**Instructions:**

* This is a tool for reference only. Use this checklist to identify all items necessary to compile a complete an Exempt Determination submission. If your study does not qualify for exemption, use the Non-Exempt Initial Submission Checklist instead. If you are unsure which type of application to submit, review our Guidance page: [Getting Started](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/application-research-human-subjects).
* Submit all materials identified below through the [Research Administration Portal (RAP).](https://irb.rap.uoregon.edu/)

|  |  |  |
| --- | --- | --- |
| **Incl.** | **n/a** | **Items** |
|  | — | Exempt Determination Application, |
|  | — | Exempt Category Worksheet(s) (if unsure which category applies, use the [Exempt Self-Assessment Tool](https://rcs.uoregon.edu/exempt-self-assessment-tool) to help you identify the categories of exemption under which your study may qualify. |
|  |  | Human Subject Conflict of Interest (COI) Form (only submit for those individuals with a potential conflict identified on the form) |
|  |  | For funded or sponsored research:   * Funding and Sponsorship Form * A copy of the grant proposal that describes the human subjects activities (you may need to get this from the EPCS record). |
|  |  | Informed Consent/Assent Materials (only when interacting or intervening with participants) |
|  |  | Appendix D - HIPAA (if accessing individually identifiable Protected Health Information for research purposes) |
|  |  | Appendix E - Research Involving Genetic Information / Tests (See our guidance page: [Research Involving DNA](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/oregon-genetic-privacy-law) (genetics) for more information). |
|  |  | HIPAA Authorization (if HIPAA applies and a HIPAA waiver has not been requested) |
|  |  | Permissions, support letters, and other approval documentation as applicable. Visit the [Permissions and Approvals](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/permissions-approvals) guidance page for more information. |
|  |  | Clearance or approval documentation from applicable UO Environmental Health and Safety oversight/inspection |
|  |  | Debriefing Materials / Script (required if the study involves deception) |
|  |  | Debriefing Approval from Participant Pool HS Coordinator (required if recruiting subjects from one of the UO [Participant Pools](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/participant-pools)) |
| **Collaboration Materials** (if working with collaborators who are external to the UO; for more information see the [Collaborations Flowchart](https://research.uoregon.edu/sites/default/files/2023-06/hrp-987_-_investigator_-_collaborations_flowchart.pdf)): | | |
| If the external researcher is not affiliated with an institution with a Federal-Wide Assurance (FWA): | | |
|  |  | External Research Personnel Spreadsheet  Documentation of CITI or alternative ethics training |
| If the external researcher is affiliated with an institution with a Federal-Wide Assurance (FWA), please contact RCS for guidance. | | |
| **Optional for submission, but strongly encouraged** (may also be requested if needed for the determination): | | |
|  |  | A Research Plan (Note: 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 generally *do not* need to be submitted to RCS with the application but should be maintained by the research team as part of the research records.** | | |
|  |  | Recruitment Materials: Emails, letters, scripts, flyers, posters, brochures, etc. |
|  |  | Release Form for Translators and Transcribers |
|  |  | Data Safety Monitoring Plan |
|  |  | Data Use Agreement(s) |
|  |  | Permissions, support letters, and other approval documentation as applicable. Visit the [Permissions and Approvals](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/permissions-approvals) guidance page for more information. |

**Suggestions and Tips:**

* Contact Research Compliance Services (RCS) at [ResearchCompliance@uoregon.edu](mailto:ResearchCompliance@uoregon.edu) or 541-346-2510 with questions.
* Additional information and resources are available on the RCS website: [Human Subjects Applications, Forms and Guidance](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-applications-forms-guidance).
* RAP specific guidance can also be found in our [RAP Guidance Library](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/human-subjects-research-guidance-library#RAP), including [Attachments - Instructions on where to attach study materials](https://research.uoregon.edu/sites/research2.uoregon.edu/files/2021-01/RAP%20Guidance%20-%20Attachments.pdf).
* **Research Plan:** It is expected that a researcher will have developed and will follow a detailed [Research Plan](https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/research-plan). It is recommended that researchers use RCS’ [Research Plan Guidance](https://research.uoregon.edu/sites/default/files/2020-03/Guidance%20-%20Research%20Plan%20V03022020-%20Open%20Sans.pdf) document to assist with developing a plan. While not required, researchers are strongly encouraged to submit a Research Plan. Having a well-developed Research Plan will assist the investigator when 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. 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.