

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.



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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		
<p><b>Protocol Review &amp; Monitoring Committee (PRMC)</b>  <b>IRB ID #: IRBAC001</b>                      Sandra Rossi                      Manager, Research Support                      Sylvester Comprehensive Cancer Center  <a href="mailto:sandrarossi@med.miami.edu">sandrarossi@med.miami.edu</a>  <a href="http://www.miami.edu">u</a>                      Questions: <a href="mailto:sccl.prmc@miami.edu">sccl.prmc@miami.edu</a> or via telephone at 305-243-6013                      For population science or social behavioral study specific requirements, please contact <a href="mailto:sbs.prmc.startup@miami.edu">sbs.prmc.startup@miami.edu</a> for more information.</p>	<p>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 system OPERA (formerly PES, which can be accessed at <a href="https://pes.sylvester.org">https://pes.sylvester.org</a>).</p>	<p><b>Modifications</b>  <b>Other Parts of Study</b>                      In most cases, protocol updates require PRMC approval if the PRMC is listed as an ancillary review committee under the parent study.</p> <p><b>Local addendum</b>                      that does not impact parent protocol <b>does not need</b> to be reviewed by PRMC.</p> <p><b>Protocol clarification memos</b> that are sent ahead of a modified study protocol <b>do not</b> require PRMC review.</p> <p>Amendments for studies that fall under the category of ETCTN, NCTN, NCI</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>

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		<p>Cancer Therapy Evaluation Program (CTEP), and cooperative group-approved <b>are not required to be submitted to the PRMC in OPERA and only require ancillary sign off in IBIS.</b></p> <p>Please note that this does not include studies being sponsored by industry or by a non-NCI-designated cancer center, which are required to be submitted to the PRMC in OPERA and signed off by PRMC in IBIS. An email will need to be sent to the PRMC manager for awareness so that PRMC can sign off in IBIS for</p>			

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		amendments that fall under this umbrella category.			
<p><a href="#">Clinical Trial Disclosure Committee (CTD)</a>  <b>IRB ID #: IRBAC002</b></p> <p>Karre Wetherington, CCRP, CCA  <i>Sr. Clinical Trial Disclosure Associate</i>  <i>Human Subject Research Office</i>                      Phone: (305) 243-1107                      E-mail: <a href="mailto:kwetherington@miami.edu">kwetherington@miami.edu</a></p>	<p>This process facilitates the UM’s compliance 42 CFR § 11, FDAAA Section 801, FDAMA Section 110, CMS, NIH and ICMJE.</p> <p>The CTD Ancillary Committee determines if a study must register on ClinicalTrials.gov. This determination includes:</p> <ul style="list-style-type: none"> <li>• Is it a clinical trial?</li> <li>• Who must register the study on ClinicalTrials.gov?</li> <li>• Does the protocol have all information needed for registration and reporting?</li> </ul>	N/A	N/A	N/A	N/A

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	<ul style="list-style-type: none"> <li>Does the informed consent form have the required CTD language?</li> </ul> <p><b>Clinical Trial Disclosure: Determination and Protocol Registration Policy</b>  <a href="https://umhs-ummg.policystat.com/policy/token_access/628beb33-c8ef-422e-b7f2-f79acb2dbe1e/">https://umhs-ummg.policystat.com/policy/token_access/628beb33-c8ef-422e-b7f2-f79acb2dbe1e/</a></p> <p><b>Clinical Trial Determination Questionnaire</b></p>				
<p><b><a href="#">Environmental Health and Safety Committee (EHS)</a></b>  <b>IRB ID #: IRBAC003</b></p> <p>Primary point of contact:  <a href="mailto:BSO_Review@miami.edu">BSO_Review@miami.edu</a></p> <p>Secondary Contacts at the Biosafety Office:  <b>Shane Gillooly</b>  <i>Biosafety Manager</i></p>	<p>EHS approval is required for studies that collect patient specimens or introduce risk group 2 agents (or higher) or any recombinant therapeutics.</p> <p><b>Requirement:</b> Complete the <a href="#">Biosafety Ancillary Risk Assessment Form</a> and upload via the Manage</p>	<p>All modifications that introduce new risk group 2 agents (or higher) or any new recombinant therapeutics not included in the previous protocol.</p> <p><b>Requirement:</b> Complete the <a href="#">Biosafety Ancillary Risk Assessment Form</a></p>	<p>Adding personnel who will be collecting human specimens, processing samples, or handling risk group 2 (or higher) agents*.</p>	N/A	<p>1) IBC Biosafety Training every three years for Clinical Staff via <a href="#">ULearn</a></p> <p>2) UHealth OSHA's Bloodborne Pathogens, Biomedical Waste, Latex Allergy and TB Training required every year via <a href="#">ULearn</a></p>

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		Other Parts of Study	Study Team Member Info		
305-243-3269 <a href="mailto:sxg1519@med.miami.edu">sxg1519@med.miami.edu</a>	Ancillary Reviews activity in IBISResearch-IRB.	and upload via the Manage Ancillary Reviews activity in IBISResearch-IRB.			
<p><b><a href="#">Embryonic Stem Cell Research Oversight Committee (ESCRO)</a></b>  <b>IRB ID #: IRBAC004</b></p> <p>Primary point of contact:                      Dr. Ellen Kapsalis  <i>Director of Compliance</i>                      IACUC / IBC / ESCRO  <a href="mailto:ekapsali@med.miami.edu">ekapsali@med.miami.edu</a></p> <p>Secondary Contact:                      Liz Meza  <i>Senior Regulatory Analyst</i>                      IACUC / IBC / ESCRO  <a href="mailto:lmeza@miami.edu">lmeza@miami.edu</a></p>	<p>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.</p> <p><b>Requirement:</b> Such submissions must be submitted to the ESCRO committee <b>outside</b> of the IRB system.</p> <p>Please visit the ESCRO committee website at <a href="https://www.research.miami.edu">https://www.research.miami.edu</a></p>	<p>Modifications to the initially approved study approved for embryonic stem cells and/or their derivatives</p> <ol style="list-style-type: none"> <li>1. update to the IB or protocol amendment</li> <li>2. protocol closure</li> <li>3. RNIs</li> </ol> <p><b>Requirement:</b> Such submissions must be submitted to the ESCRO committee <b>outside</b> of the IRB system. The review process for the ESCRO committee can occur</p>	New personnel*	Yes	Ethical Oversight of HESC Research. This is an online module available via CITI. Individuals listed or added onto a ESCRO related protocol must complete this training once. Contact Liz Meza <i>Senior Regulatory Analyst</i> IACUC / IBC / ESCRO <a href="mailto:lmeza@miami.edu">lmeza@miami.edu</a> for more information.

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	<a href="http://ami.edu/about/admin-areas/raa/escro/index.html">ami.edu/about/admin-areas/raa/escro/index.html</a> for further information.	concurrently, but the HSRO cannot release the IRB approval until ESCRO signs off.			
<p><b><a href="#">Institutional BioSafety Committee (IBC)</a></b>  <b>IRB ID #: IRBAC005</b></p> <p>Primary point of contact:  <a href="mailto:IBCsupport@miami.edu">IBCsupport@miami.edu</a></p> <p>Secondary Contact:                      Liz Meza                      Senior Regulatory Analyst                      IACUC / IBC / ESCRO  <a href="mailto:lmeza@miami.edu">lmeza@miami.edu</a></p>	<p>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).</p> <p><b>Requirement:</b> Please refer to the documents for Human Gene Transfer Research at <a href="#">Institutional Biosafety Committee (IBC)   UResearch   University of Miami</a>.</p> <p>Such submissions must be submitted directly to the IBC committee <b>outside</b> of the</p>	<p>Modifications to the initially approved study approved for the use of recombinant DNA, synthetic nucleic acid materials</p> <ol style="list-style-type: none"> <li>1. update to the IB or protocol amendment</li> <li>2. Closure of study</li> <li>3. RNIs</li> </ol> <p><b>Requirement:</b> Please refer to the documents for Human Gene Transfer Research at</p>	<p>Adding personnel for following roles:</p> <ol style="list-style-type: none"> <li>1. Change of PI</li> <li>2. <i>sub-investigator</i></li> <li>3. <i>study coordinator</i></li> <li>4. <i>Individuals administering study product (nurses, etc.)</i></li> </ol> <p><i>Lab personnel handling study product</i></p>	<p>Yes</p>	<p>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).</p> <p><b><i>This training is available via ULearn as a module titled "IBC Biosafety Training for Clinical Staff".</i></b></p>

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		Other Parts of Study	Study Team Member Info		
	IRB at <a href="mailto:IBCSupport@miami.edu">IBCSupport@miami.edu</a> .  The review process for the IBC and the IRB can occur concurrently, but the HSRO cannot release the IRB approval until IBC signs off.	<a href="#">Institutional Biosafety Committee (IBC)   UResearch   University of Miami.</a>			IBC NIH Guidelines Training (must be completed once) by PIs, sub-investigators, co-investigators.  <i>This training is a PowerPoint presentation. Contact <a href="mailto:IBCSupport@miami.edu">IBCSupport@miami.edu</a> for review and credit.</i>
<a href="#">Human Use Radiation Safety Committee (HRSC)</a> IRB ID #: IRBAC006  <b>Diana R. Hernandez</b> Radiation Control Manager 305-243-6360 <a href="mailto:drh85@med.miami.edu">drh85@med.miami.edu</a>  <b>Maxwell Amurao</b>  Executive Director, Radiation Safety  <a href="mailto:mxa5672@med.miami.edu">mxa5672@med.miami.edu</a>	Protocols involving the use of radiation or radioactive materials, including MRI, high-intensity focused ultrasound (HIFU), and theranostic research studies, are utilized for research purposes.	Modifications that introduce radiation or radioactive materials, including MRI, high-intensity focused ultrasound (HIFU), and theranostic research studies, are utilized for research purposes.	N/A	N/A	N/A

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		Other Parts of Study	Study Team Member Info		
<p><a href="#">Conflict of Interest Committee (COIC)</a> IRB ID #: IRBAC007</p> <p><b>Lory Hayes, Ph.D.</b> <i>Director of DSAM (Disclosures &amp; Scholarly Activities Management)</i> <a href="mailto:LHayes@miami.edu">LHayes@miami.edu</a></p> <p><i>DSAM email box address</i> <a href="mailto:DSAM@miami.edu">DSAM@miami.edu</a></p> <p><i>Call the UDisclose System helpline (305-243-0877) or email <a href="mailto:DSAM@miami.edu">DSAM@miami.edu</a> with questions about UM's COI policy or disclosure requirements.</i></p>	<p>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.</p> <p>Complete the the COI training and disclosure process in the UDisclose System.</p>	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 (including research), repeated annually.
<p><a href="#">Investigator Initiated Trial Services at the U (IITS-U)</a> IRB ID #: IRBAC008</p>	<p><a href="#">IITS-U</a> ancillary review is required for new studies involving an IND or IDE held by a University of Miami investigator.</p>	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

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		Other Parts of Study	Study Team Member Info		
<p><b>Nicole S. McCullough, MS, CCRP</b>                      Director, IITS-U                      Executive Dean for Research                      University of Miami, Miller                      School of Medicine                      Ph: 305-243-0493                      E-mail:                      nshank@med.miami.edu</p> <p>For New PI training:  <b>Alina Gjerpen</b>                      Project Manager, IITS-U                      Executive Dean for Research                      arg136@med.miami.edu</p> <p>For Investigator Initiated                      Trial services:</p>	<p>Before the initial ancillary approval, the PI should contact IITSU (<a href="mailto:iitsu@miami.edu">iitsu@miami.edu</a>) to discuss the monitoring plan for the study.</p> <p>In addition, IITSU coordinates training for new PIs to ensure that new PIs conducting their first interventional clinical trial at the University are aware of their responsibilities to satisfy federal regulations and University requirements (policy HSR-P-001).</p>				<p>federal regulations and University policies and procedures as per University policy HSR-P-001.</p>

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<p><b>Data Security &amp; Artificial Intelligence Ancillary Committee (DSAC)</b> IRB ID #: IRBAC009</p> <p>Primary point of contact: <a href="mailto:dsac@miami.edu">dsac@miami.edu</a></p> <p>Secondary Contact (DSAC): <b>Joey Casanova, BBA</b> <i>Data Broker Manager</i> 305-243-2631 <a href="mailto:jcasanova@miami.edu">jcasanova@miami.edu</a></p> <p>Secondary Contact (AI): Timothy R. Smith, Ph.D., CISSP, PMP Director IT - Research Informatics Governance &amp; Security 305-243-0388 <a href="mailto:txs908@med.miami.edu">txs908@med.miami.edu</a></p>	<p>Studies collecting, storing, and transmitting protected health information (PHI).</p> <p>In addition, this group will assess the use of artificial intelligence tools in research in advance of IRB review to ensure Institutional requirements are met.</p> <p>Forms: <a href="#">Research Data Security Assessment Form</a></p> <p>For information on the review process for data privacy plans, please see <a href="#">SOP-HB-008-01</a></p>	Modifications meeting criteria for review	N/A	N/A	N/A

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		Other Parts of Study	Study Team Member Info		
<b>Department Review</b>	Based on department. Usually conducted by the Department Chair or the Chair's designee.	Required for PI transfer	N/A	N/A	N/A
<b>UHealth Tower (UHT) **</b> <b>IRB ID #: IRBAC010</b>  <u>Oncology Protocols</u>  Natacha Innocent MSN-ADM, RN, CCRP Inpatient Research Nurse Specialist Hematology & Medical Oncology Oncology Inpatient Services University of Miami Hospital and Clinics UHealth Tower <a href="mailto:nxi71@med.miami.edu">nxi71@med.miami.edu</a>  Deborah Duya, BSN, RN Inpatient Research Nurse Specialist – Hematology/Oncology University of Miami Hospital and Clinics	To ensure proper oversight and resource allocation, all research studies must obtain approval from the UHT Ancillary Committee if they involve: <ul style="list-style-type: none"> <li>• Conducting any research activities within a UHT facility.</li> <li>• Accessing sensitive UHT patient information.</li> <li>• Utilizing any of the following UHT resources:                             <ul style="list-style-type: none"> <li>○ Recruiting research subjects</li> <li>○ Using UHT facilities</li> <li>○ Performing interventions on</li> </ul> </li> </ul>	Modifications that involve adding UHT to the study should be uploaded via the Manage Ancillary Reviews activity in IBIS Research-IRB.  <a href="https://redcap.miami.edu/surveys/?s=HKP9E74X7ACHTMDM">https://redcap.miami.edu/surveys/?s=HKP9E74X7ACHTMDM</a>  and upload via the Manage Ancillary Reviews activity in IBISResearch-IRB.	N/A	N/A	N/A

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<p>UHealth Tower <a href="mailto:dxid1001@miami.edu">dxid1001@miami.edu</a> 305-912-4633</p> <p><b><u>Non-Oncology Protocols</u></b></p> <p>Carlos Sandoval, MSc, MA Director of Clinical Research Operations   CTRS Office of the Executive Dean for Research University of Miami Miller School of Medicine <a href="mailto:c.sandoval1@med.miami.edu">c.sandoval1@med.miami.edu</a> 305-243-8842</p>	<p>subjects (such as tests, measurements, drug administration, or surgery)</p> <ul style="list-style-type: none"> <li>○ Obtaining informed consent from subjects</li> </ul> <p><a href="https://redcap.miami.edu/surveys/?s=HKP9E74X7ACHTMDM">https://redcap.miami.edu/surveys/?s=HKP9E74X7ACHTMDM</a></p> <p>Upload it via the Manage Ancillary Reviews activity in IBIS Research-IRB.</p>				
<p><b><u>Clinical Translational Research Site (CTRS)**</u></b> IRB ID #: IRBAC011</p> <p><b><u>Carlos Sandoval</u></b> <u>Director, CTRS Research Operations</u></p>	<p>To ensure the successful execution of your research, protocols utilizing the EDR Clinical Translational Research Site (CTRS) facilities require review by the CTRS Ancillary Committee. This step helps</p>	<ul style="list-style-type: none"> <li>• Please complete the CTRS Request form using the link provided:</li> </ul>	N/A	N/A	N/A

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<a href="#">Miami Miller School of Medicine</a> <a href="#">Office of the Executive Dean for Research - EDR</a> <a href="#">Office: (305)243-8842</a>	<p>align our resources with your study's needs.</p> <p>CTRS offers a robust suite of services designed to facilitate your clinical research study execution.  <a href="https://med.miami.edu/research/clinical-research/ctrs">https://med.miami.edu/research/clinical-research/ctrs</a></p> <ul style="list-style-type: none"> <li>• Please complete the CTRS Request form using the link provided:</li> <li>• <a href="https://redcap.miami.edu/surveys/?s=JKRHEWWKAHHMJERJ">https://redcap.miami.edu/surveys/?s=JKRHEWWKAHHMJERJ</a></li> <li>• Upload it via the Manage Ancillary Reviews activity in IBIS Research-IRB.</li> <li>• Modifications that involve adding CTRS to the study should be uploaded via the Manage Ancillary</li> </ul>	<p><a href="https://redcap.miami.edu/surveys/?s=JKRH EWWKAHHMJERJ">https://redcap.miami.edu/surveys/?s=JKRH EWWKAHHMJERJ</a></p> <ul style="list-style-type: none"> <li>• Upload it via the Manage Ancillary Reviews activity in IBIS Research-IRB.</li> <li>• Modifications that involve adding CTRS to the study should be uploaded via the Manage Ancillary Reviews activity in IBIS Research-IRB.</li> </ul>			

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	Reviews activity in IBIS Research-IRB.				
<p><b>Pathology Review Committee (RPSC) **</b> IRB ID #: IRBAC012</p> <p><b>Sandra Rosa</b> Manager, Regulatory Support</p> <p><b>Maria T. Bertoli</b> Manager, Clinical Research</p> <p><b>Sophie Egea, PhD</b> Director, Clinical Research</p> <p>Department of Pathology and Laboratory Medicine</p> <p>Research Mailbox: <a href="mailto:DPLMresearch@med.miami.edu">DPLMresearch@med.miami.edu</a></p>	<p>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.</p> <p>Review by pathology ancillary review committee is required to process all requests using human samples for research.</p> <p>Please fill out the REDCap form using this link: <a href="#">PRC Form</a>. Add the completed form as an attachment to</p>	<p>Required under the following circumstance:</p> <p>Protocol updates including human samples</p>	N/A	Protocol updates including human samples	N/A

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	<p><b>the Ancillary Review in IBISResearch.</b></p> <p>The Department of Pathology and Laboratory Medicine has 2 human research cores: Translational Research Histopathology Laboratory (TRHL) and Laboratory for Clinical Biosciences (LCB).</p> <p>*Pathology Ancillary Review approval is required before placing iLab requests.</p> <p>**Large sample and/or Tissue Microarray requests require additional approval by DPLM Adjudication Committee for Clinical Oversight of Research Data and samples (DACCORD).</p>				
<p><b>Clinical Research Laboratory Services</b> (formerly known as SCCC Research Lab &amp; Satellites- SCCC) ** IRB ID #: IRBAC013</p>	<p>Research using Clinical Research Laboratory Services (formerly known as SCCC Research Lab &amp; Satellites) facilities must be</p>	N/A	N/A	N/A	N/A

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<p><b>Shaddai Lopez</b>                      Director, CRLS                      305-243-6618 (office)                      305-243-5232 (lab)  <a href="mailto:sxl4464@med.miami.edu">sxl4464@med.miami.edu</a>                      (Lab Director E-Mail)  <a href="mailto:scccresearchlab@med.miami.edu">scccresearchlab@med.miami.edu</a>                      i.edu (General Lab E-Mail)</p>	<p>reviewed by the CRLS lab staff prior to any research lab utilization.</p> <p>Coordinators should fill out the Clinical Research Laboratory Services Feasibility Request Form and send it to:  <a href="mailto:scccresearchlab@med.miami.edu">scccresearchlab@med.miami.edu</a>,  <a href="mailto:sxl4464@med.miami.edu">sxl4464@med.miami.edu</a>,                      and  <a href="mailto:cxm2443@med.miami.edu">cxm2443@med.miami.edu</a></p> <p>If study is deemed feasible, a budget for the study will be submitted within 2 weeks of feasibility determination.</p> <p>This form must also be uploaded via the Manage Ancillary Reviews activity in IBISResearch-IRB.</p>				
<p><b>Jackson Health System – Office of Research</b></p>	<p>Approval from the JHS-ORA must be obtained for studies with any research activities</p>	<p>Notify JHS via IBIS and <a href="mailto:JHS-CTO-Submissions@jhs.miami.edu">JHS-CTO-Submissions@jhs.miami.edu</a></p>	<p>Notify JHS via IBIS</p>	<p>Notify JHS via IBIS</p>	<p>Reach out to <a href="mailto:JHS-CTO-Submissions@jhs.miami.edu">JHS-CTO-Submissions@jhs.miami.edu</a> to obtain training of</p>

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<p><b>Administration (ORA)**</b> IRB ID #: IRBAC014</p> <p><b>Katuzka Barbery, MBA</b> <i>Director of Cli Jackson Health System – Office of Research Administration (ORA)**</i> IRB ID #: IRBAC014</p> <p><b>Katuzka Barbery, MBA</b> <i>Director of Clinical Research, JHS Office of Research Administration Jackson Health System</i> 305-585-7226 <a href="mailto:Katuzka.Barbery@jhs.miami.org">Katuzka.Barbery@jhs.miami.org</a></p>	<p>(recruitment of subjects (including posting flyers), facilities use, or subject interventions such as tests, measurements, obtaining samples, drug administration, surgery, or consenting subjects) occurring at a JHS facility or any studies that involve accessing JHS patient records prior to the use of any JHS resources. Please complete the <a href="#">JHS Office Research Form</a> and upload to the IRB system via the Manage Ancillary Reviews activity, and send the <a href="#">JHS Study Calendar</a> directly to the CTO submissions inbox <a href="mailto:JHS-CTO-Submissions@jhs.miami.org">JHS-CTO-Submissions@jhs.miami.org</a></p> <p>Additional information regarding the JHS CTO approval process can be found at:</p>	<p><a href="#">mi.org</a> of any modifications to the protocol and/or ICF that may impact the budget.</p>			<p>JHS research policies and procedures prior the initiation of the study.</p>

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	<a href="#">Office of Research   Jackson Health System</a>				
<b>Schiff Center for Liver Diseases **</b> <b>IRB ID #: IRBAC015</b>  Sonia Carvalho Director, Regulatory Support <a href="mailto:scarvalho@med.miami.edu">scarvalho@med.miami.edu</a> (305) 2434639	N/A	N/A	N/A	N/A	N/A
<b>SONHS Simulation Hospital **</b> <b>IRB ID #: IRBAC016</b>  Victoria Behar-Zusman Professor, School of Nursing and Health Studies <a href="mailto:vbehar-zusman@miami.edu">vbehar-zusman@miami.edu</a> (305) 2849139  Christian Ruiz DeGennaro Director, Research Support <a href="mailto:cruiz@miami.edu">cruiz@miami.edu</a>	N/A	N/A	N/A	N/A	N/A
<b>JFK Hospital **</b> <b>IRB ID #: IRBAC018</b>	N/A	N/A	N/A	N/A	N/A

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Ancillary Review Requirements for Human Subject Research Studies					
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<p><b>Jill Kinley, DNP, APRN, CCRC</b>                      Director of Clinical Research  <a href="mailto:Jill.Kinley@HCAHealthcare.com">Jill.Kinley@HCAHealthcare.com</a>                      (561) 548-1414</p>					
<p><b>MCA Review Group</b>                      IRB ID #: IRBAC019 **  <b>Tatyana Vikhlyantseva,</b>                      Director, Research Administration  <a href="mailto:TVikhlyantseva@med.miami.edu">TVikhlyantseva@med.miami.edu</a>                      305-284-3942</p> <p><b>Bianca Kryzstof, Sr.</b>                      Manager, Research Administration  <a href="mailto:b.giorgievski@miami.edu">b.giorgievski@miami.edu</a>                      305-284-1735</p> <p><b>Jairo Lazo, Sr. Contract and Grants Analyst</b>  <a href="mailto:jjl153@miami.edu">jjl153@miami.edu</a>                      305-284-9760</p> <p><b>Yolanda Miranda, Sr.</b>                      Contract and Grants Analyst</p>	<p>All Submissions where question #5 in "Study Scope" is answered "yes".</p> <p>The purpose of this review is to confirm if a Medicare Coverage Analysis (MCA) is needed.</p> <p>ORA will be reviewing the correctness of this answer to ensure compliance with <a href="#">Clinical Trial Management (CMT) and Participant Enrollment &amp; Tracking Policy</a></p> <p>If answer is Yes and correctness confirmed by ORA, study will be tracked for billing in Velos by CRRC</p>	Revised protocols	PI changes only	N/A	N/A

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<p><a href="mailto:YMiranda2@med.miami.edu">YMiranda2@med.miami.edu</a> (305) 284-4163</p> <p><b>Rebecca Carrasco Sr.</b> <i>Contract and Grants Analyst</i> <a href="mailto:rmc198@med.miami.edu">rmc198@med.miami.edu</a> (305) 2438156</p>	<p>and MCA must be available in Velos.</p> <p>If answer is No, study will not be tracked for billing in Velos and MCA would not be developed.</p> <p>ORA will provide feedback on whether answer YES to question 5 was answered correctly and provide recommendations on required actions as applicable.</p> <p>Actions above are intended to ensure compliant research billing and eliminate the</p>				

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	requests for unnecessary MCAs.				
<p><b>Cellular Therapy Lab **</b> IRB ID #: IRBAC020</p> <p>Dr. Cara Benjamin Director, Cellular Therapy Lab c.benjamin3@med.miami.edu u O:(305) 243-5534 F: (305) 243-3408 Teams</p> <p>Veronica Reed Medical Technologist 3 vvr267@med.miami.edu (305) 243-4168</p> <p>Questions or Concerns: CTL_ClinicalTrials@med.mia mi.edu</p>	<p>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 information can be found in the <a href="#">decision tree</a>.</p> <p>Prior approval from the Cellular Therapy Interest Group must be obtained before using the service.</p> <p>Transplantation &amp; Cellular Therapy (TCT) Investigators will evaluate the study protocol, including risk assessments, intended</p>	<p>All modifications that introduce new cellular therapy products/infusion or transplant product/infusion not included in the previous protocol or IB.</p> <p>Requirement: Such submissions may need to be submitted to IBC</p>	<p>Adding personnel for following roles:</p> <ol style="list-style-type: none"> <li>1. Change of PI</li> <li>2. Sub-investigator</li> </ol>	N/A	NA

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		Other Parts of Study	Study Team Member Info		
	clinical applications, and oversight measures.  Robby Friedman Sr. Manager rxf147@miami.edu CRSBMTCellularTherapy@miamiedu.onmicrosoft.com TCTPrimaryInvestigators@miamiedu.onmicrosoft.com				

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