UNIVERSITY OF OREGON | Research Compliance Services

RAP IRB MODULE - ATTACHMENT GUIDANCE

Items	Submission Type	Where to upload in the RAP
RAP Applications (initial and modification review) ○ Exempt Determination applicable worksheets ○ Initial Review ○ Modification Review ○ Approval in Principle	Initial Review Modification*	Basic Study Information, Last Question
Continuing Review/Study Closure ○ Continuing Review Application ○ Closure Review Form ○ Supplemental materials	Continuing Review (Study Closure)	Continuing Review/Study Closure Information, Q7
Collaboration Forms and Information ○ UO is the IRB of Record (*once a participating site (pSite) is established in the RAP, the* following *may be relocated by RCS staff)* ▪ Reliance Request Form – UO the reviewing IRB ▪ Relying Site Survey ▪ Collaboration Agreement(s)/IRB Authorization Agreement(s) (IAA) ○ 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
Research Plan and the following applicable appendices (grant applications or excerpts from a grant will NOT be accepted as a Research Plan): ○ Ionizing Radiation Form (fka, Appendix C) ○ HIPAA (use of PHI) Form (fka Appendix D) ○ Genetic Materials Form (fka Appendix E)	Initial Review Modification*	Basic Study Information, Last Question
Funding and Sponsorship Form ○ 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 MEMEBERS - 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

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

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	Initial Review Modification*	Local Study Team Members, Q2
Drugs and Other Substances Form (fka, Appendix A)	Initial Review Modification*	Drugs, Q4
Drug package insert, investigator's brochure, verification of IND		
Medical Devices Form (fka, Appendix B)	Initial Review Modification*	Devices, Q3
Device product labeling/instructions, investigator's brochure, verification of IDE/HDE		
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, incl. debrief approval by pool coordinator.		
Release Form for Translators and Transcribers		
Data Safety Monitoring Plan or Board Committee Information		
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

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