Ancillary reviews are reviews by other compliance groups or individuals that inform the IRB's review of a new study or a modification to an existing study.

- Ancillary reviews may be assigned by either the researcher or the IRB.
- Once an ancillary review is triggered, researchers should work directly with those entities to ensure compliance.
- The ancillary review in Huron IRB is intended to support compliance across multiple oversight groups and not replace review processes by other compliance groups.
- Ancillary reviews are not assigned by the IRB if a project does not meet the federal definition of Human Subject Research.

The impact of an ancillary review group's approval on the IRB's review process varies.

- Typically, final IRB approval is held until the required ancillary group concludes their review.
- In some instances, the IRB will not initiate its review without documentation of approval by critical review entities.
- The IRB will not hold for the completion of ancillary reviews for studies that meet exempt criteria.
- Documentation of approval by an ancillary review group is provided to the researcher.
- In rare instances, either the ancillary review group or an IRB member may request deviations from the typical review path. An IRB member may recommend holding a submission until an ancillary approval is granted from a key committee **OR** an ancillary review group may recommend IRB review move forward while a required approval is still pending.
- Ancillary reviews that are required for IRB review/approval are not the same requirements for study activation. Study activation requirements are different and managed by Clinical Research Administration.

The tables below highlight the ancillary review groups available and illustrates the typical impact an ancillary review has on IRB review. Please contact the IRB or relevant ancillary review contacts (listed below) with any questions about the ancillary review process or specific requirements.

Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Cancer Protocol Review & Monitoring Committee (CPRMC) **IRB ID #: IRBAC001** Sandra Rossi *Manager, Research Support* *Sylvester Comprehensive Cancer Center* sandrarossi@med.miami.edu ***or*** contact via Team **Questions:** sccc.prmc@miami.edu 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** OPERA (Formerly PES)	***Protocol updates*** require PRMC approval if PRMC is listed as an ancillary review committee.	N/A	N/A	N/A
Clinical Trial Disclosure Committee (CTD) **IRB ID #: IRBAC002**	This process facilitates the UM's compliance 42 CFR § 11, FDAAA Section 801,	N/A	N/A	N/A	N/A

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Karre Wetherington, CCRP, CCA *Sr. Clinical Trial Disclosure Associate* *Regulatory Affairs & Assessment* Phone: (305) 243-1107 E-mail: kwetherington@miami.edu	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-				

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
	c8ef-422e-b7f2-f79acb2dbe1e/ **Clinical Trial Determination Questionnaire**				
Environmental Health and Safety Committee (EHS) **IRB ID #: IRBAC003** 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	EHS approval is required for studies that collect patient specimens or introduce risk group 2 agents (or higher) or any recombinant therapeutics. **Requirement**: Complete the Biosafety Ancillary Risk Assessment Form and upload via the Manage Ancillary Reviews activity in IBISResearch-IRB.	All modifications that introduce new risk group 2 agents (or higher) or any new recombinant therapeutics not included in the previous protocol. **Requirement**: Complete the Biosafety Ancillary Risk Assessment Form and upload via the Manage Ancillary Reviews activity in IBISResearch-IRB.	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 2) UHealth OSHA's Bloodborne Pathogens, Biomedical Waste, Latex Allergy and TB Training required every year via ULearn
Embryonic Stem Cell Research Oversight Committee (ESCRO) **IRB ID #: IRBAC004**	Research involving any work with the use of human embryonic stem cells and/or their derivatives must be	Modifications to the initially approved study approved for embryonic stem cells	New personnel*	Yes	Ethical Oversight of HESC Research. This is an online module available via ULearn. Individuals

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Primary point of contact: Dr. Ellen Kapsalis *Director of Compliance* *IACUC / IBC / ESCRO* ekapsali@med.miami.edu Secondary Contact: Liz Meza *Senior Regulatory Analyst* *IACUC / IBC / ESCRO* lmeza@miami.edu	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 IRB system. Please visit the ESCRO committee website at https://www.research.miami.edu/about/admin-areas/raa/escro/index.html for further information.	and/or their derivatives 1. update to the IB or protocol amendment 2. protocol closure 3. RNIs **Requirement**: Such submissions must be submitted to the ESCRO committee **outside** of the IRB system. The review process for the ESCRO committee can occur concurrently, but the HSRO cannot release the IRB approval until ESCRO signs off.			listed or added onto a ESCRO related protocol must complete this training once. Contact Liz Meza *Senior Regulatory Analyst* *IACUC / IBC / ESCRO* lmeza@miami.edu for more information.
Institutional BioSafety Committee (IBC) **IRB ID #: IRBAC005**	All clinical trial protocols that use recombinant DNA, synthetic nucleic acid materials, or a genetically	Modifications to the initially approved study approved for the use of	Adding personnel for following roles: 1. Change of PI	Yes	Biosafety Training is required every three years for all research personnel and for new

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Primary point of contact: IBCsupport@miami.edu Secondary Contact: Liz Meza *Senior Regulatory Analyst* *IACUC / IBC / ESCRO* lmeza@miami.edu	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. Such submissions must be submitted directly to the IBC committee **outside** of the IRB at IBCsupport@miami.edu. The review process for the IBC and the IRB can occur concurrently, but the HSRO cannot release the IRB approval until IBC signs off.	recombinant DNA, synthetic nucleic acid materials 1. update to the IB or protocol amendment 2. Closure of study 3. RNIs **Requirement**: Please refer to the documents for Human Gene Transfer Research at Institutional Biosafety Committee (IBC) | UResearch | University of Miami.	2. *sub-investigator* 3. *study coordinator* 4. *Individuals administering study product (nurses, etc.)* *Lab personnel handing study product*		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.***

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Human Use Radiation Safety Committee (HRSC) **IRB ID #: IRBAC006** **Diana R. Hernandez** *Radiation Control Manager* 305-243-6360 drh85@med.miami.edu **Maxwell Amurao** *Executive Director, Radiation Safety* mxa5672@med.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 Committee (COIC) **IRB ID #: IRBAC007** **Lory Hayes, Ph.D.** *Director of DSAM (Disclosures & Scholarly Activities Management)* LHayes@miami.edu	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	Modifications meeting criteria for review	Modifications meeting criteria for review	N/A	All investigators are required to complete UM's disclosure process and COI training prior to engaging in Scholarly Activities, repeated annually.

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Call the UDisclose System helpline (305-243-0877) with questions about UM's COI policy or disclosure requirements.	to develop a management plan. Complete the disclosure process in the UDisclose System.				
Investigator Initiated Trial Services at the U (IITS-U) **IRB ID #: IRBAC008** For New PI training: **Alina Gjerpen** *Project Manager, IITS-U* Executive Dean for Research arg136@med.miami.edu For Investigator Initiated Trial services: **Nicole S. McCullough, MS, CCRP** *Director, IITS-U* *Executive Dean for Research* *University of Miami, Miller School of Medicine*	IITS-U ancillary review is required for new studies involving an IND or IDE held by a University of Miami Investigator and for protocol amendment made to these studies. Before the initial ancillary approval, the PI should contact IITS-U (iitsu@miami.edu) to discuss the monitoring plan for the study.	N/A	N/A	N/A	To ensure new PIs conducting their first interventional clinical trial at the University are aware of their responsibilities to satisfy federal regulations and University policies and procedures as per University policy HSR-P-001.

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Ph: 305-243-0493 E-mail: nshank@med.miami.edu					
Data Security Ancillary Committee (DSAC) **IRB ID #: IRBAC009** Primary point of contact: dsac@miami.edu Secondary Contact: **Joey Casanova, BBA** *Data Broker Manager* 305-243-2631 jcasanova@miami.edu	Studies collecting, storing, and transmitting protected health information (PHI). Forms: Research Data Security Assessment Form For information on the review process for data privacy plans, please see SOP-HB-008-01	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) ** **IRB ID #: IRBAC010** **Oncology Protocols**	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	Modifications that are adding UHT to the study. Requirement: Please complete the UHT Research Request form in the Link	N/A	N/A	N/A

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Mitchell Diaz MSN, AGPCNP-BC Inpatient Research Nurse Specialist – Hematology/Oncology University of Miami Hospital and Clinics UHealth Tower O (305) 912-4633 mxd1433@miami.edu **Danny Pino BSN, RN, OCN, BMTCN** Inpatient Research Nurse Specialist – Hematology/Oncology University of Miami Hospital and Clinics UHealth Tower O (305) 912-4633 d.pino2@umiami.edu **Non-Oncology Protocols** **Carlos Sandoval**	recruitment, facility use, subject interventions such as tests, measurements, drug administration, surgery, or obtaining subject consent. UHT Ancillary Approval is required to determine feasibility of UHT Departments for clinical study protocols Requirement: Please complete the UHT Research Request form in the Link below: https://redcap.miami.edu/surveys/?s=HKP9E74X7ACHTMDM and upload via the Manage Ancillary Reviews activity in IBISResearch-IRB.	below: https://redcap.miami.edu/surveys/?s=HKP9E74X7ACHTMDM and upload via the Manage Ancillary Reviews activity in IBISResearch-IRB.			

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Director, CTRS Research Operations Miami Miller School of Medicine Office of the Executive Dean for Research - EDR Office: (305)243-8842					
Clinical Translational Research Site (CTRS)** **IRB ID #: IRBAC011** **Carlos Sandoval** Director, CTRS Research Operations Miami Miller School of Medicine Office of the Executive Dean for Research - EDR Office: (305)243-8842	Research protocols using the EDR Clinical Translational Research Site (CTRS) facilities must be reviewed by the CTRS Ancillary Committee. CTRS Provides the following services: Clinical Services (Nursing, Pharmacokinetics, Jackson Memorial Hospital Clinical Research Nursing Support, Laboratory processing, Clinical Study procedures, In-Patient and Outpatient Clinical Services)	N/A	N/A	N/A	N/A

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
	Clinical Research Coordinator Services (Consenting, Screening, Recruitment, Study visits, Documentation and data entry) **Requirement**: Investigators should complete the CTRS Services Requested Form				
Pathology Review Committee (RPSC) ** **IRB ID #: IRBAC012** **Sophie Egea, PhD** Director, Clinical Research Department of Pathology and Laboratory Medicine Research Mailbox: DPLMresearch@med.miami.edu	All research studies using human samples including bodily fluids (blood, urine, ascites, saliva), and/or biospecimens not limited to frozen tissue, fresh tissue, or archived tissue (paraffin embedded/FFPE), and/or slides must be reviewed by the Department of Pathology and Laboratory Medicine. Review by pathology ancillary review committee	Required under the following circumstance: Protocol updates including human samples	N/A	Protocol updates including human samples	N/A

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
	is required to process all requests using human samples for research. Please fill out the form using this link: PRC Form. The Department of Pathology and Laboratory Medicine has 2 human research cores: Translational Research Histopathology Laboratory (TRHL) and Laboratory of Clinical Biosciences (LCB). **Pathology Ancillary Review approval is required before placing iLab requests.**				
Clinical Research Laboratory Services (formerly known as SCCC Research Lab & Satellites- SCCC) ** **IRB ID #: IRBAC013**	Research using Clinical Research Laboratory Services (formerly known as SCCC Research Lab & Satellites) facilities must be reviewed by the CRLS lab	N/A	N/A	N/A	N/A

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Shaddai Lopez *Director, CRLS* 305-243-6618 (office) scccresearchlab@med.miami.edu	staff prior to any research lab utilization. Coordinators should fill out the SCCC Research Lab & Satellites Services Request Form and send it to: scccresearchlab@med.miami.edu This form must also be uploaded via the Manage Ancillary Reviews activity in IBISResearch-IRB.				
Jackson Health System – Clinical Research Review Committee – (CRRC) ** **IRB ID #: IRBAC014** **Katuska Barbery, MBA** *Director of Clinical Research, JHS Office of Research* *Jackson Health System* 305-585-7226	Approval from the JHS-CTO 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	N/A	N/A	N/A	N/A

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Katuska.Barbery@jhsmiami.org	resources. Please complete the Jackson Clinical Trials Office Application Form and upload to the IRB system via the Manage Ancillary Reviews activity, and send the JHS Study Calendar directly to the CTO. https://jhsmiami.org/jhsofficeresearch/ Additional information regarding the JHS CTO approval process can be found at: https://jacksonhealth.org/administrative/clinical-trials/				
Schiff Center for Liver Diseases ** **IRB ID #: IRBAC015** Sonia Carvalho *Director, Regulatory Support*	N/A	N/A	N/A	N/A	N/A

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
scarvalho@med.miami.edu (305) 2434639					
SONHS Simulation Hospital ** **IRB ID #: IRBAC016** Victoria Behar-Zusman *Professor, School of Nursing and Health Studies* vbehar-zusman@miami.edu (305) 2849139 Christian Ruiz DeGennaro *Director, Research Support* cruiz@miami.edu	N/A	N/A	N/A	N/A	N/A
JFK Hospital ** **IRB ID #: IRBAC018** **Jill Kinley, DNP, APRN, CCRC** *Director of Clinical Research* Jill.Kinley@HCAHealthcare.com (561) 548-1414	N/A	N/A	N/A	N/A	N/A
MCA Review Group (ORA) **IRB ID #: IRBAC019**	All Submissions where question #5 in "Study Scope" is answered "yes".	Revised protocols	PI changes only	N/A	N/A

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Tatyana Vikhlyantseva, *Director, Research Administration* TVikhlyantseva@med.miami.edu 305-284-3942 **Bianca Krysztof,** *Sr. Manager, Research Administration* b.gjorgievski@miami.edu 305-284-1735 **Amy Gonzalez,** *Sr. Contract and Grants Analyst* aeg183@miami.edu 305-284-3509	The purpose of this review is to confirm if a Medicare Coverage Analysis (MCA) is needed. ORA will be reviewing the correctness of this answer to ensure compliance with Clinical Management (CTM) and participant Enrollment and Tracking Policy. If answer is Yes, study will be tracked for billing in Velos by CRRC and MCA must be available in Velos. If answer is No, study will not be tracked for billing in Velos and MCA is not needed.				

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
	ORA will provide feedback on whether or not question 5 was answered correctly and provide recommendation on required actions as applicable. Action above would ensure compliant research billing and eliminate the requests for unnecessary MCAs.				
Cellular Therapy Lab ** IRB ID #: IRBAC020 Dr. Cara Benjamin Director, Cellular Therapy Lab c.benjamin3@med.miami.edu O:(305) 243-5534 F: (305) 243-3408	All clinical trial protocols involving recombinant DNA, synthetic nucleic acid materials, genetically modified organisms, or gene-based therapeutics require Cell Therapy Lab Ancillary Review. Detailed	All modifications that introduce new cellular therapy products/infusion or transplant product/infusion not included in the previous protocol or IB.	Adding personnel for following roles: 1. Change of PI 2. Sub-investigator	N/A	NA

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Ancillary Review Requirements for Human Subject Research Studies					
Committee Name and Contact	**Initial study**	**Modifications**		**Continuing Review**	**Training Requirements**
		Other Parts of Study	**Study Team Member Info**		
Teams Veronica Reed Medical Technologist 3 vxr267@med.miami.edu (305) 243-4168 Questions or Concerns: CTL_ClinicalTrials@med.miami.edu	information can be found in the decision tree. Prior approval from the Cellular Therapy Interest Group must be obtained before using the service. Transplantation & Cellular Therapy (TCT) Investigators will evaluate the study protocol, including risk assessments, intended clinical applications, and oversight measures. Robby Friedman Sr. Manager rxf147@miami.edu CRSBMTCellularTherapy@miamiedu.onmicrosoft.com TCTPrimaryInvestigators@miamiedu.onmicrosoft.com	Requirement: Such submissions may need to be submitted to IBC			

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