**Instructions:** Use this application to request extension of a project approval period for studies that do not require Continuing Review by the IRB.

For studies that do not require continuing review by the IRB, the project approval period is based on the anticipated end date for human subject research activities. Use this application when your project approval period is expiring and you need to extend the project period. **NOTE: If your study requires continuing review by the IRB and you want to obtain continued approval, you must submit the Continuing Review Application, do not use this form**.

Submit this form by email to ResearchCompliance@uoregon.edu.

|  |
| --- |
| 1. Study and Investigator Information
 |
|  |
| Principal Investigator (PI): |        | Today’s Date: |        |
| Faculty Advisor |        | Protocol number: |        |
| Study Title: |        |
| **Research Status (check one)** |
| * Select one of the following to indicate the study status:
 |
|  | [ ]  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) |
| 1. Progress Report
 |
| * 1. Provide a brief summary of the study’s goals and progress over the course of the most recent [approval period](#ApprovalPeriod). Describe preliminary study observations/findings and/or attach relevant information published or unpublished:
 |
|       |
| * 1. In the next year of the study, do you anticipate any major design changes or new phases of the research will commence? NOTE: This is only to assess the study progress. An amendment request will need to be submitted for review and approval in advance of implementing any changes.
 |
|  | [ ]  Yes | [ ]  No | If “yes,” explain in the text box below:  |
|       |
| * 1. State the new anticipated [end date for human subject research activities](http://rcs.uoregon.edu/content/closing-your-protocol), including analysis of identifiable participant data:
 |
| Month and year: |       |
| * 1. New and relevant information since the last [approval period](#ApprovalPeriod):
 |
| * + 1. Has there been any new and relevant information published or unpublished since the last [approval period](#ApprovalPeriod) (i.e., as a result of this research or within the field)?
 |
|  [ ]  Yes [ ]  No | If “yes”, explain and attach any abstracts, list of citations, or other relevant information: |
|       |
| * + 1. Does the study progress or any preliminary findings, or new information from the field suggest a change in previously assessed risk to participants?
 |
|  [ ]  Yes [ ]  No | If “yes”, explain and attach any abstracts, list of citations, or other relevant information: |
|       |
| * + 1. Have there been any changes in the Principal Investigator’s situation or qualifications that would impact the ability of the investigator to carry out this research in accordance with the approved protocol? Consider changes like an increase in the number of research studies, work status, funding/facilities, etc.
 |
|  [ ]  Yes [ ]  No | If “yes”, explain in the text box below: |
|       |
| * 1. Participant Enrollment:

NOTE: For exempt studies, a response is only required for 5b. Indicate ‘n/a’ for 5a and 5c. |
| * + 1. Maximum number of participants currently approved to enroll:
 |       |
| * + 1. Number of participants enrolled since the start of this research:
 |       |
| * + 1. Does the number of participants enrolled (5c) exceed the number of participants approved by the IRB (5a) above?
 |
|  [ ]  Yes [ ]  No | If “yes”, submit an [Event Report](http://rcs.uoregon.edu/content/event-reporting)  and briefly explain in the text box below: |
|       |
| * To request an increase of total maximum number of participants, an [Amendment Application](http://rcs.uoregon.edu/content/amend-existing-protocol) must be submitted for review and approval.
 |
| * 1. Participant Withdrawals:
 |
| * + 1. Number of participant withdrawals since the start of the research:
 |       |
| * + 1. Explain the reason for each participant withdrawal (e.g., dissatisfaction, relocation, etc.):
 |
|       |
| * + 1. Have a greater number of participants than expected withdrawn from the study?
 |
|  [ ]  Yes [ ]  No | If “yes”, explain in the text box below: |
|       |
| * 1. Participant Complaints:
 |
| * + 1. Have there been any complaints about the research and/or the conduct of the research?
 |
|  [ ]  Yes [ ]  No | If “yes”, explain and specify if an [Event Report](http://rcs.uoregon.edu/content/event-reporting)  has been submitted: |
|       |
| * 1. Events such as [unanticipated problems](http://www.hhs.gov/ohrp/policy/advevntguid.html#Q1), [adverse events](http://www.hhs.gov/ohrp/policy/advevntguid.html#Q2), and/or occurrences of non-compliance:
 |
| * + 1. During the last [approval period](#ApprovalPeriod), have there been any events reported to RCS and/or the IRB?
 |
|  [ ]  Yes [ ]  No | If “yes”, explain in the text box below: |
|       |
| * + 1. Have there been any events not reported to RCS and/or the IRB?
 |
|  [ ]  Yes [ ]  No | If “yes”, explain and address any impact or increased risk to participants: |
|       |
| * 1. Have there been any approved changes to your research project since the start of the research?
 |
|  [ ]  Yes [ ]  No | If “yes”, provide a brief summary of the approved amendments:  |
|       |
|  | **NOTE: No new changes may be incorporated with the continuing review application materials. Any newly proposed changes will require an** [**Amendment Application**](http://rcs.uoregon.edu/content/amend-existing-protocol)**.** |
| 1. Funding
 |
| **Has funding or sponsorship been associated with this research?***No new funding may be added with the continuing review application. Funding not previously associated with the protocol requires an* [*Amendment Application*](http://rcs.uoregon.edu/content/funded-and-sponsored-research)*.* |
|  | [ ]  Yes | [ ]  No | If “yes”, list all funding sources, include internal and external sources and indicate if funding is active: |
| **Active** | **Inactive** | **Source Name** | **Grant #** | **EPCS #** |
| [ ]  | [ ]  |       |       |       |
| [ ]  | [ ]  |       |       |       |
| [ ]  | [ ]  |       |       |       |
| [ ]  | [ ]  |       |       |       |
| [ ]  | [ ]  |       |       |       |
| [ ]  | [ ]  |       |       |       |

| 1. Clinical Trials
 |
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|  |
| --- |
| When meeting the definition of clinical trial, 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. |
| **Does the research 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?** |
|  | [ ]  Yes | [ ]  No | If “no”, skip the remainder of this section. If “yes”, review the additional responsibilities noted below and answer questions a—c below: |
| * + 1. If required by a sponsor (e.g., NIH) or other regulation(s), has the research been registered with clinicaltrials.gov and any results available been submitted as required?
 |
| [ ]  Yes [ ]  No [ ]  NA | If “no”, explain in the text box below: |
|       |
| * + 1. Have all individuals involved in the *design, conduct, oversight, and management* of the clinical trial completed Good Clinical Practice (GCP) training?
 |
| [ ]  Yes [ ]  No [ ]  NA | NOTE: Current GCP training dates need to be listed in the Research Personnel Form.If “no” or “NA”, explain in the text box below: |
|       |
| * + 1. Is your research under oversight of the 2018 HHS Common Rule Regulations?
 |
| * Research approved on or after January 21, 2019, is under the oversight of the 2018 HHS Common Rule Regulations (2018 Common Rule). Additionally, some research approved prior to January 21, 2019, has been redetermined and is now subject to the 2018 Common Rule. The 2018 Common Rule has additional requirements for the posting the consent forms for clinical trials for non-exempt research. If you are unsure of which regulations your research is subject to, contact RCS.
 |
| [ ]  Yes [ ]  No | If “yes”, answer the following: |
| * **Is the study now closed to recruitment? Select ONE of the following:**
 |
| [ ]  | No, the study is not closed to recruitment. |
| [ ]  | Yes, the study is closed to recruitment **and** the research was determined to be “exempt”. Posting the consent form is not required for exempt research. |
| [ ]  | Yes, the study is closed to recruitment **and** the informed consent form **was posted** to a federal website no later than 60 days after the last study visit by any subject? * Provide the website address for the informed consent posting in the textbox below.
 |
|       |
| [ ]  | Yes, the study is closed to recruitment **and** the informed consent form **was not posted** to a federal website no later than 60 days after the last study visit by any subject? * Explain why the consent was not posted in the textbox below
 |
|       |

| 1. Human Subjects Conflict of Interest
 |
| --- |
| * It is the responsibility of the Principal Investigator (PI) to ensure the prompt disclosure of any changes to the real, perceived, or potential conflict of interest for any research personnel, including the PI, *responsible for the design, conduct, and reporting of research*.
* The PI must review, at least annually, the [Human Subjects Conflict of Interest (COI) forms](http://rcs.uoregon.edu/content/human-subjects-applications-forms) with all personnel responsible for design, conduct, and reporting of research.
 |
| **Have there been any changes to any research personnel’s real, perceived, or potential conflicts of interest related to this research during the last** [**approval period**](#ApprovalPeriod)**?**  |
| [ ]  No changes have been identified during the last [approval period](#ApprovalPeriod). [ ]  Yes, changes were previously reported for the following individuals. Briefly describe and provide date reported. |
|       |
| **NOTE: If changes are identified to research personnel’s COI forms that have not been previously reported to the IRB, an** [**Amendment Application**](http://rcs.uoregon.edu/content/human-subjects-applications-forms)  **is required.** |
| 1. Protocol Materials
 |
| * 1. The following materials, if applicable to the protocol, must be submitted with this application:
 |

| **Attached** | **N/A** | **Material Type** |  |
| --- | --- | --- | --- |
| [ ]  | [ ]  | Research Plan* *Attach the most current approved version including applicable appendices.*
* *Note “N/A” only if the study was determined to be exempt and a Research Plan was not created for the study.*
 |  |
|  |  | Attached | n/a |  |  |
|  |  | [ ]  | [ ]  | Appendix A – Drugs |  |
|  |  | [ ]  | [ ]  | Appendix B – Medical Devices |  |
|  |  | [ ]  | [ ]  | Appendix C – Ionizing Radiation  |  |
|  |  | [ ]  | [ ]  | Appendix D - HIPAA |  |
|  |  | [ ]  | [ ]  | Appendix E – Genetic Materials |  |
| [ ]  | - | Current Personnel List (no new personnel may be added without an amendment) |  |
| [ ]  | [ ]  | Recruitment Materials* *Note “N/A” only if the study is closed to enrollment of new subjects or if the study was determined to be exempt and did not include recruitment materials.*
 |  |
| [ ]  | [ ]  | Informed Consent/Assent/Debriefing Materials* *Attach current versions of all consent, assent, parent/guardian permission, and debriefing forms.*
* *“N/A” only acceptable for studies that: (1) have previously been granted a waiver of informed consent;* ***and/or*** *(2) the study activities were limited to data analysis only during the last approval period.*
 |  |
| [ ]  | [ ]  | External/Non-UO IRB Approval(s) – documentation of continued approval |  |
| [ ]  | [ ]  | Documentation of continued clearance or approval from Environmental Health and Safety (e.g., biosafety committee approval, radiation safety committee approval, etc ) |  |
| [ ]  | [ ]  | Abstracts, a list of citations, or relevant information (see Part IV above) |  |
| [ ]  | [ ]  | DSMP - Data Safety Monitoring Plan |  |
| [ ]  | [ ]  | DSMB/DMC/Independent Monitoring – progress report and/or interim analysis |  |
| [ ]  | [ ]  | List other:  |       |  |
| [ ]  | [ ]  | List other:  |       |  |
| [ ]  | [ ]  | List other:  |       |  |

|  |
| --- |
| * 1. Describe any previously approved research activities/procedures completed or that will not continue:
 |
|       |
| * 1. List all previously approved materials no longer in use:
 |
|       |

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

|  |
| --- |
| 1. Investigator and Faculty Advisor Signatures
 |
| * 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://rcs.uoregon.edu/sites/default/files/Misc%20-%20Investigator%20Agreement.pdf).
* I understand this application for continued human subject research activities must be reviewed and approved by the University of Oregon CPHS prior to conducting continued research activities beyond the existing expiration date.
 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Click here to type name or insert electronic signature. |  | Click here to enter a date. |  |

|  |
| --- |
| **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 information reported in this form and agrees to continue to provide appropriate education, oversight, and supervision of the student investigator above, and share the responsibilities as outlined in the Investigator Agreement.
 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Click here to type name or insert electronic signature. |  | Click here to enter a date. |  |

|  |
| --- |
| **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.*
 |