**RAP Application
Modification Review**

|  |
| --- |
| **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 **Modification Review.** Use this application to request IRB review of proposed changes to **previously approved expedited or full board** research. This application can also be used to request a study previously reviewed under the pre-2018 Common Rule regulations be considered for transition to oversight under the 2018 Common Rule. **You must obtain IRB approval prior to implementing any change(s) in your research.** |

**Instructions:** Complete the form below and upload to the Basic Study Info page of the Modification/CR submission activity in the IRB Module of the Research Administration Portal (RAP). Upload all applicable research materials as prompted throughout the electronic application pages in the RAP.

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

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

|  |
| --- |
| 1. Proposed Changes to Previously Approved Research
 |
| As a result of the proposed amendment, do you need to make a change to the previously established project period?  |
| [ ]  Yes [ ]  No | Provide anticipated end date for human subject research activities (month and year):  |       |

|  |
| --- |
| 1. Research Personnel
 |
| **If you are you making any changes to research personnel at this time (e.g., adding research staff, changing PI, etc.), list the individuals below and update the RAP.** |
| [ ]  No changes to Research Personnel; proceed to Part V below. |
| [ ]  The following individuals have been added and/or updated: * NOTE: Modify applicable information regarding personnel in the RAP under **Local Study Team Members**.
 |
|  |       |
| * It is the responsibility of the Principal Investigator (PI) to ensure that any research personnel, including the PI, *responsible for the design, conduct, and reporting of research* complete the [Human Subjects Conflict of Interest (COI) form](http://rcs.uoregon.edu/node/8).
* 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
* New research personnel who have identified a real, perceived, or potential conflict of interest on their form; and
* Existing personnel who have identified a change to a real, perceived, or potential conflict of interest on their form.
 |
| [ ]  No conflicts are identified. |
| [ ]  Yes, conflicts and/or changes are identified and Human Subject COI form(s) are attached for the following individuals: |
|  |       |

|  |
| --- |
| 1. Research Risk
 |
| Based on the proposed change(s), are there any new or altered risks?  |
|  | [ ]  Yes [ ]  No | Explain in the text box below:  |
|  |       |
| In your opinion, how do the proposed change(s) impact the overall risk profile for the previously approved research (select one of the following): |
|  | [ ]  Increase | [ ]  Decrease | [ ]  Remain the same |
|  | Provide rationale and justification with support for your response. |
|  |       |
| Is the proposed amendment a result of an [unanticipated problem](http://www.hhs.gov/ohrp/policy/advevntguid.html#Q1) or [adverse event](http://www.hhs.gov/ohrp/policy/advevntguid.html#Q2)? |
|  | [ ]  Yes [ ]  No | If “Yes”, explain in the text box below |
|  |       |
| As a result of the proposed change(s), has a Data and Safety Monitoring Plan (DSMP) been created for this research? This is typically required by a sponsor or regulatory agency (e.g., FDA). |
|  | [ ]  Yes [ ]  No | If “Yes," attach a copy of the DSMP in the RAP under **Local Site Documents** and address in the Research Plan. |
| As a result of the proposed change(s), has a Data Safety Monitoring Board or Committee (DSMB/DSMC) been established for this research? This is typically required by a sponsor or regulatory agency (e.g., FDA). |
|  | [ ]  Yes [ ]  No | If “Yes," attach a copy of the DSMB/DSMC information in the RAP under **Local Site Documents** and address in the Research Plan. |

| 1. Clinical Trials
 |
| --- |
| **Based on the proposed changes, does the research now meet the definition of** [**clinical trial**](http://orcr.uoregon.edu/content/human-subjects/clinical-trials) **under NIH or other sponsor requirements and/or FDA, or 2018 HHS regulations?** |
|  | [ ]  NA | This research previously met the definition of clinical trial. |
|  | [ ]  No | This research does not meet the definition of clinical trial. |
|  | [ ]  Yes | This research now meets the definition of clinical trial under FDA, other sponsor, or 2018 HHS definition of clinical trial. |
| If “yes,” the principal investigator is responsible for ensuring the additional requirements related to conduct of clinical trials are met.* All individuals involved in the design, conduct, oversight, and management of the clinical trial must complete Good Clinical Practice (GCP) training.
* For NIH sponsored research that meets the definition of clinical trial, research must be registered with and any results submitted to clinicaltrials.gov per program requirements. This may be required by other sponsors or federal agencies.
* For non-exempt research reviewed under the 2018 Revised Common Rule, the informed consent form must be posted to a federal website after the study is closed to recruitment and no later than 60 days after the last study visit by any subject.

See the [RCS Clinical Trials](https://rcs.uoregon.edu/content/human-subjects/clinical-trials) page for more information and guidance. |

| 1. Materials
 |
| --- |
| New and revised materials must be submitted with this application. Identify additional application considerations specific to this amendment.  |
| * Check all that apply to this amendment request, and upload completed forms in the **IRB Module of the RAP** system as noted in the “Where to Upload” column.
 |
| **Check all that applyto your protocol** | **Topical Guidance** | **Applicable Forms and Supporting Materials** | **Where to Upload in the RAP** |
| [ ]  | Funding or Sponsorship | * [Funded and Sponsored Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/funded-and-sponsored-research)
 | * Funding and Sponsorship Form
 | Study FundingSources,Question 1 |
| [ ]  | Collaborative research with organizations external to the UO | * [Collaboration in Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/collaboration-research)
 | * Reliance Request Form UO as Reviewing IRB
* Relying Site Point of Contact Survey
 | Basic Study InformationQuestion 8 |
| [ ]  | 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/collaboration-research)
 | * Individual Investigator Agreement
 | Local StudyTeam Information Question 3 |
| [ ]  | Drugs and Other Substances | n/a | * Drugs and Other Substances (fka, Appendix A)
 | DrugsQuestion 4 |
| [ ]  | Investigational Device(s) | n/a | * Investigational Devices (fka, Appendix B)
 | DevicesQuestion 3 |
| [ ]  | Ionizing Radiation | * [Using Radiology Devices in Research](https://uoregon-my.sharepoint.com/personal/cduy_uoregon_edu/Documents/Microsoft%20Teams%20Chat%20Files/human-subjects-research/using-radiology-devices-research)
 | * Ionizing Radiation (fka, Appendix C)
 | Local SiteDocumentsQuestion 3 |
| [ ]  | HIPAA (Protected Health Information) | * [HIPAA and Human Subjects Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/hipaa-and-human-subjects-research)
* HIPAA Authorization Template
 | * HIPAA (fka, Appendix D)
* Submit HIPAA Authorization Form
 | Local SiteDocumentsQuestion 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 SiteDocumentsQuestion 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
* Informed Consent Template Guidance
 | * Informed consent forms, assent forms, scripts, etc.
 | Local Site DocumentsQuestion 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 (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 |
| [ ]  | Recruiting Participants | * [Recruitment](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/recruiting-research-participants) Guidance
 | * Emails, letters, scripts, flyers, posters, brochures, etc. used to recruit participants.
 | Local SiteDocuments 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 SiteDocumentsQuestion 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 SiteDocumentsQuestions 1-3 |
| [ ]  | Audio Recording, Video Recording, and/or Photography | * [Audio Recording, Video Recording, and/or Photography](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/audio-recording-video-recording-andor-photography) Guidance
 | 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 SiteDocumentsQuestion 3 |
| [ ]  | Data Monitoring Plan/Board/Committee | * [Data Safety](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/data-safety) Guidance
 | * Data Safety Monitoring Plan (DSMP) and/or
* Data Safety Monitoring Board/Committee (DSMB/C) information
 | Local SiteDocumentsQuestion 3 |
| [ ]  | Research requires approval from UO Environmental Health & Safety (EHS) | * [UO Environmental Health and Safety (EHS)](http://ehs.uoregon.edu/)
 | * Any clearance or approval documentation (e.g., biosafety committee approval, radiation safety committee approval, etc.)
 | Local SiteDocumentsQuestion 3 |
| [ ]  | Recruiting from Participant Pools (e.g., Marketing, SOJC, Psychology/Linguistics) | * [Participant Pools](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/participant-pools) Guidance
 | * Any debriefing or other pool coordinator approvals
 | Local SiteDocumentsQuestion 3 |
| As a result of the proposed changes, will any of the previously approved protocol materials no longer be used? |
| [ ]  Yes [ ]  No | If “Yes”, list materials below |
|  | **Material Name/Type/Title/Comments** |
|  | [ ]   |       |
|  | [ ]   |       |
|  | [ ]   |       |
|  | [ ]   |       |
|  | [ ]   |       |
|  | [ ]   |       |