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| **Ancillary Review Requirements for Human Subject Research Studies**  |  |
| **Committee name and contact** | **Initial study** | **Modifications** | **Continuing Review** | **Training Requirements** |
| [**Protocol Review & Monitoring Committee (PRC)**](https://umiamihealth.org/sylvester-comprehensive-cancer-center/research/research-resources/clinical-research-services/research-committees-support-unit)Pam Cooper*Manager, Research SupportSylvester Comprehensive Cancer Center*Phone 305-243-6013pamela.cooper@med.miami.edu**Questions:** sccc.prmc@miami.edu or via telephone at 305-243-6013.For population science or social behavioral study specific requirements, please contact sbs.prmc.startup@miami.edu for more information. | All cancer related studies (retrospective or prospective) require Protocol Review and Monitoring Committee (PRMC) review and approval **PRIOR** to IRB review. **Please submit all study related materials to the PRMC via the PRMC Electronic Submission (PES) Form at PES**<https://bbcapps.ad.med.miami.edu:8443/PES/login.htm> | All modifications require PRMC approval if PRMC is listed as an ancillary review committee | All modifications require PRMC approval if PRMC is listed as an ancillary review committee **New Personnel:****Please send personnel credentials (CV, initialed and dated) to** **sccc.prmc@miami.edu** | N/A | N/A |
| [**Clinical Trial Disclosure Committee (CTD)**](file:///C%3A%5CUsers%5Ccmg345%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CIVWF5DQD%5Cctd.uresearch.miami.edu)Yolanda P. Davis, CCRP*Clinical Trial Disclosure ManagerOffice of Research Compliance and Quality Assurance* Phone: (305) 243-0494E-mail: Y.P.Davis@med.miami.eductd.uresearch.miami.edu | This process facilitates the UM’s compliance 42 CFR § 11, FDAAA Section 801, FDAMA Section 110, CMS, NIH and ICMJE. The CTD Ancillary Committee determines if a study must register on ClinicalTrials.gov. This determination includes:* Is it a clinical trial?
* Who must register the study on ClinicalTrials.gov;
* Does the protocol have all information needed for registration and reporting?
* Does the informed consent form have the required CTD language?

**Clinical Trial Disclosure: Determination and Protocol Registration Policy** <https://umhs-ummg.policystat.com/policy/token_access/628beb33-c8ef-422e-b7f2-f79acb2dbe1e/> | N/A | N/A | N/A | N/A |
| [**Office of Environmental Health and Safety (EHS)**](https://ehs.miami.edu/)Primary point of contact: BSO\_Review@miami.eduSecondary Contacts at the Biosafety Office:**Shane Gillooly***Biosafety Manager*305-243-3269sxg1519@med.miami.edu**Marleina Drane**mcd944@med.miami.edu | EHS approval is required for studies that collect patient specimens or introduce risk group 2 agents (or higher) or any recombinant therapeutics. **Requirement**: [Biosafety Ancillary Risk Assessment form](https://hsro.uresearch.miami.edu/_assets/pdf/biological-ancillary-review-assessment-form_1.docx)  | All modifications that introduce new risk group 2 agents (or higher) or any new recombinant therapeutics not included in the previous protocol.**Requirement:** [Biosafety Ancillary Risk Assessment form](https://hsro.uresearch.miami.edu/_assets/pdf/biological-ancillary-review-assessment-form_1.docx) | Adding personnel who will be collecting human specimens, processing samples, or handling risk group 2 (or higher) agents\*. | N/A | 1) IBC Biosafety Training every three years for Clinical Staff via  [ULearn](https://ulearn.miami.edu/)2) UHealth OSHA's Bloodborne Pathogens, Biomedical Waste, Latex Allergy and TB Training required every year via [ULearn](https://ulearn.miami.edu/) |
| [**Embryonic Stem Cell Oversight Committee (ESCRO)**](https://www.uresearch.miami.edu/uresearch-services/escro/index.html)Dr. Ellen Kapsalis*Director of ComplianceIACUC / IBC / ESCRO*305-243-2311ekapsalis@miami.edu | Research involving any work with the use of human embryonic stem cells and/or their derivatives must be approved by the UM Embryonic Stem Cell Research Oversight Committee (ESCRO) prior to receipt of IRB approval. Requirement:  Such submissions must be submitted to the ESCRO committee **outside** of the eProst system upon receiving departmental approval. Please visit the ESCRO committee website at <https://www.uresearch.miami.edu/uresearch-services/escro/index.html>  for further information. | Modifications that introduce the use of human embryonic stem cells and/or their derivatives to the parent study.**Requirement**:  Such submissions must be submitted to the ESCRO committee **outside** of the eProst system upon receiving departmental approval.  | New personnel\* | Yes | Ethical Oversight of hESC Research. This is an online module available via ULearn. Individuals listed or added onto a ESCRO related protocol must complete this training once. |
| [**Institutional BioSafety Committee (IBC)**](https://www.uresearch.miami.edu/uresearch-services/ibc/index.html)Dr. Ellen Kapsalis*Director of ComplianceIACUC / IBC / ESCRO*305-243-2311ekapsalis@miami.edu | All clinical trial protocols that use recombinant DNA, synthetic nucleic acid materials, or a genetically modified organism or therapeutic must receive prior approval from the Institutional (IBC). **Requirement:** Please refer to the documents for Human Gene Transfer Research at [Institutional Biosafety Committee (IBC) | UResearch | University of Miami.](https://www.uresearch.miami.edu/uresearch-services/ibc/index.html) | Modifications that use recombinant DNA, synthetic nucleic acid materials, or a genetically modified organism or therapeutic.**Requirement**: Please refer to the documents for Human Gene Transfer Research at [Institutional Biosafety Committee (IBC) | UResearch | University of Miami.](https://www.uresearch.miami.edu/uresearch-services/ibc/index.html) |  | Yes | Biosafety Training is required every three years for all research personnel and for new personnel added to the study during the research. Personnel includes anyone involved with the material/agent (whether administrating it or collecting samples or transporting the material across campus).***This training is available via ULearn as a module titled “IBC Biosafety Training for Clinical Staff”.***IBC NIH Guidelines Training (must be completed once) by PIs, sub-investigators, co-investigators.***This training is a PowerPoint presentation. Contact*** ***IBCsupport@miami.edu*** ***for review and credit.*** |
| [**Human Use Radiation Safety Committee (HRSC)**](http://facilities.med.miami.edu/divisions/radiation-cont)**Rameses Herrera***ManagerRadiation Control Center*305-243-6360r.herrera1@miami.edu | Protocols where radiation/radioactive materials (not MRI, Ultrasound or Laser Treatment) or radiation producing devices are being used for research purposes | Modifications that introduce radiation/radioactive materials (not MRI, Ultrasound or Laser Treatment) or radiation producing devices to the parent study | N/A | N/A | N/A |
| [**Conflict of Interest (COI) Committee**](https://www.uresearch.miami.edu/uresearch-services/coi/guidelines/index.html)**Lory Hayes, Ph.D.** *Director of DRM* LHayes@med.miami.edu*or call the UDisclose System helpline (305-243-0877).* | The UM COI Committee acts to determine, through a risk-based, case-by-case review, whether a COI is created between a research project and an external relationship. If a COI is found, the COI Committee works with the investigator to develop a management plan. Complete the disclosure process in the UDisclose system. | Modifications meeting criteria for review | Modifications meeting criteria for review | N/A | All investigators are required to complete COI training prior to engaging in research or externally-funded educational activities, at least every four years. |
| [**Clinical Research Operations and Regulatory Support (CRORS)**](https://med.miami.edu/en/research/clinical-research/crors)**Alina Gjerpen***Project Manager, Research and Innovative Medicine**Clinical Research Operations and Regulatory Support* 305-243-0492arg136@med.miami.edu | CRORS ancillary review is required for new studies involving an investigator-held IND or IDE and for amendments to the studies. Before the initial ancillary approval the PI must contact CRORS for a monitoring cost estimate and to discuss the monitoring plan for the study.  | N/A | N/A | N/A | N/A |
| **Data Security Ancillary Committee****Andrew Hart Stoquert, JD, LLM** Data Privacy Officer, University of MiamiChief Privacy & Data Integrity Officer, University of Miami Health SystemOffice of Privacy and Data Security305-243-5000a.stoquert@med.miami.edu | Studies collecting, storing and transmitting protected health information (PHI)Forms:Research Data Security Assessment Form | Modifications meeting criteria for review | N/A | N/A | N/A |
| **Department Review**  | Based on department. Usually conducted by the Department Chair or the Chair’s designee. | Required for PI transfer | N/A | N/A | N/A |
| **UHealth Tower (UHT) \*\*****Halina Kusack, RN, BBM, MSN**Director, Clinical OperationsOffice of Clinical Research (OCR)305-243-7412 (Office)305-243-5012 (Front Desk)HXK115@med.miami.edu**Christopher Otero****BSc, BSN, RN*****Nurse Supervisor*** ***UHealth Tower (UHT) Office of Research******University of Miami Miller School of Medicine******Direct: (305) 243-1488***cxo168@miami.edu | UHT Ancillary Committee approval must be obtained for studies with any research activities at a UHT facility or any studies accessing UHT patient information, before using any UHT resources including subject recruitment, facility use, subject interventions such as tests, measurements, drug administration, surgery, or obtaining subject consent. **Requirement**: Please complete the appropriate form as indicated in eProst application and upload it into Local Site Documents when submitting this form to eProst. | Modifications that are adding UHT to the study. Requirement: Please complete the appropriate form as indicated in eProst application and upload it into Local Site Documents when submitting this form to eProst | N/A | N/A | N/A |
| **[Clinical Translational](http://research.med.miami.edu/clinical-research/ctrs)** **[Research Site (CTRS) \*\*](http://research.med.miami.edu/clinical-research/ctrs)****Halina Kusack,** **RN, BBM, MSN** *Director, Clinical* *Operations* *Office of Clinical* *Research (OCR*) 305-243-7412 (Office) 305-243-5012 (Front Desk) HXK115@med.miami.edu | Research using the UM Clinical Translational Research Site (CTRS) facilities must be reviewed by the CTRS prior to receipt of IRB approval. **Requirement**: Investigators should upload the CTRS Services Requested Form (available on the CTRS website) to the Ancillary Communication log. | N/A | N/A | N/A | N/A |
| **Pathology Review Committee (RPSC) \*\*****Omar Aljuboori***Translational Research Scientist**Department of Pathology* 305-243-9453oxa335@miami.edu | Research involving patient specimen collection at an UM patient care facility including, fluids, frozen, fresh or archived tissues, archived or slides, and/or where Pathology Department expertise, specialty and/or services is required will be reviewed by the Pathology Ancillary Review Committee. **Requirement**: The RPSC will communicate the pathology needs with the study team and identify how those needs will be met. | Required under the following circumstance:Protocol change affecting Lab samples | N/A | N/A | N/A |
| [**SCCC Research Lab & Satellites- SCCC**](https://hsro.uresearch.miami.edu/researchers/how-to-submit-to-the-irb/ancillary-committees/index.html#sccc) **\*\*****Jessika S. Gay, BSHCA***Laboratory Supervisor, SCCC Research Lab & Satellites|Clinical Translational Research Site (CTRS)*305-243-1344 (office)ResearchLabandSatellites@med.miami.edu | Research using SCCC Research Lab & Satellites facilities must be reviewed by the SCCC lab staff prior to any research lab utilization. Coordinators should fill out the [SCCC Research Lab & Satellites Services Request Form](https://hsro.uresearch.miami.edu/_assets/pdf/sccc-research-lab_satellites-service-request-form-official.doc) and send it to: ResearchLab&Satellites@miami.edu. This form must also be uploaded in the Local Site Documents section. | N/A | N/A | N/A | N/A |

\*Please see training requirements; Approval is not required for personnel removal

\*\* Approval is not required for initial studies