**RAP Application  
Exempt Determination Application**

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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 an **Exempt Determination.**  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.  **No human subject research activities may occur until an Exempt Determination is issued.** |

**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://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-09/Application%20-%20Initial%20Review_RAP.docx)

Complete the form below and upload to the Basic Study Info page of the submission activity in the IRB Module of the RAP. Upload all applicable research materials as prompted throughout this application and within the electronic application pages in the RAP.

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.

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

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

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| 1. Research Request | | |
| * 1. Exemption Verification Request (select one of the following): | | |
| **INITIAL REVIEW REQUEST** | | |
| **AMENDMENT REVIEW REQUEST** | | |
| * **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. | | |

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| 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) | |

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| 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](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_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.](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_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](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_worksheet_-_exempt_category_3.docx). | |
|  |  | Secondary research using identifiable private information or identifiable biospecimens, collected for another purpose. Complete [Exempt Category 4 Worksheet](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_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](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_worksheet_-_exempt_category_5.docx). | |
|  |  | Taste and food quality evaluation and consumer acceptance studies. Complete [Exempt Category 6 Worksheet](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_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)**.** | | | |

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| 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. **Provide an overview of your research design and methods.** | |
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|  | | 1. **Describe your study population including estimated number and age range of participants.** | |
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| 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://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-01/template_guidance_-_informed_consent.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: |
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| * 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 | |

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| 1. Developing Materials for Submission | | | | |
| * 1. Identify additional application forms to include with your submission. | | | | |
| * Check all that apply, and upload completed forms in the **IRB Module of the RAP** system as noted in the “Where to Upload” column. | | | | |
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| **Check all that apply to your protocol** | | **Topical Guidance** | **Applicable Forms** | **Where to Upload in the RAP** |
|  | Funded or Sponsored | * [Funded and Sponsored Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/funded-and-sponsored-research) | * Funding and Sponsorship Form | Study Funding Sources, Question 1 |
|  | Collaborative research with organizations external to the UO | * [Collaboration in Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/collaboration-research) | * Reliance Request Form UO as Reviewing IRB * Relying Site Point of Contact Survey | Basic Study  Information Question 8 |
|  | Collaborative research with individuals external to the UO with no other affiliation | * [Collaboration in Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/collaboration-research) | * Individual Investigator Agreement | Local Study Team Information  Question 3 |
| * 1. Develop a Research Plan and Identify Protocol Materials for Submission | | | | |
| * The list below to identify key considerations for your protocol. Use this list to (1) develop your **Research Plan** document and (2) identify other materials to upload into the RAP to complete your submission. The list below are key considerations for which the IRB will need specific information to evaluate your proposed research.   1. Develop your 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 mandatory, and a Research Plan will be required for submission.   + Identify any **supplemental content** to include within your **Research Plan** document by reviewing the **topical guidance** noted for any Key Considerations on the list below that apply to your research.   1. Develop any **supplemental forms and/or materials noted for submission** as noted for any applicable Key Considerations (e.g., appendices to the Research Plan, consent forms, etc.).   + 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 mandatory, and all data/information collection materials will be required for submission.   1. Upload all protocol materials through the **IRB Module of the RAP.** * *Other tips.*   + See the [RCS website](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-research-guidance-library) for other topical guidance that may be relevant to your research design.   + NOTE: Grant, thesis, dissertation, or course work proposals may NOT be submitted in lieu of the Research Plan. | | | | |
| **Key Considerations**  **(Check all that apply to your protocol)** | | **Topical Guidance**  **for Research Plan Content**  **& Other Resources** | **Supporting Materials to Develop & Submit** | **Where to Upload**  **in the RAP** |
|  | HIPAA (Protected Health Information) | * [HIPAA and Human Subjects Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/hipaa-and-human-subjects-research) * [HIPAA Authorization Template](https://research.uoregon.edu/sites/research2-stage.uoregon.edu/files/2020-01/template_-_hipaa_authorization.docx) | * [HIPAA](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_appendix_d-hipaa.docx) (fka, Appendix D) * HIPAA Authorization Form | Local Site Documents Question 3 |
|  | Genetic Information/Tests | * [Research Involving DNA](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/oregon-genetic-privacy-law) | * [Genetic Information/Tests](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_appendix_e-genetic_information_and_tests.docx) (fka, Appendix E) | Local Site Documents Question 3 |
|  | Clinical Trials | * [Clinical Trials](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/clinical-trials) | n/a | n/a |
|  | Consenting Participants | * [Guidance on Informed Consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/informed-consent) * [Informed Consent Template Guidance](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-01/template_guidance_-_informed_consent.pdf) | * Informed consent forms, assent forms, scripts, etc. | Local Site  Documents  Question 1 |
|  | Recruiting Participants | * [Recruitment](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/recruiting-research-participants) Guidance | * Emails, letters, scripts, flyers, posters, brochures, etc. used to recruit participants. | Local Site Documents  Question 2 |
|  | Research with Minors | * [Minors in Research](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/minors-in-research) * [Passive Parental Consent](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/passive-parental-consent-opt-out-consent) | * Parent/Guardian Permission, if applicable * Child Assent Forms/ Scripts, if applicable | Local Site Documents Question 2 |
|  | Research with Prisoners | * [Prisoners as Research Subjects](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/prisoners-research-subjects) | n/a | n/a |
|  | Compensating Participants | * [Compensation for Participation in Research Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/compensation-participation-research) | n/a | n/a |
|  | Using Translations/Translated Materials | * [Guidance on Translations and Translated Materials](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/translations-and-translated-materials) | * Translated materials that are ready at the time of submission | Local Site Documents Questions 1-3 |
|  | Audio Recording, Video Recording, and/or Photography | * [Audio Recording, Video Recording, and/or Photography](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/audio-recording-video-recording-andor-photography) Guidance | n/a | n/a |
|  | Permission/approval required beyond UO IRB (e.g., school districts, owner of a bulletin board, listservs, etc.). | * [Permissions and Approvals Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/permissions-and-approvals) | * Documentation of approval or permission when required (see guidance). | Local Site Documents Question 3 |
|  | Data Monitoring Plan/Board/Committee | * [Data Safety](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/data-safety) Guidance | * Data Safety Monitoring Plan (DSMP) and/or * Data Safety Monitoring Board/Committee (DSMB/C) information | Local Site Documents Question 3 |
|  | Research requires approval from UO Environmental Health & Safety (EHS) | * [UO Environmental Health and Safety (EHS)](http://ehs.uoregon.edu/) | * Any clearance or approval documentation (e.g., biosafety committee approval, radiation safety committee approval, etc.) | Local Site Documents Question 3 |
|  | Recruiting from Participant Pools (e.g., Marketing, SOJC, Psychology/Linguistics) | * [Participant Pools](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/participant-pools) Guidance | * Any debriefing or other pool coordinator approvals | Local Site Documents Question 3 |

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| 1. Data Sources | | |
| * 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 VIII. | |
| 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. |

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| 1. Human Subjects Conflict of Interest | | | |
| * It is the responsibility of the PI to ensure that any research personnel, including the PI and non-UO researchers, complete the [Human Subjects Conflict of Interest (COI) form](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-09/form_-_coi_RAP.docx). * 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 answer “yes” to any question on their form. | | | |
|  |  | | No conflicts are identified. |
|  |  | | Yes, conflicts are identified and Human Subject COI form(s) are included in the RAP submission for the following individuals. NOTE: Update applicable COI forms in the RAP (see [attachment guidance](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2021-01/RAP%20Guidance%20-%20Attachments.pdf)). |
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| 1. Other Institutions, Performance Sites, and Non-UO Research Personnel | | | | | | | |
| For collaborative research, additional requirements for oversight of activities conducted by collaborating researchers or at other research sites may apply. See our website for additional guidance on [Collaborative Research](http://rcs.uoregon.edu/content/Collaboration-Research).   * Review the questions below to identify specific agreement requests and/or supplemental information to include with your submission through the RAP as indicated in the prompts. | | | | | | | |
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| * 1. Will researchers at another institution be [engaged](http://www.hhs.gov/ohrp/policy/engage08.html)  in this research? | | | | | | | |
| Yes  No | |  | | | | | |
|  | * + 1. If yes, are you requesting that the IRB serve as the single IRB of record for some or all institutions/organizations? | | | | | | |
| Yes  No | | | | If “yes,” complete a **Reliance Request Form – UO Reviewing IRB** and upload to the **Basic Information Page, Question 8 of the RAP.** | | | |
|  | * + 1. Are there any institutions/organizations that will not rely on the UO for oversight? | | | | | | |
| Yes  No | | | | If “yes," review the guidance on [Collaborative Research](http://rcs.uoregon.edu/content/Collaboration-Research) then list below each institution/organization and provide an explanation for their intended human subject research oversight. | | | |
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| * 1. Will researchers who are unaffiliated with an institution be [engaged](http://www.hhs.gov/ohrp/policy/engage08.html)  in this research? | | | | | | | |
| Yes  No | | If “yes,” upload the following to **Local Study Team Members, Question 2 of the RAP.**   * [**External Research Personnel List**](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2020-12/rap_form_-_external_research_personnel.xlsx) with all independent investigators listed with their training dates. * Have each individual complete and sign an **Individual Investigator Agreement.** | | | | | |
| * 1. Does this research involve activities with other governing entities (e.g., tribes, foreign countries, etc.)? | | | | | | | |
| Yes  No | | If “yes," list the governing entities below. | | | | | |
| Name of governing entity/ies: | |  | | | | | |
| **Note**: See our website for additional guidance on documentation requirements for [permissions and approvals](http://rcs.uoregon.edu/guidance/permissions-approvals). | | | | | | | |
| Explain below whether permission or approval is required to conduct research activities from this entity or these entities. Upload any documentation of permission/approval under **Local Site Documents, Question 3 in the RAP**: | | | | | | | |
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| * 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 upload any documentation of permission/approval under **Local Site Documents, Question 3 in the RAP** | | | | | |
| Name of department(s)/ service(s): | | |  | | Permission Status (Select One): |  | Approval Attached |
|  | Approval Pending |
|  | No Approval Required |
| If no permission required, explain in text box below: | | | | | | | |
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