**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 issued expiration date, the study must either be continued or closed to maintain compliance.** If a study expires, a new Initial Review Application and supporting materials may need to be submitted and IRB approval obtained before resuming human subject research activities. Reach out to RCS if you have questions about whether this is needed.  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 question #7 in the Continuing Review/Study Closure Information section of the CR submission activity in the IRB Module of the Research Administration Portal (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.*

**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.   DEFINITION: The term approval period refers to the time since initial approval (if this is the first continuing review) or the time since the last continuing review approval). | | | | | | |
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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. A modification 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: | | | | | | |
| * + 1. Has there been any new and relevant information published or unpublished since the last [approval period](#ApprovalPeriod) (e.g., 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 that do not have a maximum number of participants currently approved to enroll, indicate ‘N/A’ for 5a and check the N/A box in 5b.  DEFINITION: a participant counts towards enrollment if they meet the definition of “human subject” at any point in their involvement.   * This includes someone who signs the consent document but does not complete the study. * It also includes situations when researchers obtain identifiable private information or biospecimens about or from an individual, even if the researchers do not interact directly with the individual. * Example: A potential participant who completes pre-screening prior to consent is not considered enrolled in the research unless the pre-screening data will also be used for research analyses or future research. However, if the pre-screening data will be used for research purposes or if an individual signs a consent form and there is further screening and screen fail at that point, that participant was enrolled and considered a withdrawal. * For flexibility, we recommend that researchers describe how many participants they plan to consent/enroll and how many participants they need to complete all study activities to achieve the aims. If needed, please consider submitting a separate modification or a MODCR (with other parts of the study selected in the scope) to revise your enrollment goals within your research plan. | | | | | | |
| * + 1. Maximum number of participants currently approved to enroll: | | | | | |  |
| * + 1. Does the number of participants enrolled exceed the number of participants approved by the IRB? | | | | | | |
| Yes  No  N/A | | | | 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, a Modification Application must be submitted for review and approval. See the [Forms and Guidance webpage](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-applications-forms-guidance) for a copy of the modification application form. | | | | | | |
| * 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: | | | | | | |
| 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 and specify if this has been submitted as [Reportable New Information](http://rcs.uoregon.edu/content/event-reporting): | | |
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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 modifications to your research project during the last [approval period](#ApprovalPeriod)? | | | | | | |
| Yes  No | | | | If yes, provide a brief summary of the approved modifications: | | |
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|  | **NOTE: No new changes may be incorporated with the continuing review application materials. Any newly proposed changes will require a Modification Application.** See the [Forms and Guidance webpage](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-applications-forms-guidance) for a copy of the modification application form. | | | | | |
| * 1. Are any items in question #6 of the RAP Continuing Review/Study Closure section of the online submission unchecked? (i.e. items that are true since the last IRB approval for all sites involved in the study) | | | | | | |
| Yes  No | | If yes, list each item below and provide an explanation for each. | | | | |
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| 1. Clinical Trials | | | | |
|  | When applicable, the principal investigator is responsible for ensuring the additional requirements related to conduct of clinical trials are met. See the [RCS Clinical Trials](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/clinical-trials) page for more information and guidance.   * 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. | | | |
| * 1. 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 | | | | If no, explain in the text box below:  If yes, enter the NCT number in the text box below. ClinicalTrials.gov assigns a unique identification code to each clinical study registered on ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419). |
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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  N/A | | | | NOTE: Current GCP training is required for FDA and NIH clinical trials but strongly encouraged for HHS clinical trials. For more information on which study team members need GCP training, see [RCS Clinical Trials](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/clinical-trials) page.  If no or N/A, 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. | |
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|  | | | 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. * 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 research personnel. |
| 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, a Modification Application is required.** See the [Forms and Guidance webpage](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-applications-forms-guidance) for a copy of the modification application form. |

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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 | | | | | | | |
| **1. Has the current approval period 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 period 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 participants 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: | | | | |  | | |