department of Human Physiology Research | * [Human Physiology Emergency Procedures](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-physiology-emergency-procedures) | n/a | n/a |
|  | Consenting Participants | * [Guidance on Informed Consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/informed-consent) * [Informed Consent Template Guidance](https://research.uoregon.edu/sites/default/files/2023-03/hrp-502a_-_template_guidance_-_informed_consent_0.pdf) | * Informed consent forms, assent forms, scripts, etc. | Local Site  Documents  Question 1 |
|  | Waiving/Altering Informed Consent (Elements) | * [Guidance on Waiver or Alteration of Informed Consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/informed-consent#5) | n/a | n/a |
|  | Waiving Documentation of Informed Consent | * [Guidance on Waiver or Alteration of Informed Consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/informed-consent#5) | n/a | n/a |
|  | Recruiting Participants | * [Recruitment Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/recruiting-research-participants) | * Emails, letters, scripts, flyers, posters, brochures, etc. used to recruit participants. | Local Site Documents  Question 2 |
|  | Research with Minors | * [Minors in Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/minors-in-research) * [Passive Parental Consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/passive-parental-consent-opt-out-consent) | * Parent/Guardian Permission, if applicable * Child Assent Forms/ Scripts, if applicable | Local Site Documents Question 2 |
|  | Research with Prisoners | * [Prisoners as Research Subjects](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/prisoners-research-subjects) | n/a | n/a |
|  | Compensating Participants | * [Compensation for Participation in Research Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/compensation-participation-research) | n/a | n/a |
|  | Using Translations/Translated Materials | * [Guidance on Translations and Translated Materials](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/translations-and-translated-materials) | * Translated materials that are ready at the time of submission | Local Site Documents Questions 1-3 |
|  | Audio Recording, Video Recording, and/or Photography | * [Audio Recording, Video Recording, and/or Photography Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/audio-recording-video-recording-andor-photography) | n/a | n/a |
|  | Permission/approval required beyond UO IRB (e.g., school districts, owner of a bulletin board, listservs, etc.). | * [Permissions and Approvals Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/permissions-and-approvals) | * Documentation of approval or permission when required (see guidance). | Local Site Documents Question 3 |
|  | Data Monitoring Plan/Board/Committee | * [Data Safety Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/data-safety) | * Data Safety Monitoring Plan (DSMP) and/or * Data Safety Monitoring Board/Committee (DSMB/C) information | Local Site Documents Question 3 |
|  | Research requires approval from UO Environmental Health & Safety (EHS) | * [UO Environmental Health and Safety (EHS)](https://safety.uoregon.edu/environmental-health-and-safety) | * Any clearance or approval documentation (e.g., biosafety committee approval, radiation safety committee approval, etc.) | Local Site Documents Question 3 |
|  | Recruiting from Participant Pools (e.g., Marketing, SOJC, Psychology/Linguistics) | * [Participant Pools Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/participant-pools) | * Any debriefing or other pool coordinator approvals | Local Site Documents Question 3 |
|  | Data Collection Tools | n/a | * Study team developed surveys, interviews, etc. | Local Site Documents Question 3 |

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| 1. Other Study Information | | | | | |
| * 1. Indicate how the participants will be recruited (check all that apply): | | | | | |
|  | Email | | | | Online |
|  | Flyer | | | | Telephone |
|  | In Person | | | | Mail |
|  | UO Marketing Pool | | | | Record or database review |
|  | UO Psychology Pool | | | | n/a – Existing Data (i.e., no contact with subjects) |
|  | UO SOJC Pool | | | |  |
|  | Other: |  | | | |
| * 1. Considering all participant groups, indicate the consent/assent process(es) involved in the research (check all that apply). | | | | | |
|  | In Person | | Remote (e.g., online, phone, Skype, etc.) | | |
|  | Other: |  | | | |
| * 1. Will this research include obtaining, accessing, or using data from outside sources, e.g., universities, data repositories, government agencies, etc.? | | | | | |
| Yes  No | | If “yes,” name the source(s) below and answer questions “a” and “b” below. If “no,” move to Part IV. | | | |
| Name of outside source(s): | |  | | | |
|  | | Yes  No | | * + 1. Are there terms, restrictions, or conditions regarding the data? | |
|  | | If “yes,” describe: | |  | |
|  | | Yes  No | | * + 1. If “yes," include a copy of the agreement in this submission and contact Innovation Partnership Services at [techtran@uoregon.edu](mailto:techtran@uoregon.edu) to ensure appropriate institutional approval is obtained to enter into the agreement. | |
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| * 1. Will this research include obtaining data from student educational records? "Education records" are records that are directly related to a student and that are maintained by an educational agency or institution or a party acting for or on behalf of the agency or institution. These records include but are not limited to grades, transcripts, class lists, student course schedules, health records (at the K-12 level), student financial information (at the postsecondary level), and student discipline files. | | | | | |
| Yes  No | | If “yes,” describe the source of the records and what data will be obtained. Answer questions “a” – “c” below. | | | |
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|  | | Yes  No | | * + 1. Will the records include individually identifiable data (e.g., names, email addresses, etc.)? | |
|  | | If “yes,” describe: | |  | |
|  | | Yes  No | | * + 1. Are all the identifiable data obtained from educational records considered directory information by the agency or institution disclosing the data? Note that what is considered directory information is determined at the institutional level, so researchers need to check with the applicable institution(s) to determine this. A list of items that are considered Directory Information at the UO can be accessed here: https://registrar.uoregon.edu/privacy. | |
|  | | Yes  No | | * + 1. Will the education records be obtained from the UO? If so, please contact the Registrar’s Office at [registrar@uoregon.edu](mailto:registrar@uoregon.edu) to ensure appropriate institutional approval is obtained. | |

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| 1. Human Subjects Conflict of Interest | | |
| * It is the responsibility of the PI to ensure that any research personnel, including the PI and non-UO researchers, complete the **[Human Subjects Conflict of Interest (COI) form.](https://research.uoregon.edu/sites/research1.uoregon.edu/files/2022-08/hrp-921_-_template_-_hs_coi_form_8.15.22.docx)** * The PI must keep completed copies of all Human Subject COI forms for their records. * The PI must submit with this application Human Subject COI forms **ONLY** for those individuals who answer “yes” to any question on their form. | | |
|  |  | No conflicts are identified. |
|  |  | Yes, conflicts are identified and Human Subject COI form(s) are included in the RAP submission for the following individuals. NOTE: Upload COI forms in the RAP – see [Attachment Guidance](https://research.uoregon.edu/sites/default/files/2021-01/RAP%20Guidance%20-%20Attachments.pdf) for where to upload documents). |
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| 1. Other Institutions, Performance Sites, and Non-UO Research Personnel | | | | | | | |
| For collaborative research, additional requirements for oversight of activities conducted by collaborating researchers or at other research sites may apply. See our website for additional guidance on [Collaborative Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/collaboration-research).   * Review the questions below to identify specific agreement requests and/or supplemental information to include with your submission through the RAP as indicated in the prompts. | | | | | | | |
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| * 1. Will researchers at another institution be [engaged](http://www.hhs.gov/ohrp/policy/engage08.html)  in this research? | | | | | | | |
| Yes  No | |  | | | | | |
|  | * + 1. If “yes,” are you requesting that the IRB serve as the single IRB of record for some or all institutions/organizations? | | | | | | |
| Yes  No | | | | If “yes,” complete a **Reliance Request Form – UO Reviewing IRB** and upload to the **Basic Information Page, Question 8 of the RAP.** | | | |
|  | * + 1. Are there any institutions/organizations that will not rely on the UO for oversight? | | | | | | |
| Yes  No | | | | If “yes," review the guidance on [Collaborative Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/collaboration-research) then list below each institution/organization and provide an explanation for their intended human subject research oversight. | | | |
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| * 1. Will researchers who are unaffiliated with an institution be [engaged](http://www.hhs.gov/ohrp/policy/engage08.html)  in this research? | | | | | | | |
| Yes  No | | If “yes,” upload the following to **Local Study Team Members, Question 2 of the RAP.**   * [**External Research Personnel Form**](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_form_-_external_research_personnel.xlsx) with all independent investigators listed with their training dates. * Have each individual complete and sign an **Individual Investigator Agreement.** * Have each individual upload a current [CITI training certification](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-education-requirement). | | | | | |
| * 1. Does this research involve activities with other governing entities (e.g., tribes, foreign countries, etc.)? | | | | | | | |
| Yes  No | | If “yes," list the governing entities below. | | | | | |
| Name of governing entity/ies: | |  | | | | | |
| **Note**: See our website for additional guidance on documentation requirements for [permissions and approvals](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/permissions-and-approvals). | | | | | | | |
| Explain below whether permission or approval is required to conduct research activities from this entity or these entities. Upload any documentation of permission/approval under **Local Site Documents, Question 3 in the RAP**: | | | | | | | |
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| * 1. Does this research require permission from an internal UO department or service (e.g., Registrar’s Office, Campus ListServ, etc.)? | | | | | | | |
| Yes  No | | If “yes," inquire with the applicable office and upload any documentation of permission/approval under **Local Site Documents, Question 3 in the RAP** | | | | | |
| Name of department(s)/ service(s): | | |  | | Permission Status (Select One): |  | Approval Attached |
|  | Approval Pending |
|  | No Approval Required |
| If no permission required, explain in text box below: | | | | | | | |
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