HRP-309 | 03/27/2024

**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.

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 “Documents” section of the RAMS 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.

The tables below highlight 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]](#footnote-1)

| **Organization** | **Review Type** | **Ancillary Review Triggered by** | **Affected IRB Submission Types** | **Relevant Contact** | **How to Obtain Review** | **Impact on IRB Review (prior to, after, or parallel with)** |
| --- | --- | --- | --- | --- | --- | --- |
| Human Research Protection Program | Human Subjects Training | all human subjects research submissions | Initial Review  Modifications  CR | [hrpp@vcu.edu](mailto:hrpp@vcu.edu) | <https://research.vcu.edu/training/citi-training/> | Prior |
| Human Research Protection Program | Good Clinical Practice Training | study meets NIH definition of clinical trial | Initial Review  Modifications CR | [indide@vcu.edu](mailto:indide@vcu.edu) | [Good Clinical Practice (GCP) training - Virginia Commonwealth University (vcu.edu)](https://research.vcu.edu/human-research/regulatory-affairs/good-clinical-practice-gcp-training/) | Prior |
| Internal DUAs:  Human Research Protection Program | Data Use Agreement (DUA) for Limited Data Set (LDS) from VCU Health System | Sharing a LDS from VCUHS to an internal entity | Initial Review  Modifications | [HRPP@vcu.edu](mailto:HRPP@vcu.edu) | Complete [HIPAA Data Use Agreement for Limited Data Set](https://research.vcu.edu/forms/) form and upload in RAMS-IRB application. | Prior/Parallel |
| Office of Research Integrity and Ethics | Conflict of interest (COI) | For expedited or full board studies,  ‘COI Investigators' (designated by the PI as having responsibility and independence in the design, conduct, and reporting of research), must complete a Financial Interest Report (FIR) in the Activities and Interests Reporting System (RAMS-AIRS) | Initial Review | [AIRS@vcu.edu](mailto:AIRS@vcu.edu) | The [Activity and Interest Reporting System](https://airs.research.vcu.edu/) (AIRS) is an electronic Research Administration Management System (RAMS) for the reporting of interests pertaining to research. | Prior |
| Cost Coverage Analysis | C Coverage Analysis | All clinical research studies | Initial Review | Contact your school or center research administration office | Contact your school or center research administration office | Prior |
| Institutional Biosafety Committee (IBC) | Oversight of rDNA research or biologically hazardous materials | Research involves use of monoclonal antibodies not FDA approved, recombinant/synthetic DNA (rDNA), or administration of pathogens to human subjects | Initial Review | [ibc@vcu.edu](mailto:ibc@vcu.edu) | [Institutional Biosafety Committee - Safety and Risk Management - Virginia Commonwealth University (vcu.edu)](https://srm.vcu.edu/labs--research/biological-safety/institutional-biosafety-committee/) | If changes are requested to protocol or consent by IBC, a modification must be submitted to the IRB. |
| Institutional Review Entity (IRE) | Oversight of DURC agents and/or toxins | Research involves one of the 15 agents/toxins designated as Dual Use Research of Concern (DURC) agents/toxins by United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern | Initial Review  CR | [jjryan@vcu.edu](mailto:jjryan@vcu.edu) | [Regulatory committees - Virginia Commonwealth University (vcu.edu)](https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/) | Prior/Parallel |
| Massey Cancer Center | Protocol Review and Monitoring Committee (PRMC) | Oncology related research | Initial Review | [masseyprms@vcu.edu](mailto:masseyprms@vcu.edu) | [Clinical Research Committees | VCU Massey Cancer Center](https://www.masseycancercenter.org/research/clinical-trials-office/clinical-research-committees) | Prior |
| VCUHS | Protocol Review Committee (PROC) | Use of VCUHS facilities or patients' medical records | Initial Review | [mary.harmon@vcuhealth.org](mailto:mary.harmon@vcuhealth.org) | [ONETRAC (vcu.edu)](https://onetrac.vcu.edu/) | Prior |
| Scientific Review Committee | Scientific Review | Greater than minimal risk studies where scientific review not provided by the study sponsor | Initial Review | [japhifer@vcu.edu](mailto:japhifer@vcu.edu) | <https://cctr.vcu.edu/support/consultation/scientific-review-committee/> | Prior |
| Research Data Privacy Program | GDPR | collecting data about a natural person in the European Economic Area (the E.U., Iceland, Liechtenstein and Norway) | Initial Review | [rescomply@vcu.edu](mailto:rescomply@vcu.edu) | [Research data privacy - Virginia Commonwealth University (vcu.edu)](https://research.vcu.edu/integrity-and-compliance/compliance/research-data-privacy/) | Prior/Parallel |
| Information Security | Security review of technology | Use of any technology platforms, apps, services, etc. that are maintained external to VCU or hosted by another institution and are NOT currently listed in the DMS system as an approved service for the storage, processing, or transmission of VCU data | Initial Review  Modifications | [infosec@vcu.edu](mailto:infosec@vcu.edu) | [Information Security | Technology Services | VCU](https://ts.vcu.edu/about-us/information-security/) | Parallel |
| Investigational Drug Pharmacy | Proper storage, handling and disposal of investigational agents | Drug and device studies | Initial Review  Modifications | Mary Pak (804) 828-7901  [mary.pak@vcuhealth.org](mailto:mary.pak@vcuhealth.org) | [Investigational Drug Services - Virginia Commonwealth University](https://research.vcu.edu/human-research/ids/) | Prior |
| Division of Sponsored Programs | Compensation for Injury consent language for industry sponsored studies | Changes to template language in ICF | Initial Review  Modifications | [ospred@vcu.edu](mailto:ospred@vcu.edu) | [Proposals and awards - Virginia Commonwealth University (vcu.edu)](https://research.vcu.edu/proposals-and-awards/) | Prior/Parallel |
| VCU Health Department of Patient Centered Services |  | Administration of satisfaction surveys to VCUHS patients | Initial Review  Modifications | [Nathan.cunningham@vcuhealth.org](mailto:Nathan.cunningham@vcuhealth.org) |  | Prior/parallel |
| Clinicaltrials.gov support office at Wright Center | clinicaltrials.gov registration | Meets NIH definition of clinical trial or other registration criteria. | Initial Review | [cctrctgov@vcu.edu](mailto:cctrctgov@vcu.edu) | [ClinicalTrials.gov - Virginia Commonwealth University](https://cctr.vcu.edu/support/consultation/clinical-trials-gov/) | Does not affect IRB review. However, when registration is required, consent language must be included. |
| Division of Sponsored Programs | Material Transfer Agreement | Whenever there is a material transfer that is not covered by any other agreement (e.g., purchase order/procurement, grant award, or sponsored clinical trial) | Initial Review  Modifications | [mtadua@vcu.edu](mailto:mtadua@vcu.edu)  (804) 828-6772 | [Pre-proposal - Virginia Commonwealth University (vcu.edu)](https://research.vcu.edu/proposals-and-awards/sponsored-project-navigator/pre-proposal/) | does not affect IRB review |
| Division of Sponsored Programs | Data Use Agreement | Any time non-public data is exchanged between entities (except sharing of Limited Data Set from VCU Health System which is reviewed by VCU IRB) | Initial Review  Modifications | [ua@vcu.edu](mailto:mtadua@vcu.edu) | [Pre-proposal - Virginia Commonwealth University (vcu.edu)](https://research.vcu.edu/proposals-and-awards/sponsored-project-navigator/pre-proposal/) | If protocol does not account for sharing, a modification must be submitted to the IRB |
| Division of Sponsored Programs | Funding Agreements | Funding provided by or collaboration with external sponsor (including Cooperative Research and Development Agreement, Expanded Access, Clinical Trial Agreement) | Initial Review  Modifications | See [DSP Decision Tree](https://research.vcu.edu/media/office-of-research-and-innovation/documents/which_osp_team_reviews_it.pdf) | [Proposals and awards - Virginia Commonwealth University (vcu.edu)](https://research.vcu.edu/proposals-and-awards/) | Prior/Parallel |
| Information Security Office | Data Management System (Data Management Plan) | Use of Category 1 Data as defined by[**VCU Data Classification Tool**](https://redcap.vcu.edu/surveys/?s=mF448s6hYI) | Initial Review | [infosec@vcu.edu](mailto:infosec@vcu.edu) | DMPs are made using the Data Management System (DMS)  <https://ts.vcu.edu/about-us/information-security/data-management-system/> | Prior/Parallel |
| Information Security Office | assessment of third-party software/platforms | use of third party software/platforms | Initial Review  Modifications | [infosec@vcu.edu](mailto:infosec@vcu.edu) | [Information Security | Technology Services | VCU](https://ts.vcu.edu/about-us/information-security/) | Prior/Parallel |
| Human Research Protection Program | Post Approval Monitoring and Quality Improvement Program (PAMQuIP) | for-cause and routine visits of human subjects research | Initial Review  CR | [pamquip@vcu.edu](mailto:pamquip@vcu.edu) | [Other submissions and monitoring - Virginia Commonwealth University (vcu.edu)](https://research.vcu.edu/human-research/hrppirb/other-submissions-and-monitoring/) | After |
| Radiation Safety Committee (RSC) | Radiation | study involves radiation exposure and/or scans involving radiation (e.g., PET, MRA, CT, DXA, nuclear medicine) | Initial Review  Modifications | [kurgatts@vcu.edu](mailto:kurgatts@vcu.edu) | [Radiation Safety - Safety and Risk Management - Virginia Commonwealth University (vcu.edu)](https://srm.vcu.edu/labs--research/radiation-safety/) | If changes are requested to protocol or consent by Radiation Safety, a modification must be submitted to the IRB. |
| Emergency Department Letter | feasibility | enrolling patients within the VCU Department of Emergency Medicine (EM) or seeking to utilize EM resources | Initial Review | [lisa.merck@vcuhealth.org](mailto:lisa.merck@vcuhealth.org) | [Research - Department of Emergency Medicine - VCU School of Medicine](https://emergencymedicine.vcu.edu/research/) | Prior |
| VCU Records and Registration | FERPA | access to student records | Initial Review | [infosec@vcu.edu](mailto:infosec@vcu.edu) or [rar@vcu.edu](mailto:rar@vcu.edu) | [Disclosure of student contact information - Records and Registration - Virginia Commonwealth University (vcu.edu)](https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/student-contact-information/) | Prior/Parallel |
| Regulatory Affairs | Investigator held IND/IDE | All protocols conducted at VCU under a VCU Faculty Held IND/IDE | Initial Review | [indide@vcu.edu](mailto:indide@vcu.edu) | [Regulatory affairs - Virginia Commonwealth University (vcu.edu)](https://research.vcu.edu/human-research/regulatory-affairs/) | Prior |
| VCUHS Department of Pathology | feasibility | study involves:  - Storage of Microbiology isolates  - New instrumentation provided by clinical trial/study sponsor, or  - Non-routine specimen processing (examples include but aren’t limited to the following: addition of reagents to samples/aliquots, buffy coat processing, DNA sample processing)  - specimen retrieval from Pathology lab | Initial Review |  | <https://pathology.vcu.edu/research/> | Prior |
| VCUHS Privacy Office | VCUHS Policy COMP-14 | access to medical records for research purposes, including screening and eligibility purposes and secondary use | Initial Review  Modifications | <https://informatics.vcu.edu/> | Consult with Informatics to ensure proposed access to medical records is an approved method. | After |
| VCU Informatics |
| VCU Dental School Privacy Office | VCU SOD | When SOD IT will be asked to provide secondary dental records data | Initial Review  Modifications | <https://support.dentistry.vcu.edu/>  [Research: Patient Data Request](https://support.dentistry.vcu.edu/userui/ticket_service_intermediate.php?QUEUE_ID=0&SERVICE_ID=12)  Contact: Mike Talley talleymw@vcu.edu | Does not affect IRB review. SOD approval depends on IRB approval. | After |
| VA Department of Behavioral Health Regional Local Human Rights Committee (LHRC) | Human research | IRB approval for research on subjects receiving state-funded services from providers of mental health, mental retardation, or substance abuse services in Virginia | Initial Review | Region 1: Cassie Purtlebaugh cassie.purtlebaugh@dbhds.virginia.gov  Region 2: Ann Pascoe ann.pascoe@dbhds.virginia.gov  Region 3: Mandy Crowder mandy.crowder@dbhds.virginia.gov  Region 4: Andrea Milhouse andrea.milhouse@dbhds.virginia.gov  Region 5: Reginald Daye reginald.daye@dbhds.virginia.gov  Facilities: Brandon Charles brandon.charles@dbhds.virginia | Contact the OHR Regional Manager (listed under relevant contacts) for specific region in which the research is conducted to obtain submission information | Obtained after IRB review and approval, before initiating the research |

1. If the requirement for an ancillary review differs for studies relying on an external IRB, the differences will be indicated in this table. [↑](#footnote-ref-1)