|  |
| --- |
| **Purpose:** This application is designed to facilitate the Institutional Review Board (IRB) review of proposed human subjects research. The IRB serves to protect the rights and welfare of human subjects in research in accordance with federal, state, and institutional regulations and policy.  |

**Instructions:** Complete this application as part of the initial protocol submission. A complete protocol submission initiates IRB review of research involving human subjects. Incomplete or unreadable applications will extend the IRB review process. Submit this application (including the [checklist](#Checklist) below) and all applicable research materials (research plan, attachments, consent form, surveys, interview guides, etc.) to ResearchCompliance@uoregon.edu. Direct any questions regarding this form or human subjects research to Research Compliance Services (RCS) by email or phone (541-346-2510). Save this form before proceeding

|  |
| --- |
| 1. Study and Investigator Information
 |
|  |
| Study Title: |        |
| Principal Investigator (PI): | Enter one PI per protocol.  | PI Department: |        |
| PI UO Email: |        | PI Telephone: |        |
| Role at UO: |   |  If other, specify role: |       |
|  |
| Faculty Advisor: | A faculty advisor must be listed on all student protocols  | Faculty Advisor Department: |        |
| Faculty Advisor UO Email: |        | Faculty Advisor Telephone: |        |
| * 1. Research Request (select one of the following):
 |
| **[ ]  Initial Review of Newly Proposed Research** |
| **[ ]  Initial Review for Expired Research** – For review of research that was previously approved by the IRB that has now expired. Answer the questions below:  |
|  | * + 1. State reason for lapse in approval:
 |
|       |
|  | * + 1. Describe the plan to prevent future lapses in approval:
 |
|       |
|  | * + 1. Has the study sponsor or funding agency been notified of the lapse in [approval period](#ApprovalPeriod)?
 |
|  | [ ]  Yes | [ ]  No | [ ]  N/A (no sponsor involved/not required) |
| If “No”, explain: |        |
|  | * + 1. Has any human subject research activity been conducted after the IRB approved expiration date?
 |
| * Once there is a lapse in IRB approval of research, investigators must stop all human subject research activities, including intervening or interacting with subjects and obtaining or analyzing identifiable private information about human subjects.
 |
|  | [ ]  Yes | [ ]  No | If “Yes”, submit an [Event Report](http://rcs.uoregon.edu/content/event-reporting) describing the number of subjects enrolled, the research interventions/activities conducted and/or the data analyzed: |
| * 1. Provide the anticipated start and end date for human subject research (month and year):
 |
| Start (month and year): |       | End (month and year):  |       |
| * 1. Complete the [Research Personnel Form](http://rcs.uoregon.edu/content/human-subjects-applications-forms). All research personnel, including the Principal Investigator, Faculty Advisors, Co-Investigators, and Research Assistants, must be listed.
 |
|  | [ ]  Research Personnel Form Attached |
| * 1. Is this research funded or sponsored from an internal UO or external source?
 |
|  | [ ]  Yes | [ ]  No | If “yes," complete and attach the [Funding and Sponsorship Form](http://rcs.uoregon.edu/content/human-subjects-applications-forms). |
|  |
| 1. Risk Assessment
 |
| * Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
 |
| **In the Principal Investigator’s opinion, this research presents (select one of the following):**  |
|  | [ ]  No greater than minimal risk; **briefly explain in text box below.** |
|  |       |
|  | [ ]  Greater than minimal risk; **briefly explain in text box below.** |
|  |       |
| 1. Research Plan
 |
| * 1. Develop a Research Plan using the [Research Plan Guidance](http://rcs.uoregon.edu/sites/default/files/Guidance%20-%20Research%20Plan.pdf) and [template.](http://rcs.uoregon.edu/sites/default/files/Template%20-%20Research%20Plan.docx) Grant, thesis, dissertation, or course work proposals may NOT be submitted in lieu of the Research Plan.
 |
| * See [RCS website](http://rcs.uoregon.edu) for topical guidance; be sure to include relevant information in the Research Plan.
 |
|  | [ ]  Research Plan Attached |
|  |
| * 1. Answer “yes” or “no” to ALL the following questions.
 |
| * If the answer to any of the following questions is “yes,” incorporate relevant information into the Research Plan and attach applicable appendix.
* All applicable appendices must be submitted with the initial application and each subsequent submission of the Research Plan.
 |
|  | * + 1. Does this research involve the use of any drug, substances, or biologics?
 |
| [ ]  Yes [ ]  No | If “yes," [Attach Appendix A – Drugs](http://rcs.uoregon.edu/node/8) |
|  | * + 1. Does this research involve the use of a medical device?
 |
| [ ]  Yes [ ]  No | If “yes," [Attach Appendix B – Medical Devices](http://rcs.uoregon.edu/node/8) |
|  | * + 1. Does this research involve the use of any ionizing radiation (X-ray, DEXA scan, etc.)?
 |
| [ ]  Yes [ ]  No | If “yes," [Attach Appendix C – Ionizing Radiation](http://rcs.uoregon.edu/node/8) |
|  | * + 1. Does this research involve the use of [**Protected Health Information**](http://rcs.uoregon.edu/node/96) (PHI)?
 |
| [ ]  Yes [ ]  No | If “yes," [Attach Appendix D – HIPAA](http://rcs.uoregon.edu/node/8) |
|  | * + 1. Does this research involve coded or identifiable DNA samples/genetic information?
 |
| [ ]  Yes [ ]  No | If “yes," [Attach Appendix E – Genetic Materials](http://rcs.uoregon.edu/node/8) |
|  |
| 1. Recruitment and Subject Population
 |
| * Copies of all [recruitment](http://rcs.uoregon.edu/content/recruiting-research-participants) materials must be submitted with this application (e.g., flyer, email text, verbal recruitment script)
 |
| * 1. Maximum number of participants to be enrolled (include breakdown for all groups as applicable):
 |
|  |       |
|  |
| * 1. Does this study include minors?
 |
|  | [ ]  Yes [ ]  No | If “yes," state the minimum and maximum ages: |       |
| * 1. Does this study include adults?
 |
|  | [ ]  Yes [ ]  No | If “yes," state the minimum and maximum ages: |       |
|  |
| * 1. Indicate how the participants will be recruited (check all that apply):
 |
|  | [ ]  Email | [ ]  Online |
|  | [ ]  Flyer | [ ]  Telephone |
|  | [ ]  In Person | [ ]  Mail |
|  | [ ]  Psychology Pool | [ ]  Marketing Pool |
|  | [ ]  SOJC Pool | [ ]  n/a – Existing Data (i.e., no contact with subjects) |
|  | [ ]  Database or record review |  |
|  | [ ]  Other: |       |
|  |
| * 1. Will all research be conducted in English?
 |
|  | [ ]  Yes [ ]  No | If “no," state what language(s) will be used in text box below? |
|  |       |
|  | Note: See our [website](http://rcs.uoregon.edu/guidance/translations-translated-materials) for requirements and guidance regarding translators and translations. |
|  |
| 1. Consent, Assent, and Permissions
 |
| * Copies of all consent materials must be submitted with this application.
* In general, a consent process that includes all the [elements of informed consent](http://www.hhs.gov/ohrp/policy/consentckls.html) and written documentation is required. The IRB may waive all or portions of these requirements. Justification for a waiver must be provided in the Research Plan.
 |
| * 1. Considering all participant groups, indicate the consent/assent process(es) involved in the research (check all that apply).
 |
|  | [ ]  In Person  |  |
|  | [ ]  Remote (e.g., online, phone, Skype, etc.) |  |
|  | [ ]  Other: |       |
|  |
| * 1. Will the consent process include all the [elements of informed consent](http://www.hhs.gov/ohrp/policy/consentckls.html)?
 |
|  | [ ]  Yes [ ]  No | If “no," [a waiver of informed consent or an alteration of the elements of informed consent](http://rcs.uoregon.edu/sites/default/files/Guidance%20-%20Informed%20Consent%20Waiver.pdf) must be approved by the IRB. Provide justification in the Research Plan. |
|  |
| * 1. Will the consent and/or assent process be documented using a written consent form that will be signed by the subject or the subject’s legally authorized representative?
 |
|  | [ ]  Yes [ ]  No | If “no," [a waiver of documentation of informed consent](http://rcs.uoregon.edu/sites/default/files/Guidance%20-%20Informed%20Consent%20Waiver.pdf) must be approved by the IRB. Provide rationale for not obtaining signed written consent in the Research Plan. |
|  |
| 1. Compensation and Reimbursement
 |
| * If [compensating participants](http://rcs.uoregon.edu/content/compensation-participation-research) using funds distributed through a UO department, consult with the department administrator to clear the method of payment and develop a tracking system in compliance with [BAO policy](http://rcs.uoregon.edu/sites/default/files/BAO%20Policy%20Payments.pdf).
 |
|  |
| * 1. Will the participants be compensated and/or reimbursed for their participation?
 |
|  | [ ]  Yes [ ]  No | If “yes," proceed to questions 2 and 3 below. If “no," proceed to the next section. |
|  |
| * 1. For what are the participants being compensated/reimbursed (check all that apply)?
 |
|  | [ ]  Time | [ ]  Meals |
|  | [ ]  Travel | [ ]  Expenses |
|  | [ ]  General incentive to participate |  |
|  | [ ]  Other: |       |
| * 1. Method of compensation/reimbursement (check all that apply)?
 |
|  | [ ]  Cash | [ ]  Psychology pool credit |
|  | [ ]  Check | [ ]  Marketing pool credit |
|  | [ ]  Gift Certificate/Card/Code | [ ]  SOJC pool credit  |
|  | [ ]  Gift Item | [ ]  Drawing |
|  | [ ]  Academic/extra credit |  |
|  | [ ]  Other: |       |
|  |
| 1. Other Institutions, Performance Sites, and Non-UO Research Personnel
 |
| * If another institution is [engaged](http://www.hhs.gov/ohrp/policy/engage08.html) in this research and it has an IRB, approval must be obtained from that institution's IRB. Otherwise, an IRB Authorization Agreement must be executed to defer IRB oversight. To request a deferral, submit an [IRB Institutional Authorization Agreement Request Form](http://rcs.uoregon.edu/node/8) for review.
* If a site/organization does not have an IRB, site/organization permission may need to be obtained.
* Documentation of [IRB determinations and Authorization Agreements](http://rcs.uoregon.edu/content/Collaboration-Research) must be in place prior to engaging in associated human subject research activities.
* See our website for additional guidance on [Collaborative Research](http://rcs.uoregon.edu/content/Collaboration-Research).
 |
|  |
| * 1. Willindividuals from other site(s)/organization(s) (e.g., universities, hospitals, etc.) with an IRB be [engaged](http://www.hhs.gov/ohrp/policy/engage08.html)  in this research?
 |
|  | [ ]  Yes [ ]  No | If “yes," list the site(s)/organization(s) below. |
| Name of site(s)/organizations: |       | Approval Status: |  |
| If no approval required, explain:  |       |
|  |
| * 1. Will research activities occur at other site(s)/organization(s) (e.g., universities, hospitals, etc.) that have an IRB?
 |
|  | [ ]  Yes [ ]  No | If “yes," list the site(s)/organization(s) below. |
| Name of site(s)/organizations: |       | Approval Status: |  |
| If no approval required, explain in text box below:  |
|       |
|  |
| * 1. Will individuals from other site(s)/organization(s) (e.g., universities, hospitals, etc.) without an IRB be engaged in this research? An [Individual Investigator Agreement](http://rcs.uoregon.edu/sites/default/files/IIA%20Form%20-%20Blank.docx) (IIA) will need to be executed.
 |
|  | [ ]  Yes [ ]  No | If “yes," list the site(s)/organization(s) below. |
| Names of researcher(s)/site(s)/ organization(s): |       |
|  |
| * 1. Will the research be conducted with any site(s)/organization(s) other than University of Oregon (e.g., public schools, tribes, non-profit organizations, companies, etc.) that do not have an IRB?
 |
|  | [ ]  Yes [ ]  No | If “yes," list the site(s)/organization(s) below. |
| **Note**: See our website for additional guidance on documentation requirements for [permissions and approvals](http://rcs.uoregon.edu/guidance/permissions-approvals).  |
| Name of site(s)/organizations: |       | Permission Status: |  |
| If no permission required, explain in text box below:  |
|       |
|  |
| * 1. Does this research involve activities outside of the United States?
 |
|  | [ ]  Yes [ ]  No | If “yes," list country (ies) below. |
| Name of country(ies): |       | Permission Status: |  |
| **Note**: See our website for additional guidance on documentation requirements for [permissions and approvals](http://rcs.uoregon.edu/guidance/permissions-approvals). |
| If no permission required, explain in text box below:  |
|       |
| * 1. Does this research require permission from an internal UO department or service (e.g., Registrar’s Office, Campus ListServ, etc.)?
 |
|  | [ ]  Yes [ ]  No | If “yes," inquire with the applicable office and provide documentation of permission. |
| Name of department(s)/service(s): |       | Permission Status: |  |
| If no permission required, explain in text box below:  |
|       |
|  |
| 1. Additional Materials
 |
| * 1. Will this research involve recruiting subjects from University of Oregon Human Subject Pool(s) (e.g. psychology, linguistics, marketing, or SOJC pools)?
 |
|  | [ ]  Yes [ ]  No | If “yes," attach debriefing materials and, if required by the subject pool coordinator, documentation of debriefing clearance. |
|   |
| * 1. Does this research involve procedures, materials, and/or a lab space that requires [UO Environmental Health and Safety (EHS)](http://ehs.uoregon.edu/) oversight or inspection?
 |
|  | [ ]  Yes [ ]  No | If “yes," attach relevant clearance or approval documentation (e.g., biosafety committee approval, radiation safety committee approval, etc.). |
|  |
| * 1. 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. |
|  |
| * 1. 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. Will this research include obtaining, accessing, or using data from outside sources, e.g., universities, data repositories, government agencies, etc.?
 |
|  | [ ]  Yes [ ]  No | If “yes,“ name the source(s) below. |
| Name of outside source(s):  |       |
|  | * + 1. Are there terms, restrictions, or conditions regarding the data?
 |
| [ ]  Yes [ ]  No | If “yes,” describe in applicable sections of the [Research Plan](http://rcs.uoregon.edu/content/research-plan). |
|  | * + 1. Does this source require a Data Use Agreement (DUA) or other agreement to use or obtain access to the data?
 |
| [ ]  Yes [ ]  No | If “yes,", include a copy of the agreement in this submission and contact Innovation Partnership Services at techtran@uoregon.edu to ensure appropriate institutional approval is obtained to enter into the agreement. |
|  |
| 1. Clinical Trials
 |
| * **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 “yes,” the principal investigator is responsible for ensuring the additional requirements related to conduct of clinical trials are met: |
| * 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.
* For NIH sponsored research that meets the definition of clinical trial and/or FDA regulated research:
	+ The 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.
	+ 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.

See the [RCS Clinical Trials](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/clinical-trials) page for more information and guidance. |
| 1. Human Subjects Conflict of Interest
 |
| * 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 those individuals who have identified a real, perceived, or potential conflict of interest on their form.
 |
|  | [ ]  | No conflicts are identified. |
|  | [ ]  | Yes, conflicts are identified and Human Subject COI form(s) are attached for the following individuals: |
|  |  |       |

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

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| 1. Conduct of the Research
	1. I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the [Belmont Report](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html), [Declaration of Helsinki](http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC20-Attach-1.pdf), the [Nuremberg Code](http://www.hhs.gov/ohrp/archive/nurcode.html), the [Common Rule,](http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html) and the ethical principles of my discipline.
	2. I accept responsibility for the conduct of this research ensuring this research is conducted according to
		1. sound research design and methods;
		2. the IRB approved protocol including the informed consent process;
		3. the applicable terms of the grant, contract and/or signed funding agreements; and
		4. applicable laws and regulations, including those for protecting the rights, safety, and welfare of human subjects.
	3. I certify that I am or my faculty advisor is sufficiently qualified by education, training, and/or experience to assume responsibility for the proper conduct of this research. I accept responsibility for ensuring that members of this research team, including study staff and trainees, are appropriately qualified, trained and supervised.
	4. I accept responsibility to personally conduct and/or directly supervise this research. I certify that I have sufficient time and resources to properly conduct and/or supervise this research for which I am responsible.
2. Ensuring and Maintaining Compliance
	1. I will comply with relevant regulatory and institutional requirements, including those relating to conflicts of interest, responsible conduct of research and research misconduct.
	2. I understand it is my responsibility to ensure that any research personnel, including myself, responsible for the design, conduct, and reporting of research declare any potential conflicts of interests related to the research and to maintain current records. I will ensure changes in conflicts of interest are promptly disclosed to the IRB.
	3. I will ensure that informed consent is obtained as approved by the IRB and a copy is provided to participants, unless the IRB waives these requirements.
	4. I will obtain initial IRB approval prior to implementing human subject research activities as well as prior approval for any amendments to this research.
	5. I will conduct this research within the approval period issued by the IRB. I agree to submit a request for continuing review of this research at least 45 days in advance of the expiration date.
	6. I will submit a closure report form prior to protocol expiration or within 45 days of completion of all activities involving human subjects or identifiable participant data.
	7. I will maintain approval, as applicable, with collaborative entities including approvals from other countries or jurisdictions.
	8. I will promptly report to the IRB (no later than seven days of discovery) any instances of noncompliance with the approved protocol or requirements of the IRB and any unanticipated problems.
	9. I will assist in the facilitation of any monitoring and/or auditing of study activities and/or records as required by the IRB, funding entities, sponsors, and any federal and state regulatory agencies.
3. Investigator Records, Reports and Documentation
	1. I will maintain research records, all protocol materials, and any other documents associated with this research (e.g., research plan, signed consent forms, and IRB correspondence).
	2. I will maintain records for at least three years after this research ends, or for the length of time specified in applicable regulations or institutional or sponsor requirements, whichever is longer. I will take measures to prevent accidental or premature destruction of these documents.
	3. I will ensure the safe and secure storage of this research data (whether in paper or electronic formats) and for protecting the confidentiality of the data in accordance with the approved protocol.
	4. I will submit written reports to the IRB and permit inspection of the research records as required by the IRB.
 |
| * By signing below, the Principal Investigator attests to having read and agrees to uphold the responsibilities and duties as outlined above. In addition, the materials provided in support of this application are an accurate reflection of the proposed research.
 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | 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.
 |

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| **REQUIRED FOR STUDENT RESEARCH** * By signing below, the **Faculty Advisor** attests he/she has read and approves the attached protocol submitted for IRB review. In addition, he/she agrees to provide appropriate education and supervision of the student investigator, and share the Principal Investigator responsibilities as stated above.
 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | 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** **and all subsequent correspondence**.
 |

**Instructions:** The purpose of this checklist is to identify all items necessary to compile a complete protocol submission. Submit all protocol materials including the checklist to ResearchCompliance@uoregon.edu. Contact Research Compliance Services (RCS) by email or phone (541-346-2510) with any questions.

* **If submitting all materials in one document, order the materials as listed below.**

|  |  |  |
| --- | --- | --- |
| **Incl.** | **n/a** | **Items** |
| [ ]  | — | Initial Review Application, completed and signed by the Principal Investigator and, if applicable, the Faculty Advisor.  |
| [ ]  | — | Research Personnel Form and solicited applicable training documentation.  |
| [ ]  | [ ]  | Human Subject Conflict of Interest (COI) Form  |
| [ ]  | [ ]  | Funding and Sponsorship Form |
| [ ]  | — | A Research Plan and applicable appendices (grant applications or excerpts from a grant will NOT be accepted as a 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: Emails, letters, scripts, flyers, posters, brochures, etc. |
| [ ]  | [ ]  | Informed Consent/Assent Materials  |
| [ ]  | [ ]  | Debriefing Materials |
| [ ]  | [ ]  | Release Form for Translators and Transcribers |
| [ ]  | [ ]  | Data Collection Materials (questionnaires, surveys, data collection forms, focus group/interview scripts, etc.) |
| [ ]  | [ ]  | Data Safety Monitoring Plan |
| [ ]  | [ ]  | Data Safety Monitoring Board/Committee information |
| [ ]  | [ ]  | Data Use Agreement(s) |
| [ ]  | [ ]  | Permissions, support letters, and IRB approval documentation as identified in Part VII of this application. |
| [ ]  | [ ]  | Clearance or approval documentation from applicable UO Environmental Health and Safety oversight/inspection |
| [ ]  | [ ]  | For funded and/or sponsored research: The human subjects portion of the grant proposal. |