UNIVERSITY OF OREGON | Research Compliance Services

RAP IRB MODULE - ATTACHMENT GUIDANCE

Note: This guidance includes details about where to upload materials in the Research Administration Portal (RAP). Different types of submissions require different documents. For more information about which documents to submit and when, see our initial review, modification review, and continuing review webpages as well as our other RAP specific guidance.

Items	Submission Type	Where to upload in the RAP
RAP Applications (initial and modification review) ○ Exempt Application ○ Exempt Category Worksheet(s) as applicable ○ Initial Review Application ○ Modification Review Application ○ Approval in Principle Application (AIP)	Initial Review Modification*	Basic Study Information, Last Question
Continuing Review Materials (if human subjects research activities are ongoing) ○ Continuing Review Application ○ Supplemental materials (e.g., DSMB/C reports, FDA reports, sponsor progress reports, monitoring reports, new information relevant to continuing review)	Continuing Review (continuing HSR)	Continuing Review/Study Closure Information, Q7
Closure Materials (note: closures are submitted via a continuing review submission) ○ Closure Application ○ Supplemental materials (e.g., DSMB/C reports, FDA final reports, sponsor reports, monitoring reports, new information relevant to continuing review)	Continuing Review (Study Closure)	Continuing Review/Study Closure Information, Q8
Continuing Review Materials (AIP only continuation) ○ Memo with a brief explanation of why you need more time than previously expected, information about your new anticipated start date for human subjects research (HSR) and confirmation that you are still *only* doing preparatory work that does not involve any HSR	Continuing Review (for an AIP only)	Continuing Review/Study Closure Information, Q7
Research Plan and the following **appendices if applicable** (note: grant applications or excerpts from a grant will NOT be accepted as a Research Plan): ○ Ionizing Radiation Form (Appendix C) ○ HIPAA (use of PHI) Form (Appendix D) ○ Genetic Materials Form (Appendix E)	Initial Review Modification*	Basic Study Information, Last Question

* Modifications include modifications to make migrated studies complete/whole.
** The Study-Related Documents smart form page will only appear for some collaborative research.

Collaboration Forms and Information ○ UO is the IRB of Record ▪ Reliance Request Form – UO the reviewing IRB ○ UO is relying on the IRB approval of another institution. ▪ Reliance Request Form – UO the relying IRB ▪ Collaboration Agreement(s)/IRB Authorization Agreement(s) (IAA) ○ Multiple IRB review ▪ *External* IRB approval documentation for collaborative studies an external IRB completed their own review.	Initial Review Modification*	Basic Study Information, Last Question
Collaboration Forms and Information (specific to Participating Site when UO is the reviewing IRB) ▪ Relying Site Survey ▪ Collaboration Agreement(s)/IRB Authorization Agreement(s) (IAA) ▪ Site Specific Documents (e.g., recruitment, consent, or data collection materials used at the site that differ from the UO versions approved on the parent study)	Participating Site (pSite)	Local Site Documents, Q1, Q2, or Q3
Funding and Sponsorship Form (if funded) ○ Including the human subjects portion of the grant proposal.	Initial Review Modification*	Study Funding Sources, Q4
PRINCIPAL INVESTIGATOR - Human Subject Conflict of Interest (COI) Form (*required for individuals who have determined a conflict of interest exists*)	Initial Review Modification*	Basic Study Information, Last Question
OTHER STUDY TEAM MEMBERS - Human Subject Conflict of Interest (COI) Form (*required for individuals who have determined a conflict of interest exists*)	Initial Review Modification*	Local Study Team Members, Q1,Q2
External Team Member Information (*team members with no institutional affiliation and who are working under the direct direction and supervision of UO investigators(s) through an Individual Investigator Agreement (IIA)*) ○ External Personnel Form ○ Individual Investigator Agreement (IIA) ○ Relevant training certificates ○ Human Subjects Conflict of Interest Form (if any personnel have a conflict)	Initial Review Modification*	Local Study Team Members, Q2
Drugs and Other Substances Form (Appendix A)	Initial Review Modification*	Drugs, Q4
Drug package insert, investigator's brochure, verification of IND		
Medical Devices Form (Appendix B)	Initial Review	Devices, Q3

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Device product labeling/instructions, investigator's brochure, verification of IDE/HDE	Modification*	(if studying device) Or Local Site Documents, Q3 (if <u>not</u> studying the device but risk/safety details are needed)
Informed Consent/Assent Materials	Initial Review Modification*	Local Site Documents, Q1 and/or Study-Related Documents**, Q1
Recruitment Materials: Emails, letters, scripts, flyers, posters, brochures, etc.	Initial Review Modification*	Local Site Documents, Q2 and/or Study-Related Documents**, Q2
Data Collection Materials (questionnaires, surveys, data collection forms, focus group/interview scripts, etc.)	Initial Review Modification*	Local Site Documents, Q3 and/or Study-Related Documents** Q3
Debriefing Materials (including debrief approval by pool coordinator)		
Release Form for Translators and Transcribers		
Data Safety Monitoring Plan or Data Safety Board/Committee Information (e.g., charter)		
Data Use Agreement(s)		
Permissions and support letters		
Clearance or approval documentation from applicable UO Environmental Health and Safety oversight/inspection		
Reportable New Information Form	Reportable New Information	Reportable New Information, Q7 or Q9

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