**Instructions:**

* This is a tool for reference only. The purpose of this checklist is to assist the investigator in identifying all items necessary to compile a complete protocol submission for expedited and full board research. If you are submitting an Exempt Determination Application, use the Exempt 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 protocol materials through the [Research Administration Portal (RAP).](file:///\\files.uoregon.edu\rsch\home\tsheehan\Tanya's%20Resources\Fixes%20group\irb.rap.uoregon.edu)
* Contact Research Compliance Services (RCS) at [ResearchCompliance@uoregon.edu](mailto:ResearchCompliance@uoregon.edu) or (541-346-2510) with any 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 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).

| **Incl.** | **n/a** | **Items** | |
| --- | --- | --- | --- |
|  | — | Initial Review Application | |
|  |  | Human Subject Conflict of Interest (COI) Form(s); 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 EPCS). | |
|  | — | Research Plan (note: grant applications or excerpts from a grant will NOT be accepted as a Research Plan). | |
| **Appendices:** | | | |
|  |  | Appendix A – Drugs & Other Substances (Required if the study specifies the use of an approved drug or biologic, uses an unapproved drug or biologic, or uses a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition) | |
|  |  | Appendix B - Investigational Device (Required if the study evaluates the safety or effectiveness of a device or uses a humanitarian use device (HUD)) | |
|  |  | Appendix C - Ionizing Radiation (Required if the research involves ionizing radiation that is solely for the purpose of the research or affects the implementation of standard of care ionizing radiation that participant is receiving) | |
|  |  | Appendix D – HIPAA / Use of Protected Health Information (PHI) – (Required if study involves HIPAA protected health information obtained from or used by a HIPAA covered entity) | |
|  |  | 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). | |
| **Supplemental Materials:** | | | |
|  |  | Recruitment Materials: Emails, letters, scripts, flyers, posters, brochures, etc. | |
|  |  | Screening materials or scripts | |
|  |  | Informed Consent/Assent Materials | |
|  |  | Debriefing Materials / Script (required if the study involves deception) | |
|  |  | HIPAA Authorization (if HIPAA applies and a HIPAA waiver has not been requested) | |
|  |  | 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)) | |
|  |  | Data Collection Materials (questionnaires, surveys, data collection forms, focus group/interview scripts, etc.) | |
|  |  | Data Safety Monitoring Plan (only needed for greater than minimal risk studies if the details are not in the Research Plan or when funder requires one) | |
|  |  | Data Safety Monitoring Board/Committee information | |
|  |  | 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 | |
| **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): | | |
|  | **Incl.** | **n/a** | **Items** |
|  |  |  | External Research Personnel Spreadsheet  Individual Investigator Agreements (IIAs)  Documentation of CITI or alternative ethics training |
|  | If the external researcher is affiliated with an institution with a Federal-Wide Assurance (FWA), and UO will be the single IRB of record (sIRB): | | |
|  | **Incl.** | **n/a** | **Items** |
|  |  |  | Reliance Request Form – UO Reviewing  Relying Site Survey (required for each participating site) |
|  | If the external researcher is affiliated with an institution with a Federal-Wide Assurance (FWA), and the other institution will be the single IRB of record (sIRB): | | |
|  | **Incl.** | **n/a** | **Items** |
|  |  |  | Reliance Request Form – UO Relying |
|  | If external researcher is affiliated with an institution with a Federal-Wide Assurance (FWA), and each institution will do their own review: | | |
|  | **Incl.** | **n/a** | **Items** |
|  |  |  | Approval letter from other institution(s) |
| **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.** | | | |
|  |  | 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. | |
|  |  | Release Form for Translators and Transcribers | |