**RAP Application  
Study Closure**

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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 requesting **Study Closure** of previously approved exempt, expedited or full board human subject research.  For studies previously reviewed and approved by the IRB or determined exempt, the study can be closed if you have finished obtaining data through intervention or interaction with subjects or obtaining/using identifiable private information about the subjects. Use this form to request closure. The closure review will determine if this research is eligible for closure and notification of the determination will be provided to the investigator. |

**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. Research Status | | | | | |
| **1. Select one of the statuses (A – D) below. If none are applicable, this research may not be eligible for closure.** | | | | | |
| **A. Research not started (i.e., no subjects enrolled and study never commenced).   *Explain why this study never commenced below, then skip to Part IV, sign, and submit this form to Research Compliance Services.*** | | | | | |
| **B. Enrollment closed; research activities limited to analysis of data only.**   * *All of the following conditions must apply*   No data is being obtained through intervention or interaction with subjects,  Data is not identifiable (i.e., data has been de-identified and code keys linked with identifiers have been destroyed); *and*  Only de-identified data is being analyzed | | | | | |
| **C. Study complete/data analysis is complete.**   * *All of the following conditions must apply*   No data is being obtained through intervention or interaction with subjects,  Data is not identifiable (i.e., data has been de-identified and code keys linking to identifiers have been destroyed); *and*  Data is not being analyzed; *or*, for multi-site study, UO site is no longer engaged. | | | | | |
| **D. Study and data analysis complete. Retaining identifiers for possible future use or for safety purposes.**   * *All of the following conditions must apply*   No data is being obtained through intervention or interaction with subjects, *and*  Maintaining individually identifiable private information but no longer using, studying, or analyzing the data.  If wishing to retain identifiable information, this must have been explained in the approved protocol Research Plan and Informed Consent. If this was not previously approved, contact RCS for guidance. | | | | | |
| 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: | | | | | |
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| * 1. Participant enrollment:   NOTE: For exempt studies, a response is only required for 2b. Indicate n/a for 2a and 2c. | | | | | |
| * + 1. Maximum number of participants approved to enroll by the IRB: | | | |  | |
| * + 1. Number of participants enrolled since the start of this research: | | | |  | |
| * + 1. Does the number of participants enrolled exceed the number of participants approved by the IRB? | Yes  No | If “yes,” explain and submit as [Reportable New Information](http://rcs.uoregon.edu/content/event-reporting) or specify if the Reportable New Information has previously been submitted: | | | |
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| * 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.): |  | | | | |
| * + 1. Have a greater number of participants than expected withdrawn from the study? | Yes  No | If “yes,” explain. | | | |
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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 [Reportable New Information](http://rcs.uoregon.edu/content/event-reporting) has been submitted: | | | |
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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), has any [Reportable New Information](http://rcs.uoregon.edu/content/event-reporting) been submitted to RCS and/or the IRB? | Yes  No | If “yes,” explain | | | |
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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. Investigational drug(s) and devices: | | | | | |
| * + 1. Did this research involve an investigational drug(s)? | | | Yes  No | | |
| If “Yes”, indicate **one** of the following: | | | | |
| All unused supplies of the investigational drug have been returned to the sponsor/IND holder.   * If the sponsor is the investigator, explain how unused supplied are managed: | | | | | |
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| **-OR-** | | | | | | |
| Unused supplies do not expose humans to risks from the drug and alternative disposition has been arranged for unused supplies   * Explain how unused supplied are managed: | | | | | |
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| * + 1. Did this research involve an investigational device(s)? | | | Yes  No | | |
| If “Yes”, indicate **one** of the following: | | | | |
| All devices have been used for the research or returned to the appropriate entity (e.g., sponsor, manufacturer, etc.). | | | | | |
| **-OR-** | | | | | | |
| Devices have not been returned, but do not expose humans to risk.   * Justify why devices remain with the local investigators: | | | | | |
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| 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://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 | | | 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 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. | |
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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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