**Note:** The chart below is intended to be used as a reference tool for researchers so they can keep track of which permissions need to be submitted to the RCS/IRB within the Research Administration Portal (RAP) submission and which materials need to be maintained for their records but do not need to be formally submitted via the RAP. Some situational circumstances may impact what is noted below and the RCS/IRB can request materials if needed for the review. The information below applies to projects for which the University of Oregon IRB is the IRB of record and is not deferring oversight to an external IRB. If in doubt, researchers should contact RCS

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| Certificates of Confidentiality (CoC) | Yes | It depends – see notes | *Applies to all review types (exempt, expedited, full board).*<br><br>Some studies automatically receive a certificate of confidentiality (CoC) while other CoCs must be applied for and obtained only after review by the National Institutes of Health (NIH) or another federal agency. For example, NIH funded studies involving identifiable sensitive information that are initiated or ongoing on December 13, 2016, are automatically granted a CoC. Several non-NIH HHS agencies, including CDC, FDA, HRSA, SAMHSA, and IHS, issue COCs also. For more information about CoCs, see the NIH CoC FAQs.<br><br>For studies undergoing expedited or full board review and studies undergoing limited IRB review (e.g., exempt categories 2iii and 3iii), the RCS/IRB needs to ensure there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (§46.111(a)(7)). When release of information could result in physical risks of harm or could result in criminal or civil liability, a CoC may be a key factor in minimizing risk and maximizing participant confidentiality. If researchers are applying for a CoC (i.e., the CoC is not automatically granted) and the IRB deems the CoC a necessary requirement, a CoC contingency will be added to the approval letter. Contingent IRB approval can be given with the requirement that researchers submit documentation in a future modification from the NIH or other federal agency granting the CoC. When a contingency applies, researchers must obtain IRB approval for the modification containing the CoC confirmation before obtaining the identifiable sensitive data or enrolling participants for that aspect of the study. Researchers should consult any contingency language on their approval letters and contact RCS with any questions. |
| Data Use Agreements (DUAs) | Yes | No | *Applies to all review types (exempt, expedited, full board).*<br><br>Researchers should maintain records of Data Use Agreements (DUAs) and ensure RCS/IRB is aware of any requirements that impact the research plan, consent form, or other research materials. A copy of the DUA is generally not required to be included in the RAP. The Industry, Innovation and Translation (IIT) office at the UO and/or Purchasing and/or Contracting Services (PCS) may reach out to RCS to ensure agreements are consistent with IRB approved materials. |
| Department of Defense (DoD) | Yes | Yes | *Applies to all review types (exempt, expedited, full board).*<br><br>If DoD funded/supported: Review by the Office of Human Research Oversight (OHRO) of the DoD will be required. UO IRB approval is required before researchers submit to the DoD. |

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| | | | Contingent IRB approval can be given with the requirement that researchers submit documentation of that DoD/OHRO approval to the UO IRB via a future modification and obtain IRB approval for that modification before using DoD funds or working with DoD affiliated personnel.<br><br>If targeting DoD personnel as participants, permission may be required from local command before enrolling DoD personnel. UO IRB approval is generally required before researchers submit to local command. The researcher should contact the corresponding office to determine whether their review is required. Researchers should provide approval from each applicable command or confirmation from them that no local command review/approval is needed.<br>• If enrolling Army personnel: Army Human Research Protections Office (AHRPO); usarmy.ncr.hqda-otsg.mbx.otsg-ahrpo@health.mil; 703-681-6565<br>• If enrolling Air Force personnel: Air Force Research Laboratory; 711HPW.IR.dl.all@wpafb.af.mil; 937-904-8100<br>• If enrolling Navy or Marines personnel: Office of Naval Research; sevgi.bullock@navy.mil; 703-696-2864<br>• **Current Contact Information:**<br>  • Naval Sea Systems Command (NAVSEA) – harriss.ganey@navy.mil<br>  • ARI - nicole.j.thompson14.civ@mail.mil or robert.o.simmons2.civ@mail.mil<br>  • AHRPO - usarmy.ncr.hqda-otsg.mbx.otsg-ahrpo@health.mil<br>Contingent IRB approval can be given with the requirement that researchers submit documentation of local command approval or confirmation from local command that no formal review is required. If such a contingency applies, the communication from local command will need to be submitted through the RAP via a future modification and that modification will require IRB approval before researchers conduct research with DoD affiliated personnel.<br><br>If some research activities do not involve use of DoD funds, do not involve DoD affiliated personnel and do not otherwise engage the DoD, those activities may begin once IRB approval is obtained. Researchers should consult any contingency language on their approval letters and contact RCS with any questions. |

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| Environmental Health and Safety (EHS) and/or Institutional Biosafety Committee (IBC) Approval | Yes | Yes | *Applies to all review types (exempt, expedited, full board).*<br><br>EHS/IBC review is required when the study involves one or more of the following:<br>• Obtaining/handling biospecimens (e.g., blood, tissue, cells, saliva, saliva, urine, sweat, emesis/vomit, feces/stool)<br>• Infectious pathogens<br>• Biological toxins<br>• Recombinant or synthetic nucleic acids (rsNA) which may also be called "Recombinant DNA"<br><br>If required, EHS/IBC approval is generally required before final IRB approval can be granted. However, in circumstances where there are multiple phases/populations and EHS/IBC approval is not needed for an earlier phase or one of the study populations, IRB approval can be granted with a contingency that does not permit that later phase/population to begin without a mod documenting EHS/IBC approval for those aspects of the study. Researchers with EHS/IBC related questions should reach out to EHS or the IBC directly (see EHS contact information and/or IBC information). |
| Export Control | It depends – see notes | No | *Applies to all review types (exempt, expedited, full board).*<br><br>Export control regulations apply to university research and scholarship when:<br>• International employees, visiting scholars, or students conduct research at the UO<br>• Employees travel abroad with research-related items, software, equipment, and/or information<br>• Employees engage in collaborations with researchers, academics, organizations located outside the U.S.<br>• Items, software, and/or information are shipped outside of the U.S.<br>• Sponsored research contains clauses requiring confidentiality<br>• A non-disclosure agreement is in place for an employee or the employee's unit<br><br>Studies with an international component or international collaborators will be referred to Export Control for review after IRB approval. Export control will reach out to researchers if any additional information or changes are needed. If nothing is needed, Export Control may not communicate with researchers. In the rare event that Export Control requirements impact the IRB approved procedures or materials, researchers will be responsible for submitting a |

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| | | | modification to their IRB projects. Researchers with Export Control related questions should contact exportcontrols@uoregon.edu. |
| FERPA Exception to Informed Consent requiring agreement (for both UO and non-UO records) | Yes | No | *Applies to all review types (exempt, expedited, full board).*<br><br>The Family Educational Rights and Privacy Act (FERPA) applies to the use and disclosure of education records. FERPA includes requirements for signed and dated informed consent (34 CFR 99.30). However, in some cases, FERPA permits exceptions to these consent requirements (34 CFR 99.31). When FERPA applies and a study is approved with a waiver of consent or waiver of documentation of consent, researchers must obtain a FERPA exception from the educational agency or institution that maintains the education records before beginning the research. Researchers are not required to provide documentation of this exception to the IRB unless it is requested. However, they must be able to provide documentation of this exception in the event of audit. If an exception is not granted and signed and dated consent is required due to FERPA, a modification will be required to the IRB submission to address those consent requirements and obtain IRB approval for the updated details and materials before initiating that aspect of the study. |
| FERPA (institutional/ registrar approval) | Yes | It depends -<br><br>Yes, for UO student data<br><br>No for non-UO student data | *Applies to all review types (exempt, expedited, full board).*<br><br>If obtaining non-UO FERPA protected data, researchers need to contact the educational agency or institution that maintains the education records before beginning the research. Researchers are not required to provide documentation of institutional/registrar approval for FERPA to the IRB unless it is requested. However, they must be able to provide documentation of this exception in the event of audit. Also see additional info above for situations specific to consent waivers.<br><br>If obtaining UO student FERPA protected data, registrar approval is needed before IRB approval can be granted for the use of the FERPA protected data. If possible, researchers should obtain registrar approval prior to or during the IRB review process and provide that documentation within the RAP. Researchers should reach out to the UO registrar or assistant registrar directly or can use the registrar's office contact form. In cases where researchers are requesting a waiver of consent or a waiver of documentation of consent, it may not be possible to obtain IRB approval without prior registrar approval. However, if there is no consent waiver and there are other parts of the study that can be done without the FERPA protected data, contingent IRB approval may be able to be provided with the requirement that researchers submit registrar |

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| | | | approval via a future modification and obtain IRB approval for that modification before obtaining any UO student FERPA protected data for their research. |
| IDE Materials (FDA regulated study with a significant risk device and an IDE from the FDA) | Yes | Yes | *All studies with an IDE require full board review*<br><br>Whenever possible, IDEs from the FDA should be obtained before the study even goes to full board for review. The FDA sometimes does not approve a device study immediately and requires changes before they will issue IDE or has requirements associated with the study that the IRB should know about before reviewing. If the IRB requires an FDA IDE, there are some instances when documentation of the FDA IDE approval may be provided after board review but before approval is released. However, if the FDA has requirements or limitations, the IRB will need to re-review.<br><br>Studies under an abbreviated IDE (Non-significant risk devices) and IDE exempt studies do not require authorization from the FDA prior to initiation. |
| IND Materials (FDA regulated study with an IND from the FDA) | Yes | Yes | *All studies with an IND require full board review*<br><br>Whenever possible, INDs from the FDA should be obtained before the study even goes to full board for review. The FDA sometimes does not approve a drug study immediately and requires changes before they will issue IND or has requirements associated with the study that the IRB should know about before reviewing. If the IRB requires an FDA IND, there are some instances when documentation of the FDA IND approval may be provided after board review but before approval is released. However, if the FDA has requirements or limitations, the IRB will need to re-review.<br><br>Studies that are IND exempt will not require authorization from the FDA prior to initiation. |

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| International research (taking place in other countries or with international collaborators) | Yes | Yes, expedited/FB only | *Applies to all review types (exempt, expedited, full board):*<br><br>Each country has their own requirements (see international compilation of HSR standards) and researchers must be familiar with those requirements and communicate them to the RCS/IRB within their IRB submission. Regardless of review type, documentation of country authorization or confirmation that country authorization is not required for this research should be obtained from a relevant ethics/regulatory body or designee in the country prior to beginning the research and should be maintained by researchers so it can be provided in the event of audit.<br><br>*Applies to expedited and full board:*<br>If a study is undergoing non-exempt review (e.g., expedited or full board review), documentation of country authorization/approval or confirmation that no additional country authorization/approval is required should be provided within the initial study documents. In cases where UO IRB approval is required before the other country ethics/regulatory board will consider permitting research, contingent IRB approval may be able to be provided with the requirement that researchers submit documentation of that other country approval to the UO IRB via a future modification and obtain IRB approval for that modification before conducting research in that country. |
| Other organization if engaged in research (e.g., consenting, conducting research interventions or interactions) | Yes | Yes | *Required documentation may vary depending on review type*<br><br>The type of documentation and how it is submitted in the RAP will depend on a number of factors including whether the external organization has a Federal Wide Assurance (FWA) and whether your study is undergoing exempt or non-exempt review. See the Collaborations Flowchart on the Collaborations website for more information. When applicable, reliance agreements such as the IRB Authorization Agreement (IAA), SMART IRB agreement, or Individual Investigator Agreement (IIA), documentation of external IRB approval, and other materials must be included in the IRB submission. |
| Other organization (if only assisting with recruitment) | Depends on organization | No | *Applies to all review types (exempt, expedited, full board).*<br><br>When organizations are only assisting with recruitment, including advertisement of research opportunity, RCS does not generally require documentation of their willingness to do those activities. However, if the other organization will be involved with consenting, doing other activities that would engage the organization in the research (e.g., answering questions about |

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| | | | the research, conducting interventions), or providing funding; additional documentation may be needed. Some organizations may have a formal review process for assisting with recruitment while others will not. Researchers should check with the organization and provide those details within their IRB submissions. |
| Other organization (if only serving as data collection location/providing resources) | Depends on organization | No | *Applies to all review types (exempt, expedited, full board).*<br><br>When organizations are only providing space for conducting the research or researchers are using external resources (e.g., using space/facilities for hosting interviews or focus groups, using resources like listservs or blogs), this should be described in the IRB materials such as the research plan. RCS does not generally require documentation of permission for these limited situations. However, if the other organization will also be involved with consenting, doing other activities that would engage the organization in the research (e.g., answering questions about the research, conducting interventions), or providing funding; additional documentation may be needed. Some organizations may have a formal review process for serving as a data collection location or requesting use of resources. Researchers should check with the organization and provide those details within their IRB submissions. |
| Material Transfer Agreements (MTAs) | Yes | No | *Applies to all review types (exempt, expedited, full board).*<br><br>Researchers should maintain records of Material Transfer Agreements (MTAs) and ensure RCS is aware of any requirements that impact the research plan, consent form, or other research materials. A copy of the MTA is generally not required to be included in the RAP. The Industry, Innovation and Translation (IIT) office at the UO and/or Purchasing and/or Contracting Services (PCS) may reach out to RCS to ensure agreements are consistent with IRB approved materials. |
| Memorandums of Understanding (MOUs) | Yes | No | *Applies to all review types (exempt, expedited, full board).*<br><br>Researchers should maintain records of Memorandums of Understanding (MOUs) and ensure RCS is aware of any requirements that impact the research plan, consent form, or other research materials. A copy of the MOU is generally not required to be included in the RAP. The Industry, Innovation and Translation (IIT) office at the UO and/or Purchasing and/or Contracting Services (PCS) may reach out to RCS to ensure agreements are consistent with IRB approved materials. |
| Radiation Safety Approval | Yes | Yes | *All studies involving research radiation require full board review* |

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| | | | Radiation safety review is required when the research procedures involve any radiation (e.g., CT scans, DEXA/DXA scans, X-rays, administration of radioactive material to participants). When participants are receiving radiation for standard of care and not for research purposes, radiation safety review may not be needed. However, if participants are receiving additional or different radiation for research compared to what they would receive if they did not participate, radiation safety review will be needed. Examples where radiation safety review is needed include:<br>• X-ray generating equipment<br>• Radio-labeled materials<br>• Sealed Sources - Radioisotopes in a sealed solid form (e.g. button sources)<br>• Far ultraviolet generating equipment - wavelengths < 124 nm<br><br>If required, radiation safety approval is generally required before final IRB approval can be granted. However, in circumstances where there are multiple phases/populations and radiation safety approval is not needed for an earlier phase or one of the study populations, IRB approval can be granted with a contingency that does not permit that later phase/population to begin without a mod documenting radiation safety approval for those aspects of the study.<br><br>Researchers with radiation safety related questions should contact the radiation safety contact (see radiation safety website). |
| Schools/School districts | Yes | It depends -<br><br>Only required to be included in the RAP if there is a formal research/ethics review process by the school system | *Applies to all review types (exempt, expedited, full board).*<br><br>Researchers should maintain documentation for their records. Some schools/school districts have their own formal ethics/IRB process. Researchers must check in with the schools/districts to confirm their processes and inform RCS of those processes. If the schools/school districts have a formal research/ethics review requirement, documentation of that approval is required to be submitted via a modification. |
| Tribal approval | It depends – see notes | It depends – see notes | *Applies to all review types (exempt, expedited, full board).* |

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| | | | Documentation of tribal support is required when one of the following occurs:<br>• Researchers are working with tribal populations on tribal land (e.g. reservation, tribal facility),<br>• are using tribe resources,<br>• the study is funded and/or supported by Indian Health Services,<br>• the tribe has a formal process that requires approval prior to initiation of research activities,<br>• or the tribe requires approval to work with the population.<br><br>Documentation of tribal support can include a review letter, letter of support, or documentation that no review is required by the tribe.<br><br>**When targeting tribal populations, researchers must always check with the tribe regarding their requirements.** When a tribe has a formal process and requires an application/approval before working with them, RCS and the IRB will always respect the wishes of the tribe. If a tribe requires tribal approval before study initiation, it is a requirement for IRB approval and tribal approval should be provided in the RAP.<br><br>When required, tribal permissions either need to be provided before initial IRB approval (e.g., if all participants are part of the tribal population) or can be submitted via a modification (e.g., if some populations are not tribal and some research can take place without tribal approval).<br><br>In cases where the tribes will not review or consider any request for research without prior IRB review and approval, please communicate those requirements in your IRB submission. The IRB may be able to provide a contingent IRB approval with the requirement that researchers submit documentation of tribal support to the IRB via a future modification before enrolling tribal participants in the research.<br><br>Each tribe is unique and has their own rules and procedures regarding research within their communities. For example, researchers must be aware of requirements specific to the tribe (e.g., data disposition, use and ownership requirements, requirements for publication review, |

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| | | | access to technology and transportation). Those requirements must also be described within the IRB submission. |