



ANCILLARY COMMITTEES FOR HUMAN SUBJECTS RESEARCH

Some research involves certain activities that require specialized review. For example, when a study involves radiation, the research must undergo review by the Human Use Radiation Safety Committee (HRSC). There could be instances where some studies require review by more than one of the 14 ancillary review committees. If your research is subject to ancillary review, you must submit the research to that Committee according to the Committee's requirements. You must refer to the *Human Subject Research Office [Ancillary Committees Website](#)* for required forms and additional information.

QUICK REFERENCE GUIDE



PROTOCOL REVIEW & MONITORING COMMITTEE (PRMC)

IRB ID #:
IRBAC001

All cancer related studies (retrospective or prospective) require PRMC review and approval **PRIOR** to IRB review. **Qs:** Sandra Rossi, Manager, Research Support | Sylvester Comprehensive Cancer Center | sandrarossi@med.miami.edu or via MSTeams. **Qs:** 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.



SCCC RESEARCH LAB & SATELLITES - SCCC

Research using SCCC Research Lab & Satellites facilities must be reviewed by the SCCC lab staff **PRIOR** to any research lab utilization. **Qs:** Jull Frank Chica, MBA, Supervisor | SCCC Research Laboratory & Satellites | Office of Clinical Research (OCR) | 305-243-1344 (office) | jchica@med.miami.edu

SCCCIRB ID #:
IRBAC013

CLINICAL TRANSLATIONAL RESEARCH SITE (CTRS)

IRB ID #:
IRBAC011

Research using the UM Clinical Translational Research Site (CTRS) facilities must be reviewed by the CTRS. **Qs:** Carlos Sandoval, Director, CTRS Research Operations, Office of the Executive Dean for Research - EDR, **P:** 305-243-8842 | **E:** c.sandoval1@med.miami.edu



EMBRYONIC STEM CELL OVERSIGHT COMMITTEE (ESCRO)

Research involving any work with the use of human embryonic stem cells and/or their derivatives must be approved by the ESCRO **PRIOR** to receipt of IRB approval. **Qs:** **Dr. Ellen Kapsalis | Director of Compliance | IACUC / IBC / ESCRO | 305-243-2311 | ekapsalis@miami.edu OR Liz Meza, Senior Regulatory Analyst, IACUC / IBC / ESCRO, lmeza@miami.edu**

IRB ID #:
IRBAC004

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

IRB ID #:
IRBAC005

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 IBC. **Qs:** IBCsupport@miami.edu **OR** Liz Meza, Senior Regulatory Analyst, IACUC / IBC / ESCRO, lmeza@miami.edu



CONFLICT OF INTEREST (COI) COMMITTEE

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. All investigators must complete the disclosure process in the UDisclose system **BEFORE** engaging in research. **Qs:** Lory Hayes, Ph.D., Director of DSAM | LHayes@med.miami.edu or call the UDisclose System helpline:(305-243-0877).

IRB ID #:
IRBAC007

CLINICAL RESEARCH OPERATIONS AND REGULATORY SUPPORT (CRORS)

IRB ID #:
IRBAC008

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. **Qs:** Nicole S. McCullough, MS, CCRP Director, Clinical Research Operations & Regulatory Support (CRORS) **P:** 305-243-0493 **E:** nshank@med.miami.edu





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DATA SECURITY ANCILLARY COMMITTEE (DSAC)

IRB ID #:
IRBAC009

Required for studies in which data is being shared outside of the University of Miami or being stored in systems not provided and maintained for by the University of Miami may be subject to review by the DSAC **PRIOR** to receipt of IRB approval. **Qs:** dsac@miami.edu **OR** Secondary Contact: **Joey Casanova, BBA/Data Broker Manager / P: 305-243-2631/E: jcasanova@miami.eduResearch**



CLINICAL TRIAL DISCLOSURE COMMITTEE (CTD)

The CTD determines if a study must register on ClinicalTrials.gov. This determination includes asking: **1)** Is it a clinical trial? **2)** Who must register the study on ClinicalTrials.gov **3)** Does the protocol have all information needed for registration and reporting? **4)** Does the informed consent form have the required CTD language? **Qs:** Karre Wetherington, CCRP, CCA/ Sr. Clinical Trial Disclosure Associate Regulatory Affairs & Assessment **P:** (305) 243-1107 **E:** kwetherington@miami.edu

IRB ID #:
IRBAC002

HUMAN USE RADIATION SAFETY COMMITTEE (HRSC)

IRB ID #:
IRBAC006

Protocols where radiation/radioactive materials (**not MRI, Ultrasound or Laser Treatment**) or radiation producing devices are being used for research purposes. **Qs:** RCC@med.miami.edu **OR** Sean O. Wilson, Radiation Safety Officer 305-243-6360, sow10@med.miami.edu | Diana R. Hernandez Radiation Control Manager, 305-243-6360, drh85@med.miami.edu



OFFICE OF ENVIRONMENTAL HEALTH AND SAFETY (EHS)

EHS approval is required for studies that collect patient specimens **or** introduce risk group 2 agents (or higher) **or** any recombinant therapeutics **PRIOR** to receipt of IRB approval. Primary point of contact: **BSO_Review@miami.edu** Secondary Contacts at the Biosafety Office: **Shane Gillooly, Biosafety Manager, 305-243-3269, sxg1519@med.miami.edu | Quintin James, qaj3@miami.edu | Melanie Peapell, 305-243-3269, MPeapell@med.miami.edu**

IRB ID #:
IRBAC003

PATHOLOGY REVIEW COMMITTEE (RPSC)

IRB ID #:
IRBAC012

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. **Qs:** DPLMResearch@miami.edu **OR** Omar Aljuboori, Translational Research Scientist, Department of Pathology and Laboratory Medicine **P:** 305-243-9453 **E:** oxa335@miami.edu



UHEALTH TOWER (UHT)

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. **Qs:** Oncology Protocols: Mitchell Diaz MSN, AGPCNP-BC, **P:** (305) 912-4633 **E:** mxd1433@miami.edu **OR** Danny Pino BSN, RN, OCN, BMTCN, **P:** (305) 912-4633 **E:** d.pino2@umiami.edu **Non-Oncology Protocols:** Carlos Sandoval, Director, CTRS Research Operations, Director, Office of the Executive Dean for Research - EDR, **P:** 305-243-8842 | **E:** c.sandoval1@med.miami.edu

IRB ID #:
IRBAC010

JACKSON HEALTH SYSTEM – CLINICAL RESEARCH REVIEW COMMITTEE (JHS-CRRC)

IRB ID #:
IRBAC014

Approval from the JHS-CRRC must be obtained for studies with any research activities (including recruitment of subjects, facilities use, or subject interventions such as tests, measurements, drug administration, surgery, or consenting subjects) occurring at a JHS facility or any studies that involve accessing JHS patient information **PRIOR** to the use of any JHS resources. **Qs:** Katuska Barbery, MBA, Director of Clinical Research, JHS Office of Research, Jackson Health System, 305-585-7226, Katuska.Barbery@jhsmiami.org





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MCA REVIEW GROUP (ORA)



Required for all submissions where question #5 in "Study Scope" is answered "yes". The purpose of this review is to confirm if a **Medicare Coverage Analysis (MCA)** is needed. **Qs:** Tatyana Vikhlyantseva, Director, Research Administration, 305-284-3942, TVikhlyantseva@med.miami.edu | Bianca Krysztof, Sr. Manager, Research Administration, 305-284-1735, b.gjorgievski@miami.edu | Amy Gonzalez, Sr. Contract and Grants Analyst, 305-284-3509, aeg183@miami.edu



SCHIFF CENTER FOR LIVER DISEASES

Required for research activities that are conducted or overseen by the local investigator at Schiff Center for Liver Diseases. **Qs:** Sonia Carvalho Director, Regulatory Support, 305-243-4639, scarvalho@med.miami.edu

**IRB ID #:
IRBAC015**

SONHS SIMULATION HOSPITAL

**IRB ID #:
IRBAC016**

Research activities are conducted or overseen by the local investigator at SONHS Simulation Hospital. **Qs:** Victoria Behar-Zusman, Professor, School of Nursing and Health Studies, 305-284-9139, vbehar-zusman@miami.edu **OR** Christian Ruiz DeGennaro Director, Research Support cruiz@miami.edu.

RESEARCH FEASIBILITY COMMITTEE

All new industry-sponsored clinical research studies, will be reviewed for feasibility by the **Miller School of Medicine (MSOM) Research Feasibility Committee (RFC)** prior to IRB submission. **Qs: RFC at msomfeasibility@med.miami.edu**



JFK HOSPITAL

**IRB ID #:
IRBAC018**

Required if research activities are conducted or overseen by the local investigator at JFK Hospital. **Qs:** Jill Kinley, DNP, APRN, CCRC Director of Clinical Research, (561) 548-1414, Jill.Kinley@HCAHealthcare.com

