**RAP Application  
Continuing 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 **Continuing Review** including:   * Continuing IRB approval of previously expedited or full board human subject research, or * An extension of project approval for studies that do not require a regulatory continuing review by the IRB.   **Before the currently issue expiration date, the study must either be continued or closed to maintain compliance.** If a study is allowed to expire, a new Initial Review Application and supporting materials will need to be submitted and IRB approval obtained before resuming human subject research activities.  If the remaining research activities will no longer include intervening/interacting with subjects and/or analyzing identifiable participant information, this study may be eligible for closure, see the [RCS website](http://rcs.uoregon.edu/content/closing-your-protocol) for more detail.  The Principal Investigator (PI) is responsible for maintaining IRB approval and must provide the IRB with all required materials to request continuing review in a timely manner (a minimum of 45 days in advance of the IRB approval expiration date).  **Allowing a protocol to expire is considered non-compliance. If a study expires before continued approval is secured, no human subject research activities may occur until approval is secured.** |

**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.

Information reported on this form should reflect activities having occurred over the course of the most recent approval period unless otherwise specified. ***Approval period*** *refers to the time since the initial approval (if this is the first continuing review for this protocol) or since the last continuing review approval.*

Changes cannot be incorporated into the continuing review materials. In order to be in compliance with federal regulations a [Modification Application](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/modifying-amending-existing-protocol) must be submitted for separate review of proposed changes.

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

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

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| 1. Progress Report | | | | | |
| * 1. Provide a brief summary of the study’s progress and describe preliminary study observations/findings during the last [approval period](#ApprovalPeriod): | | | | | |
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| * 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: | |
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| * 1. State the 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: | | |
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| * + 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: | | |
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| * + 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: | | |
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| * 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 during the last [approval period](#ApprovalPeriod): | | | | |  |
| * + 1. Number of participants enrolled since the start of this research: | | | | |  |
| * + 1. Does the number of participants enrolled (3c) exceed the number of participants approved by the IRB (3a above)? | | | | | |
| Yes  No | | | If “yes”, submit this as [Reportable New Information](http://rcs.uoregon.edu/content/event-reporting) and briefly explain in the text box below: | | |
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| * To request an increase of total maximum number of participants, an [Modification Application](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/modifying-amending-existing-protocol) must be submitted for review and approval. | | | | | |
| * 1. Participant Withdrawals: | | | | | |
| * + 1. Number of participant withdrawals during the last [approval period](#ApprovalPeriod): | | | | |  |
| * + 1. Explain the reason for each participant withdrawal (e.g., dissatisfaction, relocation, etc.): | | | | | |
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| * + 1. Number of participant withdrawals since the start of the study: | | | | |  |
| * + 1. Have a greater number of participants than expected withdrawn from the study? | | | | | |
| Yes  No | | | If “yes”, explain in the text box below: | | |
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| * 1. Participant Complaints: | | | | | |
| * + 1. Have there been any complaints about the research and/or the conduct of the research during the last [approval period](#ApprovalPeriod)? | | | | | |
| Yes  No | | | If “yes”, explain and specify if this has been submitted as [Reportable New Information](http://rcs.uoregon.edu/content/event-reporting): | | |
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| * 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: | | |
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| * + 1. During the last [approval period](#ApprovalPeriod), 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: | | |
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| * 1. Have there been any approved changes to your research project during the last [approval period](#ApprovalPeriod)? | | | | | |
| Yes  No | | | If “yes”, provide a brief summary of the approved amendments: | | |
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|  | **NOTE: No new changes may be incorporated with the continuing review application materials. Any newly proposed changes will require an** [**Modification Application**](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/modifying-amending-existing-protocol)**.** | | | | |

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| 1. Clinical Trials | | | | |
|  | 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://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/clinical-trials) page for more information and guidance. | | | |
| **Does the research 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?** | | | | |
|  | 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 | | | | NOTE: Current GCP training dates need to be listed in the Research Personnel Form.  If “no”, explain in the text box below: |
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| * + 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: |
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| * + 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 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 | |
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| 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](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-09/form_-_coi_RAP.docx) 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. |
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| **NOTE: If changes are identified to research personnel’s COI forms that have not been previously reported to the IRB, an** [**Modification Application**](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/modifying-amending-existing-protocol)  **is required.** |

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| 1. Protocol Materials |
| * 1. Describe any previously approved research activities/procedures completed or that will not continue: |
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| * 1. List all previously approved materials no longer in use: |
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| 1. Lapsed Approval | | | | | | | |
| **Has the current approval for your study lapsed/expired?** | | | | | | | |
| Yes  No | | | | If no, stop here. The application is complete.  If yes, complete the remainder of this section.. | | | |
| If your study’s approval has lapsed/expired, no human subject research activities may occur until IRB approval is re-established unless the IRB finds it is in the best interest for participant`s to continue participation | | | | | | | |
| * + 1. It is the responsibility of the principal investigator to ensure continued approval is maintained. Explain the circumstances for the lapse and measures in place to prevent future study lapses: | | | | | | | |
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| * + 1. Has any human subject research activity been conducted after the IRB approved expiration date? | | | | | | | |
| 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. | |
| * + 1. Endorse **ONE** of the following: | | | | | | | |
|  | | | 1. All human subject research activities including interactions with participants and/or identifiable participant information has ceased and will not resume until continued approval is issued. | | | | |
|  | | | 1. Continuing human subjects research activities during the lapse is in the best interest of research participants. Provide the explanation and justification below for the IRB to consider. | | | | |
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|  | * + 1. If the study is sponsored or funded, has the sponsor/funding agency been notified of the lapse in [approval](#ApprovalPeriod)? | | | | | | |
|  | | Yes  No | | | | | N/A (no sponsor involved/not required) |
| If “No”, explain: | | | | |  | | |