HRP-309 | 3/29/2024

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.

**How can I view my study’s assigned ancillary reviews?**

The assigned ancillary reviews and information about their review is available under the “Reviews” tab on a study page.

**Are ancillary reviews required when the IRB review is conducted outside of the University of Minnesota (commercial IRB, external IRB reviews)?**

Yes, all ancillary reviews and institutional requirements continue to apply even if the UMN IRB has ceded its review to external IRB. IMPORTANT NOTE: You may have ongoing obligations to ancillary reviewers that differ from HRPP/ETHOS requirements for studies relying on an external IRB. You are responsible for working with those ancillary review groups for what may be required over the course of the study (e.g., Fairview Research Administration, Radiation Safety, CPRC, etc.).

**What does it mean when “no” is selected to “is a response required?” Why is the group assigned if no response is needed?**

Ancillary reviews groups often have both initial and ongoing oversight responsibilities. If a study is submitted with documentation of an ancillary review group’s approval, the group will still be assigned as an ancillary reviewer. In these cases, the ETHOS Reviews tab for the study will indicate that a response is not required. The group is tagged in ETHOS only for the purpose of allowing ongoing access to the study and all subsequent submissions.

**The tables 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.[[1]](#endnote-2)**

| **Organization** | **Review Type** | **Ancillary Review Triggered by** | **Affected IRB Submission Types** | **Contact Info** | **How to Request Review** | **Impact on IRB Review**(prior to, after, or parallel with)[[2]](#endnote-3) |
| --- | --- | --- | --- | --- | --- | --- |
| Fairview | Fairview Compliance – billing compliance, recruitment, IDS compliance | When Fairview/MHealth staff, locations or resources are indicated in ETHOS or in protocol (see PI affiliation, study staff and sites and resources pages) or when AHC-IE is used | * Initial Review
* Modifications that add Fairview resources, staff or locations or that alter the Fairview recruitment plan
* OnCore Calendars
* RNI’s for studies that include Fairview resources, staff, or locations
 | Fairview Research Administrationancillaryreview@Fairview.org612-672-7690 | Through assignment of ancillary review. May be assigned by either the researcher or IRB analyst. | Must be completed prior to or during IRB Pre-Review. |
| [Cancer Protocol Review Committee (CPRC)](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee) | Any study related to cancer patients, cancer treatments, cancer screening/prevention, or tobacco. | Protocol description CPRC review is not required for Retrospective Chart Review, Retrospective Sample Review, or Prospective Specimen Repository studies | * Initial Review
* Modification that includes a protocol update or change
 | ccprc@umn.eduemail correspondence preferred | Submission of CPRC Application and protocol. Gillette excluded | Must be completed prior to or during IRB Pre-Review.\*Note: If approval documentation is provided in the IRB submission, this ancillary review in ETHOS must be finalized before full IRB approval can be granted. |
| [HRPP Scientific Assessment](https://drive.google.com/open?id=1TR2pVI9vCabCjQVadUfr0WQDnl6jVMxr) | Research Design, Merit | Medical research that does not qualify for expedited review under 45CFR46.110 if the scientific review requirement is not met via other acceptable means. | * Initial Review
* Significant modifications as determined by pre-review or committee review
 | hrpp@umn.edu 612-626-5654 | Through assignment of ancillary review. May be assigned by either the researcher or IRB analyst. | Must be completed prior to or during IRB Pre-Review. |
| Regulatory Review | Drug/Device Guidance | All studies (including reliance submissions) involving evaluation of drugs, devices. Biologics, tobacco or dietary supplements. | * Initial Review
* Modifications  that include significant alterations
* RNIs that trigger FDA correspondence
 | medreg@umn.edu612-626-5654 | Requested via assignment of ancillary review.  May be assigned by either the researcher or IRB analyst | Must be completed prior to or during IRB Pre-Review. |
| Sponsor-Investigator Compliance | Review of projects with an investigational drug or device where the FDA holder is an affiliated PI. Confirming compliance with institutional and FDA requirements. | Projects with an investigational drug or device where the FDA holder is an affiliated PI. | * Initial Review
* Modifications that include an IND or IDE
 | medreg@umn.edu | Assigned based on the protocol submitted in ETHOS | Must be completed prior to final IRB approval. |
| Expert Consults | Consultation Service – assigned to individuals based on documented expertise, including Office of the General Counsel | IRB pre-review indicates additional expertise is needed, study includes a capacity assessment tool other than the UBACC or MacCAT-CR. and/or counsel on applicability of laws affecting human research.  | * Initial Review
* Any submission requiring additional expertise
 | N/A | IRB Analysts request consultation prior to review. | Must be completed prior to or during IRB Pre-Review. |
| Gillette Research Compliance | Gillette HIPAA FCOI Compliance | When Gillette staff, locations or resources are indicated in ETOHS or in protocol (see PI affiliation, study staff and sites and resources pages) | * Initial Review
* Continuing review
* Modifications which add Gillette staff/resources
* RNI’s related to Gillette
 | Elizabeth Nelsonresearch@gillettechildrens.com 651-229-1745 | Through assignment of ancillary review.  | Must be completed prior to or during IRB Pre-Review. |
| Gillette Scientific Review | Research design, scientific merit (Gillette Studies only) | When Gillette staff, locations or resources are indicated in ETHOS or in protocol (see PI affiliation, study staff and sites and resources pages) | * Initial Review

Significant modifications as determined by review | Elizabeth Nelsonresearch@gillettechildrens.com651-229-1745 | Contact Gillette for additional information | Must be completed prior to or during IRB Pre-Review. |
| [CTSI Best Practices Integrated Informatics Core](https://ctsi.umn.edu/services/data-informatics/biomedical-informatics-and-data-access)Formerly Academic Health Center – Information Exchange (AHC-IE) |  Confirmation of IRB Approval to ensure appropriate access | Indicate ‘Yes’ on the Sites and Resources page for AHC-IE | * Initial Review
* Modifications which add or modify data from AHC-SDE
 | Information Exchangebpic@umn.edu | Submission of the [Informatics Consultation Request Form](https://redcap.ahc.umn.edu/redcap/surveys/?s=gmfwoj8yGJ) and protocol outside of ETHOS.Assignment of AHC-IE also requires assignment of Fairview ancillary review.Gillette excluded | Must be completed prior to final IRB approval is granted. Exempt determinations will be held if the abbreviated application process is requested. |
| CTSI Monitoring | Confirmation of appropriate use of CTSI monitoring servicesPlease review eligibility criteria at https://ctsi.umn.edu/services/regulatory/clinical-trial-monitoring. | * Studies that state they will use CTSI monitors

Studies that involve a UMN-investigator held IND, IDE, or designated NSR-IDE by the UMN IRB | * Initial Review
* Modifications that add a drug or device
 | Sydney Vielfencl003@umn.edu612-626-0549 | Requested via assignment of ancillary review. May be assigned by either the researcher or IRB analyst. | Must be completed prior to final IRB approval is granted. |
| [All University Radiation Protection Committee (AURPC)](https://radsafety.umn.edu/) | Radiation Safety | Protocol indicates use of:x-ray imaging, radiopharmaceuticals, external beam or brachytherapy | * Initial Review
* Significant modifications
 | Bryce Armstrongbarmstro@umn.edu612-626-6764 | Through submission of AURPC [Human Use application](https://radsafety.umn.edu/sites/radsafety.umn.edu/files/hus_application_2016.docx) See [Submission Resources](https://radsafety.umn.edu/human-use-application-and-resources) for additional guidance  | Must be completed prior to final IRB approval is granted.  |
| [Biorepository and Laboratory Services (BLS)](https://ctsi.umn.edu/services/biospecimen-support) Formerly BioNET | BLS (BioNET)Oversight | Use of BLS (BioNET) or the need to access/collect tissue or accessing BLS data for research is indicated in the protocol | * Initial Review
* Modifications which add or modify BLS (BioNet) services
 | bionet@umn.edu  | Request through registration via CTSI Portal.Gillette excluded | Must be completed prior to final IRB approval is granted.  |
| [Center for Magnetic Resonance Research (CMRR) Safety Committee](https://www.cmrr.umn.edu/preirb/) | CMRR Safety Approval | CMRR selected on the Sites and Resources page, including the MR scanner at MiDB | * Initial Review
* Modifications which add CMRR
 | Jeramy KulesaAnde2445@umn.edu612-625-8847 | Application available <https://www.cmrr.umn.edu/preirb/> | Must be completed prior to final IRB approval is granted.  |
| Clinicaltrials.gov  | Clinicaltrials.gov compliance | If response to question 4 on study scope page, Does your study need to be registered at ClinicalTrials.gov" is “NO” Data/Specimen only protocols do not require this review. | * Initial Review
 | Sydney Vielfencl003@umn.edu | Through assignment of ancillary review via ETHOS | Must be completed prior to final IRB approval is granted.Note: For initial study submissions, ancillary review is to be completed prior to final IRB approval, not the CT.GOV# registration. |
| [HRPP Education and Training](https://research.umn.edu/units/irb/education-training/required-training) | Other | There are questions regarding training completions or consult request for CAPA education opportunities | * Initial Review
* Modifications
* Continuing Review
 | Courtney Jarboecjarboe@umn.edu612-626-5141 | Contact Courtney Jarboe if there are questions about IRB training requirements. | Must be completed prior to final IRB approval is granted. |
| [Health Information and Privacy Compliance Office (HIPCO)](https://www.healthprivacy.umn.edu/research) | HIPAA complianceHIPAA training compliancePrivacy law applicability (international and domestic) in the collection, transmission, and storage of health data. | Study includes use of Individually Identifiable Health Information (Not just PHI as defined by HIPAA) | * Initial Review
* Modifications when there are changes to data collection, transmission or storage
* Additions of personnel if training completion is not visible in ETHOS (HIPAA applicable studies only)
 | HIPCOPrivacy@umn.edu612-624-7447 | Assigned automatically based on the protocol[Hybrid Entity Guidance](https://healthprivacy.umn.edu/hipaa-compliance/hipaa-compliance-university)Gillette excluded if no UMN personnel or resources involved. | Must be completed prior to final IRB approval is granted.Note: If the IRB does not approve a waiver or alteration of HIPAA Authorization, HIPCO will be tagged again as an ancillary review to ensure HIPAA compliance. |
| [Office of Institutional Compliance – Conflict of Interest](https://compliance.umn.edu/conflictHome.htm) | Conflict of Interest | Indication that any study team member affiliated with the University of Minnesota has a conflict of interest | * Initial Review
* Modifications
* Continuing Review
 | Seth Beccardbecca002@umn.edu 612-625-2210 | Report of External Professional Activities (REPA) formGillette excluded | Must be completed prior to or during IRB Pre-Review.Note: Exception may be made if requested by the OIC and IRB leadership. |
| Institutional Biosafety Committee (IBC) including rDNA Advisory Committee | IBC OversightrDNA Advisory CommitteeNote to IRB analyst: include comment explaining rationale for assigning ancillary review | Use of recombinant and synthetic nucleic acid, toxins or infections agents (bacteria or viruses). Includes Human Gene Transfer, IE, genetically engineered viruses/bacteria/cells, use of RNA or DNA.Any overlap projects that have application components that fit the policies for stem cell research or fetal tissue research that are reviewed by those respective oversight groups. | * Initial Review
* Modifications to protocols
 | Greg ParkParkx479@umn.edu 612-626-2161 | Application submitted via eprotocol.umn.edu  | Must be completed prior to final IRB approval is granted. |
| [Fetal Tissue Research (FTR)](https://research.umn.edu/units/obao/research-oversight-areas/fetal-tissue-research-ftr)Note: Assign ancillary review to IBC | OtherNote to IRB analyst: Include comment explaining rationale for review assignment | All research involving use of human fetal tissue research.  | * Initial Review
* Modifications to protocols that would include a new use of Fetal Tissue
 | Greg ParkParkx479@umn.edu 612-626-2161 | Contact [OBAO](https://research.umn.edu/units/obao) for submission instructions  | Must be completed prior to final IRB approval is granted. |
| [Stem Cell Research Oversight (SCRO)](https://research.umn.edu/units/obao/research-oversight-areas/stem-cell-research-oversight-scro)  Note: Assign ancillary review to IBC | OtherNote to IRB analyst: include comment explaining rationale for assignment | All research involving use of human embryos or embryonic stem cells - unless used for reproductive purposes | * Initial Review
* Modifications that include new use of human embryonic or embryonic stem cell
 | Greg ParkParkx479@umn.edu 612-626-2161 | Contact [OBAO](https://research.umn.edu/units/obao) for submission instructions.  | Must be completed prior to final IRB approval granted. |
| [OnCore](https://ctsi.umn.edu/tools/oncore-ctms/studies-enter-oncore) | OnCore registration compliance | If response to the question “Does your study need to be registered OnCore” on the study scope page is “No” or “I don’t know”See [decision tree](https://sites.google.com/umn.edu/oncoredecisiontree/home) for additional guidance | * Initial Review
* Note: when applicable, an Oncore Calendar must be submitted to Fairview for review.
 | OnCore Teamoncore@umn.edu 612-626-3080 | Completed via ancillary review in ETHOS. This is a collaboration between the IRB and OnCore to ensure OnCore compliance. For more information about Gillette excluded | Does not affect IRB approvalStudies determined by IRB review to be Exempt do not require registration Oncore |
| [Community- University Health Care Center](https://www.google.com/url?client=internal-element-cse&cx=002834015805923805805:c-0k--9bdkk&q=https://cuhcc.umn.edu/&sa=U&ved=2ahUKEwistMi00onuAhWVGFkFHUbnAncQFjABegQIAhAB&usg=AOvVaw2R6-oZwyd0n55FZTLJdCRi) | CUCHCC | When “CUHCC – Community-University Health Care Center” is selected as a research location | * Initial review or modifications that add CUHCC as a site
 | Heather Ogrenhlogren@uumn.edu | Via submission of the ancillary review | Does not affect IRB approval |
| [UHS-Controlled Substances Program](https://uhs.umn.edu/department-environmental-health-safety/lab-research-safety/controlled-substances/controlled) | University Health and Safety Compliance – controlled substances program compliance | When controlled substances use is indicated in ETHOS or in protocol | * Initial Review
* Modifications that add controlled substances use
 | Controlled Substances Programcshelp@umn.edu612-625-7227 | Through assignment of ancillary review. May be assigned by either the researcher or IRB analyst. | Must be completed prior to final IRB approval.  |
| Office of Native American Affairs | Provided to create awareness of research projects and to provide consultation when requested by the IRB | When research is conducted with Tribal partners, Tribal communities, Tribal-serving institutions, Indigenous Peoples, places and objects of cultural significance. | * Initial Application
* Modifications that request new inclusion criteria
* RNIs
 |  [Ofice of Native American Affairs](https://naa.umn.edu/) | By request of the IRB | In most instances this ancillary review will not impact IRB review or approval  |
| eConsent via REDCap | Confirmation of IRB approval prior to moving eConsent to production in REDCap | When protocol indicates use of eConsent via REDCap | * Initial review or modifications that request use of eConsent
 | CTSI REDCapredcap@umn.eduSee [How to Use REDCap eConsent](https://ctsi.umn.edu/news/how-use-redcap-electronic-consent) | Through request to move an eConsent project in REDCap to production | Does not impact IRB approval – no response required from REDCap |

1. If the requirement for an ancillary review differs for studies relying on an external IRB, indicate the differences in this table. [↑](#endnote-ref-2)
2. [↑](#endnote-ref-3)