WORKSHEET: Ancillary Review Matrix

Ancillary reviews are reviews by other compliance groups or individuals that inform the IRB’s review of a new study or a modification to an existing study.

* Ancillary reviews may be assigned by either the researcher or the IRB.
* The IRB typically assigns ancillary reviews during the pre-review of a submission.
* Once an ancillary review is triggered, researchers should work directly with those entities to ensure compliance.
* The ancillary review in Huron IRB is intended to support compliance across multiple oversight groups and not replace review processes by other compliance groups.
* Ancillary reviews are not assigned by the IRB if a project does not meet the federal definition of Human Subject Research.

The impact of an ancillary review group’s approval on the IRB’s review process varies.

* Typically, final IRB approval is held until the ancillary group concludes their review.
* In some instances, the IRB will not initiate its review without documentation of approval by critical review entities.
* The IRB will not hold for the completion of ancillary reviews for studies that meet exempt criteria.
* Documentation of approval by an ancillary review group is provided to the researcher. The researcher is responsible for uploading that documentation in the “Supporting Documents” section of the Huron IRB application to which it relates.
* In rare instances, either the ancillary review group or an IRB member may request deviations from the typical review path. An IRB member may recommend holding a submission until an ancillary approval is granted from a key committee **OR** an ancillary review group may recommend IRB review move forward while a required approval is still pending.
* Ancillary reviews that are required for IRB review/approval are not the same requirements for study activation. Study activation requirements are different and managed by Clinical Research Administration.

The table below highlights the ancillary review groups available and illustrates the typical impact an ancillary review has on IRB review. Please contact the IRB or relevant ancillary review contacts (listed below) with any questions about the ancillary review process or specific requirements.

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| **Organization** | **Review Type** | **Ancillary Review Triggered by** | **Affected IRB Submission Types** | **Contact Info** | **How to Obtain Review** | **Impact on IRB Review**  (prior to, after, or parallel with) |
| Cannabis Research Review Committee **(**[**CRRC**](https://research.uci.edu/ref/cannabis-research/index.html)**)** | Feasibility and compliance | Research involving cannabis | Initial review and amendment | Ms. Grace Park  parkgj@uci.edu | Ms. Grace Park: parkgj@uci.edu | CRRC review may occur in parallel with the IRB |
| Center for Clinical Research **(CCR)** | Feasibility and compliance | Clinical trials using UCI Health items and services, for the purpose of Qualified Clinical Trial (QCT) determination and subsequent Coverage Analysis (CA). | Initial review | [UCIclinicaltrials@hs.uci.edu](mailto:UCIclinicaltrials@hs.uci.edu) | [UCIclinicaltrials@hs.uci.edu](mailto:UCIclinicaltrials@hs.uci.edu) | CCR review may occur in parallel with the IRB |
| Chao Family Comprehensive Cancer Center **(CFCCC)** Protocol Review and Monitoring Committee **(PRMC)** | Feasibility and compliance | Research that is cancer- related and hypothesis driven. The research involves interaction with participants including obtaining consent. | Initial review; renewal if the IRB determines confirmation of review and/ or review comments may impact the IRB determination. | [CancerCenter\_Committees@hs.uci.edu](mailto:CancerCenter_Committees@hs.uci.edu) | [CancerCenter\_Committees@hs.uci.edu](mailto:CancerCenter_Committees@hs.uci.edu) | Investigator-initiated studies that are greater than minimal risk require Cancer Center approval prior to IRB submission |

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| Clinical Engineering **(CE)** | Safety | When research is in an area that operatives under the medical center license and/ or equipment used for hospital patients and research subjects | Initial review and amendment | 714-456-5366 | 714-456-5366 | CE review may occur in parallel with the IRB |
| Conflict of Interest Oversight Committee **(**[**COIOC**](https://research.uci.edu/ref/conflict-of-interest/research-disclosures/irb.html)**)** | Disclosable financial conflict of interest | When researchers report a disclosable financial conflict of interest | Initial review and amendment | Ms. Nadia Wong  [nadiaw@uci.edu](mailto:nadiaw@uci.edu) | Ms. Nadia Wong  [nadiaw@uci.edu](mailto:nadiaw@uci.edu) | COIOC review may occur in parallel with the IRB |
| Dual Use Research Committee **(**[**DURC**](https://research.uci.edu/ref/durc/index.html)**)** | Feasibility and compliance | When research could be misapplied to pose a threat | Initial review and amendment | Ms. Grace Park  parkgj@uci.edu | Ms. Grace Park: parkgj@uci.edu | DURC review may occur in parallel with the IRB |
| Environmental Health and Safety **(**[**EHS**](https://www.ehs.uci.edu/)**)** | Feasibility and compliance | When research involves a controlled substance on campus | Initial review and amendment | [occhlth@uci.edu](mailto:occhlth@uci.edu) | [occhlth@uci.edu](mailto:occhlth@uci.edu) | EHS review may occur in parallel with the IRB |
| Epidemiology and Infection Prevention **(**[**EIP**](https://research.uci.edu/human-research-protections/irb-application-process/other-institutional-requirements/epidemiology-and-infection-prevention/)**)** | Safety | When research involves devices or biologic or infectious agents (e.g. live vaccine, probiotic) | Initial review and amendment | 714-456-5221 | 714-456-5221 | EIP review may occur in parallel with the IRB |
| Export Control Review Process  **(**[**EXP CTRL**](https://research.uci.edu/ref/export-controls/index.html)**)** | Feasibility and compliance | When research involves sanctioned nations | Initial review and amendment | [exportcontrol@uci.edu](mailto:exportcontrol@uci.edu) | [exportcontrol@uci.edu](mailto:exportcontrol@uci.edu) | EXP CTRL review may be in parallel; IRB may grant conditional approval if more than a general license is needed |

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| Human Stem Cell Research Oversight Committee **([hSCRO](https://research.uci.edu/human-stem-cell-research/))** | Feasibility and compliance | When research involves human material (e.g., gametes, embryos, fetal tissue and pluripotent cells, etc.). [See website](https://research.uci.edu/human-stem-cell-research/) for full requirements. | Initial review and amendment | [hSCRO@uci.edu](mailto:hSCRO@uci.edu) | [hSCRO@uci.edu](mailto:hSCRO@uci.edu) | hSCRO review may be in parallel; IRB may grant conditional approval pending hSCRO approval. |
| Institutional Biosafety Committee **(**[**IBC**](https://www.ehs.uci.edu/research-safety/biosafety/ibc/index.php)**)** | Safety | When research involves hazardous biomaterials and recombinant / synthetic nucleic acids, human gene transfer and blood draws that are done for research, on campus. [See website](https://www.ehs.uci.edu/research-safety/biosafety/ibc/index.php) for full requirements | Initial review and amendment | Ms. Alice Lee:  949-824-8024, [ibc@uci.edu](mailto:ibc@uci.edu) | Ms. Alice Lee:  949-824-8024, [ibc@uci.edu](mailto:ibc@uci.edu) | IBC review may be in parallel; IRB may grant conditional approval pending IBC approval. |
| Investigational Drug Service [**(IDS**](https://research.uci.edu/wp-content/uploads/Investigational-Drug-Services-Guideline-for-Consultation-and-Waiver-Process.pdf)**)** | Safety, feasibility and compliance | When research involves an investigational drug. When a study is an Investigator Initiated Trial (IIT), IDS approval is required prior to final IRB approval | Initial review and amendment | Dr. Zahra Azadbadi,  IDS Supervisor  714-456-7833, zazadbad@uci.edu | Dr. Zahra Azadbadi,  IDS Supervisor  714-456-7833, zazadbad@uci.edu | IDS review may be in parallel for IITs; IRB may grant conditional approval pending IDS approval of an IIT. |
| Laser Safety Committee **(**[**LSC**](https://www.ehs.uci.edu/radiation-safety/index.php)**)** | Safety | When research involves a laser on campus | Initial review and amendment | [radsafety@uci.edu](mailto:radsafety@uci.edu) | [radsafety@uci.edu](mailto:radsafety@uci.edu) | LSC review may occur in parallel with the IRB |

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| OR/Procedural Services Committee | Feasibility and compliance | When research involves the surgical units | Initial review and amendment | Ms. Laura Bruzzone: lbruzzon@uci.edu | Ms. Laura Bruzzone: lbruzzon@uci.edu | Review may occur in parallel with the IRB |
| Pathology Clearance **(PATH)** | Feasibility and compliance | When research involves specimens from clinical care | Initial review and amendment | Dr. Robert Edwards: ([redwards@uci.edu](mailto:redwards@uci.edu)) or  Delia Tifrea: ([dtifrea@hs.uci.edu](mailto:dtifrea@hs.uci.edu)). | Dr. Robert Edwards: ([redwards@uci.edu](mailto:redwards@uci.edu)) or  Delia Tifrea: ([dtifrea@hs.uci.edu](mailto:dtifrea@hs.uci.edu)). | PATH review may occur in parallel with the IRB |
| Radiation Safety Committee **(RSC)** | Safety, feasibility and compliance | When research involves radiation in research. [See website](https://ehs.uci.edu/radiation-safety/rua.php) for applications and additional information. | Initial review and amendment | Barbara Hamrick:  714-456-5607, [bhamrick@uci.edu](mailto:bhamrick@uci.edu) | Barbara Hamrick:  714-456-5607, [bhamrick@uci.edu](mailto:bhamrick@uci.edu) | RSC review may be in parallel; IRB may grant conditional approval pending RSC approval |
| Radioactive Drug Research Committee **(RDRC)** | Safety, feasibility and compliance | When research involves the use of radioactive materials in research  **Important Note: RDRC is inactive at UCI** | Initial review and amendment | [Contact HRP Staff](http://www.research.uci.edu/compliance/human-%20%20research-protections/about-the-irb/hrp-contact-%20list.html) | [Contact HRP Staff](http://www.research.uci.edu/compliance/human-%20%20research-protections/about-the-irb/hrp-contact-%20list.html) | RDRC comments and approval (or evidence of an IND) is required prior to IRB review |
| Research Revenue Integrity (**RRI**) | Feasibility and compliance | When researchers use UCI Health services (RRI to ensure services are identified, coded, recharged or billed correctly) | Initial review and amendment | [ResearchRevenueIntegrityCRBCRFA@hs.uci.edu](mailto:ResearchRevenueIntegrityCRBCRFA@hs.uci.edu) | [ResearchRevenueIntegrityCRBCRFA@hs.uci.edu](mailto:ResearchRevenueIntegrityCRBCRFA@hs.uci.edu) | RRI review may be in parallel with the IRB |
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| Restricted Party Screening (**RPS**)  [exportcontrol@uci.edu](mailto:exportcontrol@uci.edu) | Feasibility and compliance | Within the UC System, we use Visual Compliance to perform Restricted Party Screenings (RPS) to ensure we are not interacting with restricted, denied, or debarred parties in violation of U.S. law. Without proper authorization such as an export license, the government prohibits U.S. individuals and organizations from collaborating with or providing materials, services, and financial support to these restricted parties. | Initial review and amendment | Exportcontrol@uci.edu | [Exportcontrol@uci.edu](mailto:Exportcontrol@uci.edu) | RPS review may be in parallel with the IRB |

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| Scientific Review  (Statistical Methods) (**SR**) | Feasibility and compliance | When research has not received prior scientific method / peer review. Typically, the research is greater than minimal risk. The IRB Chair can require SR review for minimal risk research as well. | Initial review | [Contact HRP Staff](http://www.research.uci.edu/compliance/human-%20%20research-protections/about-the-irb/hrp-contact-%20list.html) | [Contact HRP Staff](http://www.research.uci.edu/compliance/human-%20%20research-protections/about-the-irb/hrp-contact-%20list.html) | SR comments and conditional approval is required for IITs prior to IRB review |