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.

**ANCILLARY COMMITTEES FOR HUMAN SUBJECTS RESEARCH**

**PROTOCOL REVIEW & MONITORING COMMITTEE (PRMC)**

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 | sccc.prmc@miami.edu or via telephone at 305-243-6015. 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

**CLINICAL TRANSLATIONAL RESEARCH SITE (CTRS)**

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

**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: Larry Hayes, Ph.D, Director of DSAM | lhayes@med.miami.edu or call the UDisclose System helpline (305-243-0877).

**INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)**

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

**CLINICAL RESEARCH OPERATIONS AND REGULATORY SUPPORT (CRORS)**

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

This Ancillary Committees for Human Subjects Research Quick Reference Guide was developed by the Advocacy & Quality Champions Group.
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QUICK REFERENCE GUIDE

DATA SECURITY ANCILLARY COMMITTEE (DSAC)
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?

HUMAN USE RADIATION SAFETY COMMITTEE (HRSC)
Protocols where radiation/radioactive materials (not MRI, Ultrasound or Laser Treatment) or radiation producing devices are being used for research purposes. Qs: RRC@med.miami.edu OR Sean O. Wilson, Radiation Safety Officer 305-243-6360, sow10@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 Gilllooly, Biosafety Manager, 305-345-3269, sxg1519@med.miami.edu OR Quintin James, qaj3@miami.edu OR Melanie Peapell, 305-243-3269, mpeapell@med.miami.edu

PATHOLOGY REVIEW COMMITTEE (RPSC)
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: RCC@med.miami.edu OR Omar Alyoubi, Radiation Control Manager, 305-243-6360, drh85@med.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 requiring use of any UHT patient information, PRIOR to receipt of IRB approval. Qs: RRC@med.miami.edu OR Secondary Contact: Joey Casanova, BBA/Data Broker Manager / P: 305-243-2631/E: jcasanova@med.miami.edu

JACKSON HEALTH SYSTEM – CLINICAL RESEARCH REVIEW COMMITTEE (JHS-CRRC)
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: D. Aljuboori, 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, bkrysztof@med.miami.edu | Amy Gonzalez, Sr. Contract and Grants Analyst, 305-284-3509, agegl83@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

SONHS SIMULATION HOSPITAL
Research activities are conducted or overseen by the local investigator at SONHS Simulation Hospital. Qs: Sonia Carvalho, Director, Regulatory Support, 305-243-4639, scarvalho@med.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
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

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