**Not for submission. This list is imbedded in the exempt determination application and is shown here for informational purposes only.**

**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.

* **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.**

|  |  |  |
| --- | --- | --- |
| **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.