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 **E:** sandrarossi@med.miami.edu **OR** via MSTeams. **Qs**: sccc.prmc@miami.edu **OR** via telephone **P:** 305-243-6013

For population science or social behavioral study specific requirements, please contact sbs.prmc.startup@miami.edu for more information.

CLINICAL RESEARCH LABORATORY SERVICES (CRLS)

SCCCIRB ID #: IRBAC013

Research using Clinical Research Laboratory Services must be reviewed by the CRLS lab staff **PRIOR** to any research lab utilization.
Qs: Shaddai Lopez, Director, CRLS **P:** 305-243-6618 (office)
E: scccresearchlab@med.miami.edu

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)

IRB ID #: IRBAC004

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 **P:** 305-243-2311 **E:** ekapsalis@miami.edu **OR Liz Meza**, Senior Regulatory Analyst, IACUC / IBC / ESCRO **E:** lmeza@miami.edu

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 **E:** lmeza@miami.edu

CONFLICT OF INTEREST (COI) COMMITTEE

IRB ID #: IRBAC007

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 **E:** LHayes@med.miami.edu **OR** call the UDisclose System Helpline **P:** 305-243-0877

INVESTIGATOR INITIATED TRIAL SERVICES AT THE U (IITS-U)

IRB ID #: IRBAC008

IITS-U ancillary review is required for new studies involving an IND or IDE held by the University of Miami Investigator and for protocol amendments made to the studies. **Qs: Nicole S. McCullough**, MS, CCRP Director, Investigator Initiated Trial Services at the U (IITS-U)
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, CHRC, CIP, Data Broker Manager P: 305-243-2631 E: jcasanova@miami.edu**

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: Diana R. Hernandez, Manager, Radiation Control
P: 305-243-6360 **E:** 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

IRB ID #: IRBAC003

Secondary Contacts at the Biosafety Office:
Shane Gillooly, Biosafety Manager **P:** 305-243-3269 **E:** sxg1519@med.miami.edu
Melanie Peapell P: 305-243-3269 **E:** MPeapell@med.miami.edu

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 Sophie Egea, PhD**, Director, Clinical Research Department of Pathology and Laboratory Medicine

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, Office of the Executive Dean for Research - EDR, **P:** 305-243-8842 **E:** c.sandoval1@med.miami.edu

IRB ID #: IRBAC010

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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
P: 305-585-7226 **E:** Katuska.Barbery@jhsmiami.org

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
P: 305-284-3942 **E:** TVikhlyantseva@med.miami.edu **OR**
Bianca Krysztof, Sr. Manager, Research Administration
P: 305-284-1735 **E:** b.gjorgievski@miami.edu **OR**
Amy Gonzalez, Sr. Contract and Grants Analyst
P: 305-284-3509 **E:** aeg183@miami.edu

SCHIFF CENTER FOR LIVER DISEASES

IRB ID #: IRBAC015

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
P: 305-243-4639 **E:** carvalho@med.miami.edu

SONHS SIMULATION HOSPITAL

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 **P:** 305-284-9139 **E:** vbehar-zusman@miami.edu **OR Christian Ruiz DeGennaro**, Director, Research Support **E:** cruiz@miami.edu

IRB ID #: IRBAC016

RESEARCH FEASIBILITY COMMITTEE (RFC)

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
P: 561-548-1414 **E:** Jill.Kinley@HCAHealthcare.com

IRB ID #: IRBAC018

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