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| **Purpose:** Some categories of minimal risk research qualify for exemption from the federal regulations and do not require additional oversight by the Institutional Review Board (IRB) or may only require limited IRB oversight; however, these studies do require review by Research Compliance Services (RCS) to determine their eligibility and the degree of IRB oversight. An exempt determination from RCS is required in order to conduct exempt human subject research at the University of Oregon. Use this form to request an exempt determination from RCS. |

**Instructions:**

* **Initial requests:** Complete this form only after you have assessed (use [self-assessment tool](https://rcs.uoregon.edu/exempt-self-assessment-tool)) that your study may qualify for exemption under one of the exemption categories.
* **Amendment requests:** To amend research previously determined exempt,complete this form only after you have assessed (use [self-assessment tool](https://rcs.uoregon.edu/exempt-self-assessment-tool)) that your study may still qualify for exemption. Provide responses according to the amended research plans. If your study is no longer eligible for exemption, stop and prepare an [Initial Review Application.](https://rcs.uoregon.edu/content/human-subjects-applications-forms)

RCS will review and verify the exempt determination. If RCS determines the study does not qualify for exemption, you will need to prepare and submit a protocol using the Initial Review Application.

If you self-determine your study qualifies for exemption, complete this application and submit the items noted in the Submission Checklist at the end of the form to Research Compliance Services (RCS).

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Study and Investigator Information | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Title: | | | | | | | |  | | | | | | | | | | | | | | | | | | |
| Principal Investigator (PI) Name: | | | | | | | | Enter one PI per protocol. | | | | | | | | | | | PI Department: | | |  | | | | |
| PI UO Email: | | | | | | | |  | | | | | | | | | | | PI Telephone: | | |  | | | | |
| Role at UO: | | | | | | | |  | | | | | | | | | | | If other, specify role: | | |  | | | | |
| * A faculty advisor must be listed on all student protocols. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Faculty Advisor: | | | | | | | | | | | |  | | | | | | | Faculty Advisor Department: | | | |  | | | |
| Faculty Advisor UO Email: | | | | | | | | | | | |  | | | | | | | Faculty Advisor Telephone: | | | |  | | | |
| * 1. Exemption Verification Request (select one of the following): | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **INITIAL REVIEW REQUEST** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * **What are the anticipated project dates for beginning and ending human subjects research?** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Start (month and year): | | | | | | | | | | | | | | | | |  | | | End (month and year): | | | |  | | |
| **AMENDMENT REVIEW REQUEST** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * **Describe the changes:** | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * **Provide a rationale for the changes:** | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * **Is the project end date changing?** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | | | | Revised End Date (month and year): | | | | |  | | | | | |
| * For amendment requests, provide responses in the remainder of this form according to the amended research plans. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Research Personnel Form. All research personnel, including the Principal Investigator, Faculty Advisors, Co-Investigators, and Research Assistants, must be listed on the research personnel form. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 a [Funding and Sponsorship Form](http://rcs.uoregon.edu/content/human-subjects-applications-forms#2) for each source of funding. | | | | | | | | | | | | |
| 1. Screening | | | | | | | | | | | | | | | | | | | | | | | | | |
| * Complete this section to identify study characteristics that do not qualify for exemption. | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Below are specific characteristics that disqualify a study for exemption. Answer the following: | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | * + 1. Does this research involve the use of any drug, substances, or biologics? | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | * + 1. Does this research involve the use of an investigational medical device? | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | * + 1. Does this research involve the use of any ionizing radiation (X-ray, DEXA scan, etc.)? | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | * + 1. Does this research involve the use of genetic information and/or tests? | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | * + 1. Does this research propose to study prisoners as a targeted population?   Note: If a participant becomes a prisoner, the study will no longer qualify for exemption. | | | | | | | | | | | | |
| * 1. In some circumstances, studies that otherwise qualify for exemption must undergo expedited or full board review by the IRB. These are typically due to additional, study specific circumstances. Answer the following to determine if your study is otherwise ineligible for exemption: | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | * + 1. Is there a state, federal or other applicable law (e.g., tribal or other international law) that prohibits an exemption determination? | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | * + 1. Does the agency funding your research or an agency with whom you are working prohibit an exemption determination and require that you have IRB approval? | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | * + 1. Any other study specific requirements that prohibit exemption (e.g., sponsor’s requirements)? | | | | | | | | | | | | |
| * **If you answered “yes” to any of the questions above, stop completing this form and proceed with preparing an** [**Initial Review Application.**](https://rcs.uoregon.edu/content/human-subjects-applications-forms#1) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Exempt Category(ies) (§\_.104) | | | | | | | | | | | | | | | | | | | | | | | | | |
| * Based on the brief description and/or your completion of the [self-assessment tool](https://rcs.uoregon.edu/exempt-self-assessment-tool), select one or more of the categories below that appear to be applicable to your research. Then complete the Exempt Category Worksheet(s) as directed. | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Research conducted in an established or commonly accepted educational setting that specifically involves normal educational practices. Complete [Exempt Category 1 Worksheet](http://rcs.uoregon.edu/sites/default/files/Worksheet_Exempt_Category_1.docx). | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Research that ONLY includes interactions involving:   1. Educational tests (cognitive, diagnostic, aptitude, achievement), OR 2. Survey procedures, OR 3. Interview procedures, OR 4. Observation of public behavior   Complete [Exempt Category 2 Worksheet.](http://rcs.uoregon.edu/sites/default/files/Worksheet_Exempt_Category_2.docx) | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Research involving ONLY benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording. Complete [Exempt Category 3 Worksheet](http://rcs.uoregon.edu/sites/default/files/Worksheet_Exempt_Category_3.docx). | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Secondary research using identifiable private information or identifiable biospecimens, collected for another purpose. Complete [Exempt Category 4 Worksheet](http://rcs.uoregon.edu/sites/default/files/Worksheet_Exempt_Category_4.docx). | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Research and demonstration projects conducted or supported by a Federal department or agency that is designed to study, evaluate, improve, or otherwise examine public benefit or service programs. Complete Exempt [Category 5 Worksheet](http://rcs.uoregon.edu/sites/default/files/Worksheet_Exempt_Category_5.docx). | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Taste and food quality evaluation and consumer acceptance studies. Complete [Exempt Category 6 Worksheet](http://rcs.uoregon.edu/sites/default/files/Worksheet_Exempt_Category_6.docx). | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | — Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use for which [*broad consen*](https://rcs.uoregon.edu/guidance/broad-consent)*t* is required.  **NOTE: UO IRB does not plan to implement the broad consent option at this time. Limited exceptions may be considered.  Please contact Research Compliance Services if you are interested in requesting an exception and having your research considered under this category.** | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Secondary research involving the use of identifiable private information or identifiable biospecimens for which [*broad consent*](https://rcs.uoregon.edu/guidance/broad-consent) was obtained.  **NOTE: If you propose submitting a study for consideration under this exemption category, you must consult with RCS to obtain the category worksheet for submission due to the additional consent provisions and tracking requirements.** | | | | | | | | | | | | | | | | | | | | | |
| * **If you were unable to identify an applicable exemption category and/or the worksheet(s) leads you to determine the study does not qualify for exemption, stop completing this form and proceed with preparing an** [**Initial Review Application**](https://rcs.uoregon.edu/content/human-subjects-applications-forms#1)**.** | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Research design and methods | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * Attach a [research plan](https://rcs.uoregon.edu/content/research-plan) to this application detailing the information solicited below or provide responses to the following questions. *Check either 1 or 2 below.* | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | Research plan attached, skip to Part V  – OR - | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | No research plan attached, answer the following questions. | | | | | | | | | | | | | | | | | | | |
|  | | | | | | 1. **Briefly describe the purpose of your research and the anticipated contributions to generalizable knowledge (e.g., research aims, description of any anticipated publications, etc.).** | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | 1. **Provide an overview of your research design and methods.** | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | 1. **Describe your study population including estimated number and age range of participants.** | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Informed ConsenT | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * Obtaining the informed consent of potential participants is ethically important in the responsible conduct of research. While the informed consent process for exempt research does not need to include all elements of informed consent in the Common Rule regulations, researchers should employ a consent process when interacting with participants. * Researchers are strongly encouraged to continuing using the [informed consent guidance](https://rcs.uoregon.edu/content/informed-consent) and [template](http://rcs.uoregon.edu/sites/default/files/Template%20GUIDANCE%20-%20Informed%20Consent%20v12202017.pdf). * At minimum, the informed consent process needs to include disclosure of the following to participants:   + That the activity involves research.   + A description of the procedures.   + That participation is voluntary.   + Name and contact information for the Researcher. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Does the research involve interaction with participants? | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | | If “yes," the research design must include an informed consent process or provide justification for not obtaining informed consent from participants. | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | Research plan is attached and includes a description of the informed consent process or justification for not obtaining informed consent  – OR -  Describe the informed consent process or provide justification for not obtaining informed consent from participants below: | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. If conducting an informed consent process, provide a copy of the informed consent form and/or script. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Informed Consent Form/Script attached.  n/a - not conducting informed consent | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Does this research involve the use of [Protected Health Information](http://rcs.uoregon.edu/content/protected-health-information) (PHI)? | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes  No | | | | | | | | | | | | | | If “yes," [Attach Appendix D – HIPAA](http://rcs.uoregon.edu/node/8#3). | | | | | | | | | | | | |
| 1. OTHER INSTITUTIONS, PERFORMANCE SITES, AND NON-UO RESEARCH PERSONNEL | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * Instructions: Complete all required fields to prepare this form for submission to RCS. Upload attachments as prompted. If you have multiple files, these will need to be bundled into a single file before being uploaded. * See our website for additional guidance on [Collaborative Research](http://rcs.uoregon.edu/content/Collaboration-Research). | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Will individuals from outside of the UO (e.g., other universities, hospitals, etc.) be [engaged](http://www.hhs.gov/ohrp/policy/engage08.html) in this research? | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes No | | | | | | | | | | * If yes, one of the following agreements/approvals is necessary to provide oversight for their involvement with the research: * If any individual is acting independent of an institution with an IRB or their institution is not required to have an IRB, an [Individual Investigator Agreement](http://rcs.uoregon.edu/node/8#2) for the individual will need to be executed. * If any individual is acting as an agent of an institution with an IRB, either IRB approval or an IRB Authorization Agreement (IAA) will need to be requested. To request an IAA be considered, submit an [IRB Institutional Authorization Agreement Request Form](http://rcs.uoregon.edu/node/8#2). | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | **Name all individuals acting independent of any site/organization:**   * These individuals will need to complete the Individual Investigator Agreement (IIA). | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Attach any IRB approvals and/or executed IRB collaborative agreements. | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | **Name all individuals acting as an agent of another site/organization with an IRB. Indicate whether the IRB will conduct their own review or enter into a** [collaborative agreement](http://rcs.uoregon.edu/content/Collaboration-Research)**:** | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Attach any IRB approvals and/or executed IRB collaborative agreements. | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | **Name all individuals acting as an agent of another site/organization without an IRB:**   * These individuals will need to complete the Individual Investigator Agreement (IIA). | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Attach any IRB approvals and/or executed IRB collaborative agreements. | | | | | | | | | | | | | | | | |
| * 1. Will research activities occur at other site(s)/organization(s) other than UO (e.g., public schools, tribes, non-profit organizations, companies, etc.)? | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes No | | | | | | | | | | * 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 one of the participating institution’s IRB. To request a deferral, submit an [IRB Institutional Authorization Agreement Request Form](http://rcs.uoregon.edu/node/8#2) for review. * If a site/organization does not have an IRB, the site/organization may need grant permission to conduct the research. * 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. | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | **List all sites and describe the status of any required approvals:**   * See our website for additional guidance on documentation requirements for [permissions and approvals](http://rcs.uoregon.edu/guidance/permissions-approvals). | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Attach any IRB approvals and/or executed IRB collaborative agreements. | | | | | | | | | | | | | | | | |
| * 1. Does this research involve activities outside of the United States? | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes No | | | | | | | | | | If yes, list the country(ies) below and indicate the status of permissions. | | | | | | | | | | | | | | | | |
|  | | | | | | | | | |  | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | **Are there additional requirements that apply to research conducted in the listed country(ies)? (e.g., European Union and the General Data Protection Regulations)**   * See our website for additional guidance on documentation requirements for [permissions and approvals](http://rcs.uoregon.edu/guidance/permissions-approvals). | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Yes, there are additional requirements that apply | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | If yes, describe and discuss how these are addressed for the proposed research and include any approval documentation. | | | | | | | | | | | | | | | | |
|  | | | | | | | | | |  | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | No, there are no additional requirements that apply | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | If no permission required, explain. | | | | | | | | | | | | | | | | |
|  | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| * 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, list the departments and include applicable documentation of permission. If permission is pending or no permission is required, explain. | | | | | | | | | | | | | | | | |
|  | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| 1. Additional Materials | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Will this research involve recruiting subjects from a University of Oregon Human Subject Pool(s) (e.g. psychology/linguistics, marketing, or SOJC pools)? | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Yes No | | | | | | | | | | If yes, list the subject pool that will be used below. | | | | | | | | | | | | | | | | |
|  | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| NOTE: Be sure you are familiar with requirements of the pool (e.g., the pools require specific standardized consent language). Ensure you have developed debriefing materials and obtained clearance from the pool coordinator when debriefing is required. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 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. 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 and answer questions “a” and “b” below. If “no,” move to Part VII. | | | | | | | | | | | | | | | |
| Name of outside source(s): | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | Yes  No | | | | | | | * + 1. Are there terms, restrictions, or conditions regarding the data? | | | | | | | | |
|  | | | | | | | | | | | If “yes,” describe: | | | | | | |  | | | | | | | | |
|  | | | | | | | | | | | Yes  No | | | | | | | * + 1. If “yes," include a copy of the agreement in this submission and contact Innovation Partnership Services at [techtran@uoregon.edu](mailto: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**](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 “yes,” 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. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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#2). * 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. | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | Yes, conflicts are identified and Human Subject COI form(s) are attached for the following individuals: | | | | | | | | | | | | | | | | | | | | | |
|  | | | | |  | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | No conflicts are identified. Keep a copy of COI form(s) for your records, but do not submit with the application. | | | | | | | | | | | | | | | | | | | | | |

*[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 ensuring this research is conducted according to:       1. sound research design and methods;       2. the parameters of the research plan and activities described in these application materials;       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. 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 RCS.    3. I will ensure that prospective agreement and/or informed consent is obtained and a copy is provided to participants, when appropriate.    4. I will ensure all research activities are either determined exempt or have the necessary IRB approval prior to beginning human subject research activities. I will obtain confirmation of continued exemption or otherwise seek IRB approval for any amendments to this research.    5. I will conduct this research within the approved project period. I will submit a closure report form prior to the protocol expiration or within 45 days of completion of all activities involving human subjects or identifiable participant data. Alternatively, I agree to submit a progress report to request continued approval and extend the project period at least 45 days in advance of the expiration date.    6. I will maintain approval, as applicable, with collaborative entities including approvals from other countries or jurisdictions.    7. I will promptly report to RCS and/or the IRB (no later than seven days of discovery) any instances of noncompliance and any unanticipated problems.    8. I will assist in the facilitation of any monitoring and/or auditing of study activities and/or records as required by RCS, the IRB, funding entities, sponsors, and/or 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, consent materials, and RCS and/or 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 records.    3. I will ensure the safe and secure storage of this research information (whether in paper or electronic formats) and will protect the confidentiality of the information in accordance with any provisions described in the protocol.    4. I will submit written reports to RCS and/or the IRB and permit inspection of the research records as required by RCS and/or 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. |

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| **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 below, the Faculty Advisor attests he/she has read and approves the attached protocol submitted for 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. |

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| **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:** Use this checklist to identify all items necessary to compile a complete exempt determination submission. Submit all materials identified below to ResearchCompliance@uoregon.edu. Contact Research Compliance Services (RCS) by email or phone (541-346-2510) with any questions.

**NOTE:** Save this form for the life of the study as it can be updated for future amendment submissions related to the study.

* **If submitting all materials in one document, order the materials as listed below.**
* **For amendments, supplemental materials should be submitted with changes clearly delineated using tracked changes or highlighting.**

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| **Incl.** | **n/a** | **Items** |
| **Required for Submission:** | | |
|  | — | Exempt Determination Application, completed and signed by the Principal Investigator and, if applicable, the Faculty Advisor |
|  | — | Exempt Category Worksheet(s), completed by the Principal Investigator |
|  | — | Research Personnel Form and solicited applicable training documentation |
|  |  | Human Subject Conflict of Interest (COI) Form (**only for those individuals with a potential conflict identified on the form**) |
|  |  | Funding and Sponsorship Form with the human subject portion of the grant proposal (**only if the study is supported by an award**) |
|  |  | Informed Consent/Assent Materials (**only when interacting with participants**) |
|  |  | Appendix D - HIPAA (**if accessing individually identifiable Protected Health Information for research purposes**) |
|  |  | HIPAA Authorization Form (**if accessing individually identifiable Protected Health Information for research purposes**) |
|  |  | Permissions, support letters, and approval documentation as identified in Part IV of this application |
|  |  | Clearance or approval documentation from applicable UO Environmental Health and Safety oversight/inspection |
| **Optional for submission, but strongly encouraged:** | | |
|  |  | A Research Plan and applicable appendices (grant applications or excerpts from a grant will NOT be accepted as a Research Plan) |
|  |  | Data Collection Materials (questionnaires, surveys, data collection forms, focus group/interview scripts, etc.) |
| **The following are items that the investigator should develop as part of conducting ethical research. These items *do not* need to be submitted to RCS with the application but should be maintained as part of the research records and study administration materials.** | | |
|  |  | Recruitment Materials: Emails, letters, scripts, flyers, posters, brochures, etc. |
|  |  | Debriefing Materials |
|  |  | Release Form for Translators and Transcribers |
|  |  | Data Safety Monitoring Plan |
|  |  | Data Use Agreement(s) |

**Suggestions and Tips:**

* **Research Plan:** It is expected that a researcher will have developed and will follow a detailed [Research Plan](http://rcs.uoregon.edu/content/research-plan). It is recommended that researchers use RCS’ [Research Plan Guidance](http://rcs.uoregon.edu/sites/default/files/Guidance%20-%20Research%20Plan.pdf) document to assist with developing a plan. While not required, researchers are strongly encouraged to submit a Research Plan with this application to assist with the review of the proposed study activities. Having a well-developed Research Plan will assist the investigator when working through this form and answering the targeted questions and will assist RCS’ verification of the exempt determination. Additionally, if the proposed research does not qualify for exemption, IRB review is necessary and a Research Plan will be required for submission.
* **Data/Information Collection Materials:** It is strongly encouraged that a researcher has developed data/information collection materials and assessments (if possible) when developing a research plan and when working through this form. Researchers are strongly encouraged to submit data/information collection materials and assessments (questionnaires, surveys, data collection forms, interview guides/scripts, etc.) to assist RCS’ verification of the exempt determination. Additionally, if the proposed research does not qualify for exemption, IRB review is necessary and all data/information collection materials will be required for submission.