Navigating IRB Ancillary Reviews

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Why do we need additional ancillary reviews?

IRB's Role

- The rights and welfare of human research participants are protected
- Research is guided by the ethical principles of respect for persons, beneficence, and justice
- Research is conducted with the highest level of expertise and integrity
- Research complies with applicable laws

Ancillary Committees Role

- Institutional Feasibility
- Scientific Merit
- Expertise in an area
- Compliance to a state law or local policy
- Coordination between UVM and UVMHN
- Expertise in assessing risk in a specific area

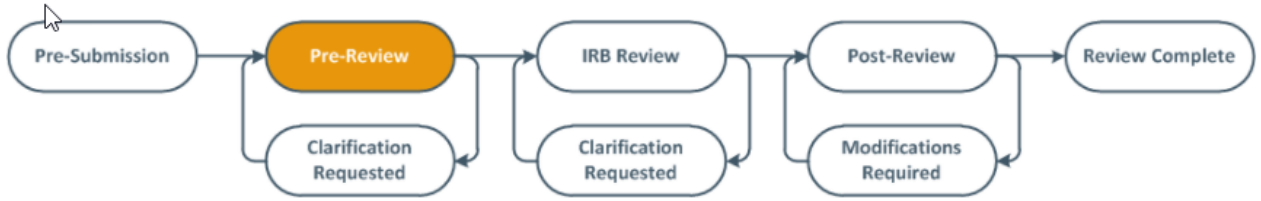
What types of ancillary reviews does the UVM IRB utilize?

Regulatory Reviews

- Institutional Biosafety Committee (IBC)
- Radiation Safety
- UVMHN Data Management Office (DMO)

Institutional Reviews

- Protocol Review and Management Committee (PRMC)
- Clinical Research Center Scientific Advisory Committee (SAC)
- UVMMC Investigational Pharmacy
- Office for Clinical Trials Research (OCTR)
- UVM Medical Center Compliance Office
- Faculty Sponsor



History | Funding | Contacts | Training | Documents | IRB Assignment Details | Reviews | Snapshots

There is no Pre-Review to display at this time.

There is no Non-Committee Review to display at this time.

There is no Committee Review to display at this time.

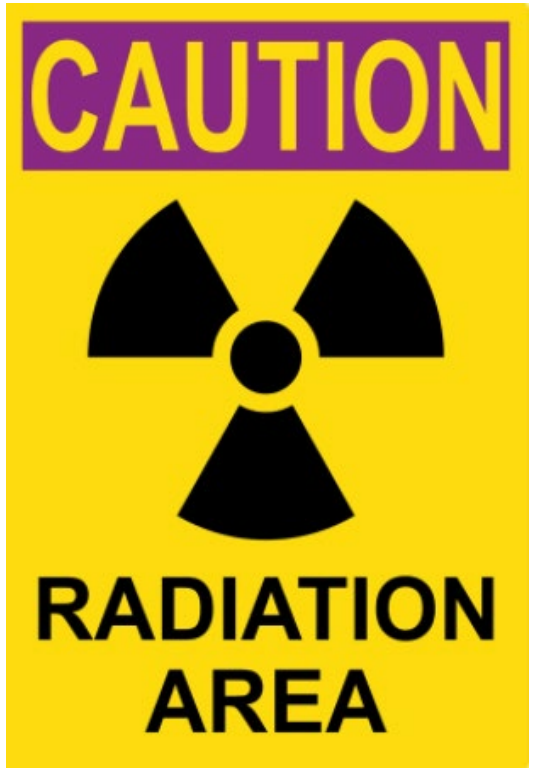
Ancillary Reviews

Review Type	Organization	Person	Reqd	Accepted	Comments
Billing Compliance		Denise Quint	yes	yes	Bill hold - No
OCTR Contract Review	IRB Ancillary-OCTR-Contract	Mark Tomase Brooke Cote Kimberly Luebbers	yes		
OCTR Invoice Review	IRB Ancillary-OCTR-Invoice	Gregory Barrows Kimberly Luebbers	yes		
UVMHN Data Management Office	IRB Ancillary-UVMHN Data Management Office	Elizabeth Carter Allison Holm	yes		

How are ancillary reviews tracked in UVMClick?

Regulatory Ancillary Review Committees

Radiation Safety



- Any protocols involving the application of radioactive materials, radioisotopes, and/or radiation treatment to humans for ***nonclinical purposes*** will undergo an ancillary review
- Separate reviews are assigned for UVMMC and UVM locations
- The radiation safety officers review the protocol and consent and ensure the added risk of the radiation exposure is adequately addressed
- It's a ***regulatory requirement*** that UVM and UVMMC ensure adherence to local state and federal radiation safety practices

10. * **Does the protocol involve exposure of human subjects to ionizing radiation? (All protocols involving radiation exposure to human subjects, when the exposure is not considered standard of care, must be referred to the appropriate radiation safety committee for review. The following questions will help to determine whether review is required.)**

- (●) **Yes** ( ) No

11. * **Is the radiation exposure considered standard of care?**

- ( ) Yes (●) **No**

12. * **What is the purpose of the radiation exposure to subjects in the study?**

- [x] Imaging
- [ ] Treatment

13. * **What is the source of the radiation exposure to subjects in the study?**

- [ ] Radioactive materials
- [x] External sources (electronically produced radiation such as from x-ray generators or linear accelerators)

14. * **Where will the procedures involving radiation taking place?**

(If using CRC DEXA, check UVM)

- [x] UVM (university campus)
- [x] UVMMC Hospital/Clinic

Data Management Office (DMO)

- Any study involving secondary research that will be supported by data requested through the DMO and includes PHI from any UVM Health Network affiliate, must be reviewed and approved by the DMO and UVM IRB prior to release of the information from the DMO.
- The protocol can be assigned directly to the DMO IRB Analyst to ensure congruence with the IRB protocol and the ServiceNow request for an Exemption 4iii determination.
- An ancillary review can be assigned to the DMO Data Governance Team when only a portion of the protocol is requesting data for secondary research from the DMO.

1. Complete the required DMO data request form (DMO Template_Research); on the UVM Health Network Intranet: https://fahc.sharepoint.com/teams/DMO or contact AskDMO@UVMHealth.org
2. Submit a data request to the DMO through the ServiceNow Customer Portal by using the Data or Reporting form: https://uvmhealth.service-now.com/sp?id=sc_home#tab-popular-items
3. Respond in a timely manner to the DMO Team through the ServiceNow ticket.
4. Respond in a timely manner to the IRB Analyst through UVMClick.
5. The ServiceNow request MUST match the IRB protocol and UVM HIPAA Waiver page in Click. Ensure your data fields in both systems are the same.
6. The ancillary review will be approved, and data released once all the steps above are completed.

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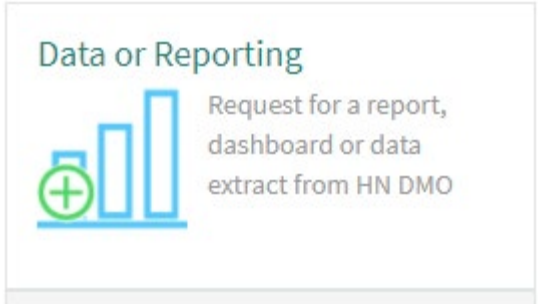
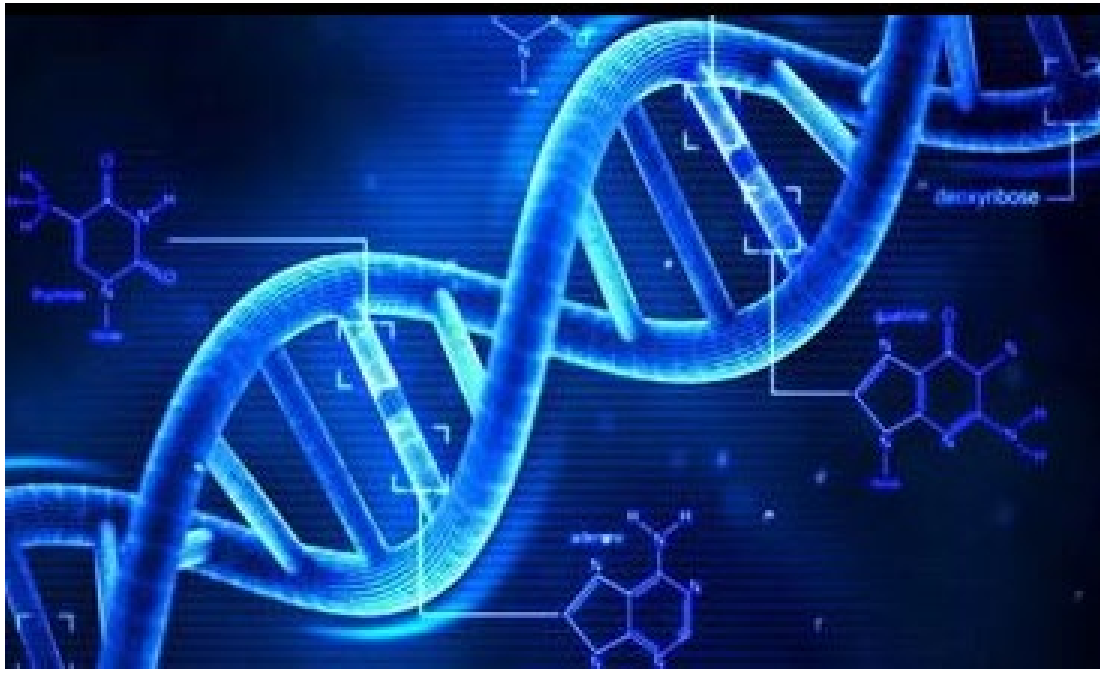


Institutional Biosafety Committee (IBC)

IRB protocols involving the use of recombinant DNA, gene therapy or biohazardous agents require IBC review and approval, as mandated by NIH.

Approval to begin activities will not be released until IBC approval is obtained.

Submissions may be made to both Committees simultaneously, but human subject activities must not begin until both Committees have approved the protocol.



Institutional Ancillary Review Committees

Protocol Review and Monitoring Committee (PRMC)

- Review by the PRMC is independent of the review by the IRB.
- PRMC and IRB, share Committee review correspondence and outcomes with each other.
- This is required for all initial submissions and modifications.
- PRMC's review focuses on scientific merit and institutional priority for oncology patients and tumor tissue

THE University of Vermont CANCER CENTER

What Does the Cancer Center Need to Review?

- The PRMC reviews clinical research focused on cancer as well as research using oncology tissue, either prospectively or retrospectively.
- The clinical research may be interventional or observational in design.
- The research may also be designed to evaluate the delivery, process, management, organization, or financing of health care regarding cancer patients.
- The PRMC also reviews cancer registry studies and bio-repositories.

What Does the Cancer Center Not Need to Review?

- The PRMC does not review non-human laboratory studies (such as mouse or cell-line studies).
- The PRMC does not review retrospective chart review studies (exemption 4iii determinations)

Clinical Research Center

The CRC can provide scientists the infrastructure necessary for the efficient and productive conduct of high-quality clinical research.

Resources for researchers, trained research professionals, space to conduct research, standard research equipment.

Ability to conduct overnight or extended stay visits.

CRC has its own scientific review process and will utilize the materials submitted in CLICK for their review

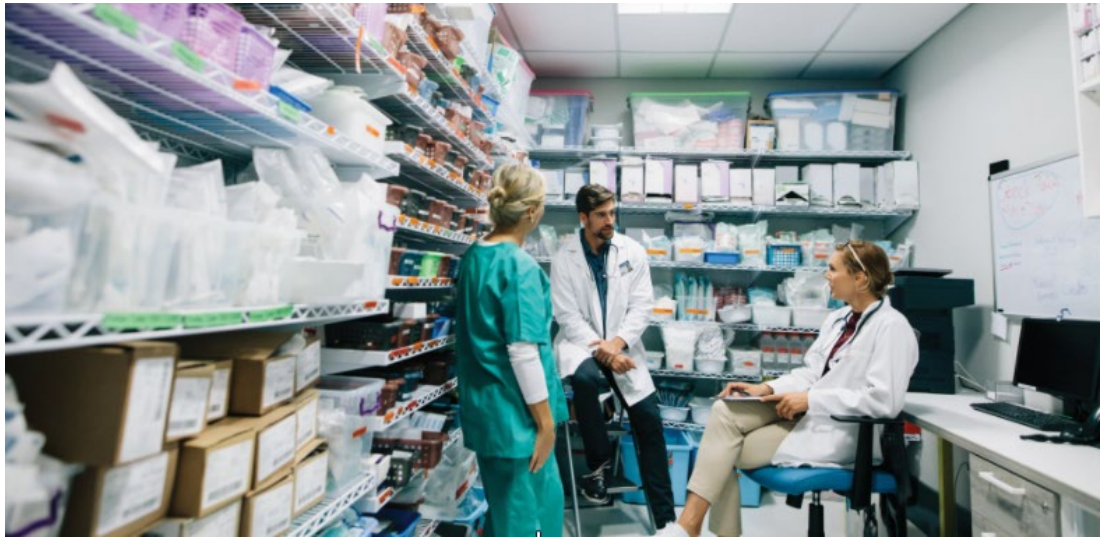
Requires a CRC Resource Request Form to facilitate review and develop a costing for the services being requested.

CRC committee review is performed in parallel with the IRB review however, the IRB will not release their approval until the CRC approval is completed.

CRC staff who support research in the center must be added as key personnel before CRC approval will be granted.

Investigative Drug Services (IDS)

- A feasibility review of all protocols that utilize UVMMC Investigational Drug Service (IDS) to receive, store, control, or dispense an investigational agent require ancillary pharmacy approval.
- Ancillary reviews will be assigned to IDS when the RPO has identified a protocol using an investigational drug or approved drug in an investigational manner.
- IDS will need to review and approve a research study using IDS prior to beginning resaerch or adding to a Committee agenda.



Faculty Sponsor

Student/trainee = undergrad, graduates, post-docs, med students, residents and fellows

Students, non-faculty and staff wanting to serve as a PI must obtain their faculty sponsor review and approval through the UVMClick system prior to IRB review.

An ancillary review will be assigned to the role of faculty sponsor in the UVMClick system.

Billing Compliance

The IRB assists UVM Medical Center Compliance in identifying protocols that require a coverage analysis and billing plan and will only release final protocol approval when the billing plan is complete.

The billing plan ensures the consent form and contract are congruent and are compliant with Medicare guidelines, the consent form adequately and accurately informs the research participant of the cost of services and ensures patients are not billed for research procedures.

Please contact Denise Quint at Denise.Quint@uvmhealth.org for questions

Protocols which are supported by an industry sponsor where money, materials (test articles, equipment, or other supplies), or intellectual property are exchanged require a contract or agreement be in place between the sponsor and either UVM or UVM Medical Center.

Most industry-sponsored research contract review is done through the Office of Clinical Trial Research (OCTR) however a select few are handled through SPA.

Many times, this contract review is the final step to protocol approval and release, researchers should plan accordingly and submit their contracts to the appropriate individuals early in the review process.

Sponsor Contracts

Sponsor Invoices

Fees **will** be applied to these types of protocols:	Fees **will not** be applied to these types of protocols:
• Industry • Pharmaceutical companies • Other for-profit entities • Non-profit entities where such fees are not prohibited • Investigator-initiated protocols with for profit sponsors • Protocols initiated by affiliated Health Network sites	• Federal or federal flow through • State of Vermont • Non-profit where fees are prohibited • Investigator-initiated internally - funded studies

Data Use Agreements (DUA)

- Data Use Agreements are contractual documents used for the transfer of non-public data subject to restrictions on its use.
- DUAs serve to outline the terms and conditions of the transfer.
- Agreements address issues such as limitations on use of the data, obligations to safeguard the data, liability for harm arising from the use of the data, publication, and privacy rights associated with confidential or protected data.
- The understanding established by a DUA can help avoid later issues by clearly setting forth the expectations of the provider and recipient.
- DUA’s involving UVMHN data are reviewed by OCTR
- DUA’s involving non-PHI data may be reviewed through UVM SPA