**RAP Application
Modification 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 **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):**

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

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| 1. Modification Information
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| If you have not provided rationale for your changes within the Modification Summary in the [Research Administration Portal](https://irb.rap.uoregon.edu/), please provide the rationale below (e.g., reasons for increasing the number of participants, rationale for design changes, basis for making risk changes etc.) |
| [ ]  N/A Rationale provided within the modification summary |
| Rationale: |
|       |
| Will you notify/re-consent current or former participants due to the proposed changes? |
| [ ]  Yes (If Yes, please also check the applicable boxes in Question 2 of the Modification Information section of your  online submission, “Notification of subjects”)[ ]  No (If No, please explain why re-consent/notification is not necessary – for example, changes only impact future participants not current or former participants)[ ]  N/A no participants have ever been enrolled on this study |
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| 1. Research Risk
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| 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: |
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| Is the proposed change 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. If you have submitted this as Reportable New Information (RNI), please also include the RNI submission number in your response. |
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| 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., NIH, 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., NIH, 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. |

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| 1. Human Subjects Conflict of Interest
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| * 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: Update applicable COI forms in the RAP (see [attachment guidance](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2021-01/RAP%20Guidance%20-%20Attachments.pdf)). |
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| 1. Clinical Trials
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| **Based on the proposed changes, does the research now meet the definition of** [**clinical trial**](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/clinical-trials) **under NIH or other sponsor requirements and/or FDA, or 2018 HHS regulations?** |
|  |  [ ]  No | This research does not meet the definition of clinical trial ( include explanation below).      |
|  | [ ]  Yes | This research now meets the definition of clinical trial under FDA, other sponsor, or 2018 HHS definition of clinical trial. |
|  | [ ]  N/A | This research previously met the 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 and/or certain FDA regulated 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 that meets the definition of clinical trial, 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://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/clinical-trials) page for more information and guidance. |

| 1. Materials
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| 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.
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| **Check all that applyto your protocol** | **Topical Guidance** | **Applicable Forms and Supporting Materials****(see** [**Forms and Guidance Website**](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-applications-forms-guidance) **for 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 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
* External Team Member Spreadsheet
 | Local StudyTeam Information Question 3 |
| [ ]  | Drugs and Other Substances | n/a | * Drugs and Other Substances (Appendix A)
 | DrugsQuestion 4 |
| [ ]  | Investigational Device(s) | n/a | * Investigational Devices (Appendix B)
 | DevicesQuestion 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 (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 (Appendix D)
* HIPAA Authorization Template
 | 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 (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 Guidance](https://research.uoregon.edu/sites/default/files/2023-03/hrp-502a_-_template_guidance_-_informed_consent_0.pdf)
 | * Informed Consent Template
 | 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 | * 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 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
* Assent Templates (Age 7-11) (Age 12-17)
 | 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 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 SiteDocumentsQuestion 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 SiteDocumentsQuestion 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 SiteDocumentsQuestion 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 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. Please also use the document ‘Update’ feature in the RAP to add ‘RETIRED’ to the beginning of each document name. |
|  | **Material Name/Type/Title/Comments** |
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