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| **Purpose:** This application is designed to help facilitate review of changes to an existing protocol and to assure compliance of the federal regulations as set forth in [45 CFR Part 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). |

**Instructions:** Use this application to request IRB review of proposed changes to **previously approved expedited or full board** research. You must obtain IRB approval **prior** to implementing any change(s) in your 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. Submit this application and all applicable research materials solicited in the checklist at the end of the form to ResearchCompliance@uoregon.edu. Save this form before proceeding.

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| 1. Study and Investigator Information
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|  |
| Principal Investigator (PI): |        | Today’s Date: |        |
| Faculty Advisor |        | Protocol number: |        |
| Study Title: |        |
| Research Status (check one) |
|  | [ ]  Project not yet started (no subjects being recruited) |
|  | [ ]  Currently in progress (subjects being recruited)  |
|  | [ ]  Closed to new subject entry (long term follow-up only or data analysis)  |
| Transition to the Revised Common Rule |
|  | * Revisions to the federal regulations governing human subjects research known as the Common Rule are effective January 21, 2019. **Protocols that were initially approved or determined exempt prior to January 21, 2019 may remain under the pre-2018 Common Rule regulations or have the option of transitioning to comply with the 2018 Common Rule**. You may request that your study be assessed for transition. This assessment will determine if your study is a good candidate for transition and identify changes necessary to comply with the revised 2018 Common Rule.
 |
|  | **Select one option below:** |
|  | [ ]  My study was initially approved after January 21, 2019 or has already transitioned to the 2018 Common Rule. |
|  | [ ]  My study was already assessed for transition to the 2018 Common Rule. |
|  | [ ]  I am requesting that this study NOT be *assessed* for transition to the revised 2018 Common Rule at this time. |
|  | [ ]  I am requesting that this study be *assessed* for transition to the revised 2018 Common Rule |
|  |  | If requesting assessment for transition, provide anticipated end date for human subject research activities (month and year): |       |
|  | * For more information about the revised 2018 Common Rule and transition considerations, please see our dedicated webpages [here](http://rcs.uoregon.edu/content/research-involving-human-subjects/changes-to-common-rule). If you are unsure about your study’s status, please contact RCS at reseearchcompliance@uoregon.edu or 541-346-2510.
* Protocols recommended for transition to the revised 2018 Common Rule may be asked to submit previously approved materials and/or make revisions to those materials to comply with the revised 2018 Common Rule.
 |
| 1. Proposed Changes to Previously Approved Research
 |
| Give a brief description of the proposed change(s). |
|       |
| Describe the rationale for the change(s). |
|       |
| 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 attach an updated** [**Research Personnel Form**](http://orcr.uoregon.edu/index.cfm?action=irb&sub=forms) **highlighting those individuals.** |
| [ ]  No changes to Research Personnel; proceed to Part V below. |
| [ ]  Research Personnel Form is attached; the following individuals have been added and/or updated:  |
|  |       |
| * 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 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 and address in the Research Plan. |
| 1. Collaborations
 |
| * **As a result of the proposed change(s), will the research be conducted with institutions, or at site(s)/organization(s) other than University of Oregon (e.g., public schools, tribes, non-profit organizations, companies, hospitals, universities, etc.)?**
 |
|  | [ ]  Yes | [ ]  No | If “Yes”, explain and attach applicable permission and/or approval documentation:  |
|  |       |
| 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. Current training dates need to be listed in the Research Personnel Form.
* 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. Revisions to any previously approved protocol materials must be submitted with proposed changes clearly indicated (e.g., using track changes).  |
| Check material type below and indicate if this is new or revised. |

|  | **Material Type** | **New** | **Revised** | **Title(s)/Comments/Other** |
| --- | --- | --- | --- | --- |
|  | [ ]  | Form - Personnel | [ ]  | [ ]  |       |
|  | [ ]  | Form - Conflict of Interest | [ ]  | [ ]  |       |
|  | [ ]  | Form - Funding | [ ]  | [ ]  |       |
|  | [ ]  | Research Plan | [ ]  | [ ]  |       |
|  |  |  | Incl. | n/a |  |  |  |  |
|  |  |  | [ ]  | [ ]  | Appendix A - Drugs | [ ]  | [ ]  |       |
|  |  |  | [ ]  | [ ]  | Appendix B - Medical Devices | [ ]  | [ ]  |       |
|  |  |  | [ ]  | [ ]  | Appendix C - Ionizing Radiation | [ ]  | [ ]  |       |
|  |  |  | [ ]  | [ ]  | Appendix D - HIPAA | [ ]  | [ ]  |       |
|  |  |  | [ ]  | [ ]  | Appendix E - Genetic Materials | [ ]  | [ ]  |       |
|  | [ ]  | Recruitment Materials | [ ]  | [ ]  |       |
|  | [ ]  | Consent/ Assent Materials | [ ]  | [ ]  |       |
|  | [ ]  | Debriefing Materials |  |  |  |
|  | [ ]  | Data Collection Materials/Instruments | [ ]  | [ ]  |       |
|  | [ ]  | Data Safety Monitoring Plan |  |  |  |
|  | [ ]  | Data Safety Monitoring Board/Committee Information | [ ]  | [ ]  |       |
|  | [ ]  | Permissions/ Support Letters/ Outside IRB Approval | [ ]  | [ ]  |       |
|  | [ ]  | For funded/sponsored Research: Human Subjects portion of grant Proposal | [ ]  | [ ]  |       |
|  | [ ]  | Other (specify) | [ ]  | [ ]  |       |
|  | [ ]  | Other (specify) | [ ]  | [ ]  |       |
|  | [ ]  | Other (specify) | [ ]  | [ ]  |       |

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| 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** |
|  | [ ]  |       |
|  | [ ]  |       |
|  | [ ]  |       |
|  | [ ]  |       |
|  | [ ]  |       |
|  | [ ]  |       |

*[Remainder of page intentionally left blank; acknowledgements and signature page to follow.]*

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| 1. Investigator and Faculty Advisor Signatures
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| * By signing below I certify that I will conduct this research as approved by the University of Oregon CPHS (IRB) and in accordance with the [Investigator Agreement](http://orcr.uoregon.edu/index.cfm?action=irb&sub=forms).
* I understand that any changes listed above may not be implemented in the human subjects research until this amendment has been approved by the CPHS (IRB).
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|  | Click here to type name or insert electronic signature. |  | Click here to enter a date. |  |

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| **Principal Investigator Signature Date** * *Electronic signatures acceptable. The name of the Principal Investigator may be typed in the signature line.*
* *If the person emailing this application is not the Principal Investigator, the Principal Investigator must be copied on this application submission.*
 |
|  |
| **REQUIRED FOR STUDENT RESEARCH** * By signing this form, the Faculty Advisor attests that (s) he has reviewed the proposed change and agrees to provide appropriate education, oversight, and supervision of the student investigator above, and share the above Principal Investigator responsibilities.
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|  | Click here to type name or insert electronic signature. |  | Click here to enter a date. |  |

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| **Faculty Advisor Signature Date** * *Electronic signatures acceptable. The name of the Faculty Advisor may be typed in the signature line.*
* *If the person emailing this application is not the Faculty Advisor, the Faculty Advisor must be copied on this application submission.*
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