# **Institutional Review Board (IRB) Authorization Agreement**

The purpose of this Institutional Review Board Authorization Agreement (the “Agreement”) is to allow institutions who sign this Agreement to cede Institutional Review Board responsibilities to the University of Miami’s (the “Institution” or “UM”) Institutional Review Board (the “UM IRB” and/or “Designated IRB”).

**Name of Institution or Organization Providing IRB Review** (Designated IRB):

The University of Miami Institutional Review Board

IRB Registration #: IRB00005621, IRB00005622, IRB00006078, IRB00000260, IRB00010711

Federalwide Assurance (FWA) #: FWA00002247

**Name of Institution(s) Relying on the Designated IRB** (Relying Institution):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Registration #: \_\_\_\_\_\_\_\_\_\_\_ Federalwide Assurance (FWA) #: \_\_\_\_\_\_\_\_\_\_

By signing this Agreement, the Relying Institution agrees that it may rely on the Designated IRB for review and continuing oversight of its human subjects research (the “Ceded Review”), as detailed further in this Agreement. In turn, the UM IRB accepts responsibility for IRB review and oversight of the Ceded Review in accordance with the terms of this Agreement.

(Check one)

 (\_\_\_) This agreement is limited to the following specific protocol(s):

          Name of Research Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

          Name of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

          Sponsor or Funding Agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Award Number, if any: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 UM Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 UM IBIS Submission number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(\_\_\_)  This agreement applies to all human subjects research studies conducted at Relying institution

 for:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ .

**Terms of Agreement**

1. Mutual Terms

This Agreement is to set forth the respective authorities, roles, and responsibilities of each party when a Ceded Review is accepted by the Designated IRB Institution in accordance with the process set forth herein. For purposes of this Agreement, “Research” means any non-exempt human subjects research within the meaning of the Federal Policy for the Protection of Human Subjects or within the meaning of any other federal human subject research regulations or policies. As used in this Agreement, Research may reference a specific study or protocol in which there will be a UM and relying party operating pursuant to the terms of this Agreement, or collectively the studies subject to Ceded Review under this Agreement.

Both the Designated IRB and the Relying Institution agree that review and approval of human subjects research under this Agreement shall be conducted in compliance with the federal regulations as codified in 45 CFR 46 and 21 CFR 50 & 56 (as applicable), other pertinent federal regulations, state and local laws, and all applicable human research protection program (HRPP) policies at the Designated IRB’s Institution.

Both the Designated IRB and the Relying Institution agree that they are primarily responsible for safeguarding the rights and welfare of research participants and that the rights and welfare of participants must take precedence over the goals and requirements of the research.

Both the Designated IRB and the Relying Institution agree that the obligations and liabilities of the Designated IRB are limited to its regulatory review and oversight of Research covered by this Agreement and that the Designated IRB will ensure its reviews and determinations are in accordance with all applicable federal regulations and human subjects protection requirements, state and local laws, and institutional policies and procedures.

Both the Designated IRB and the Relying Institution agree to develop or maintain standard operating procedures (“SOPs”) consistent with this Agreement.

This Agreement does not preclude the Relying Institution or its researchers from taking part in research not covered by this Agreement, or from participating in any other IRB authorization or reliance agreements.

This Agreement meets federal requirements for the designation of another institution’s IRB as the reviewing IRB, as set forth in the Office for Human Research Protections (“OHRP”) document Terms of the Federalwide Assurance.. This signed Agreement will be kept on file at each signatory institution and will be provided to OHRP or other federal agencies upon request.

1. Eligibility and Process to Participate in Agreement

The Relying Institution’s eligibility for participation in this Agreement is contingent on meeting the following requirements:

1. Point of Contact. The Relying Institution identifies at least one individual who will serve as the contact person responsible for communicating on behalf of the Relying Institution with respect to matters concerning the initial and ongoing implementation of this Agreement.
2. Study Site Participation. The Relying Institution is participating in and/or conducting research at a study site (*e.g*., a research office or clinic where the Designated IRB contacts the Principle Investigator or research team for day-to-day business).
3. Duration and Nature of Ceded Review.

When review of Research is ceded under this Agreement, the Research will remain under the oversight authority of the UM IRB for as long as IRB review is required for the particular Research, presuming that participation of the UM IRB and the Relying Institution in this Agreement has not terminated pursuant to Section VI herein. The Relying Institution acknowledges and agrees that its withdrawal of Research from Ceded Review may be subject to other requirements or affect its continued involvement in the Research pursuant to or as a result of law, regulation, funding policies, or agreements, or other external sources apart from this Agreement, and that in no event shall the UM IRB or UM be responsible for such requirements or consequences. In cases in which the Relying Institution will continue with the Research, the UM IRB and the Relying Institution will work together to facilitate the transfer of IRB oversight to another IRB with the goals of ensuring the continued protection of human subjects and of limiting the potential disruption to the Research.

1. Roles, Responsibility, and Authority of Designated IRB and Relying Institution
2. Federalwide Assurance. Designated IRB’s Institutionwill maintain a current, approved FWA with OHRP.
3. Designated IRB Review in Accordance with FWA. The Designated IRB will perform initial review and continuing oversight of the Research subject to this Agreement, including review of informed consent forms, modifications to previously approved research, continuing reviews, and reportable events including unanticipated problems and noncompliance, in accordance with the human subjects protection requirements of the Relying Institution’s OHRP-approved FWA and the federal regulations and ethical principles referenced therein. Review by the Designated IRB will take into account the requirements of the local research context identified by the Relying Institution.

1. Investigator Conflicts of Interest. The Designated IRB will have the authority to impose additional prohibitions or conflict management requirements that are more stringent or restrictive than what is contained in the Relying Institution’s policies or what the Relying Institution has implemented. The Designated IRB may require that such additional prohibitions or conflict management requirements are necessary for the Designated IRB to approve the Research. The Designated IRB will apply its standard policies regarding confidentiality of review information to disclosures and other information submitted to it regarding conflicts of interest.
2. Suspension or Termination of IRB Approval. The Designated IRB has the authority to suspend or terminate approval of all or part of Research that is not being conducted in accordance with the Designated IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval includes a statement of the reasons for the Designated IRB’s action and is reported promptly to the Principal Investigator (or the Coordinating Center), appropriate institutional officials, department or agency head and regulatory agencies in compliance with 45 CFR 46.103(b)(5)(ii), 45 CFR 46.113, 21 CFR 56.108(b)(3) and 21 CFR 56.113.
3. Informed Consent Form. The Designated IRB will review informed consent forms for each research study included under this Agreement. The forms will be consistent among sites except for site-specific language included by the Relying Institution. The Designated IRB will provide approved informed consent forms for each site to the Principal Investigator or the Coordinating Center to distribute to Investigators for use at their sites.
4. HIPAA Authorization. The Designated IRBwill perform the initial determinations required by the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations (collectively, “HIPAA”) with respect to the mechanisms for permitting the use and disclosure of Protected Health Information (“PHI”) for the Research reviewed under this Agreement, namely authorization and waivers of authorization for use and disclosure of PHI as applicable.

Other than the initial determinations regarding mechanisms for use and disclosure of PHI referenced above, each party shall be independently responsible for its own HIPAA compliance and obligations (for example, minimum necessary requirements, or accounting of disclosures of PHI made pursuant to a waiver of authorization) in connection with the Research subject to this Agreement.

1. Reports to Sponsors and Oversight Authorities. The Designated IRB will report to sponsors/funding agencies, OHRP, FDA, and/or other oversight authorities of unanticipated problems involving risks to subjects or others, serious or continuing non-compliance, and suspension or termination of IRB approval in connection with the Research subject to this Agreement, and will provide a copy of any such reports to the Relying Institution. The Designated IRB will provide the Relying Institution the opportunity to review and comment on the report before it is sent. Submission of such a report by the Designated IRB does not preclude the Relying Institution from submitting its own report.
2. Designated IRB Decisions; Minutes. Determinations made by the Designated IRB will be communicated to the Coordinating Center and/or the Principal Investigator in writing. The Designated IRB will maintain IRB records in accordance all applicable federal, state, and local regulations, including 45 CFR 46.115, and will make records available when and as required by law. Relevant minutes of the Designated IRB’s meetings pertaining to a research study will be made available to the Relying Institution and the Coordinating Center upon request.
3. Post-Approval Monitoring. The Designated IRB reserves the right to conduct post-approval monitoring of the Research subject to this Agreement. The Designated IRB agrees that the Relying Institution may also conduct post-approval monitoring of Research subject to this Agreement either in addition to, or in conjunction with the Designated IRB. The Designated IRB and the Relying Institution will notify the Principal Investigator or the Coordinating Center of such post-approval monitoring.
4. Federalwide Assurance. The Designated IRB and the Relying Institution will notify the Designated IRB promptly in writing if its FWA is threatened, terminated, or expires for any reason.
5. Acceptance of and Cooperation with the Designated IRB’s Decisions; Amendments. The Relying Institution will accept the decisions and requirements of the Designated IRB with respect to the Researchsubject to this Agreement. The Relying Institution or its research personnel may not initiate any Research or change to the Research, except where necessary to eliminate apparent immediate hazards to subjects, without first receiving prior approval from the Designated IRB.
6. Notification of Investigator Status. The Relying Institution and site Investigator(s) and study team agree to promptly inform the Coordinating Center of suspension or termination of Investigator duties or privileges pertaining to the Research subject to this Agreement.
7. Investigator Responsibilities. The Relying Institution will ensure its Investigators are aware of all of their responsibilities in the conduct of human subjects research including, but not limited to the following:
	1. Investigator is responsible for complying with the determinations and requirements of the Designated IRB.
	2. Investigator is responsible for record keeping and reporting, and for providing information requested by the Designated IRB, should there be any, in a timely manner.
	3. Investigator agrees to disclose to both the Designated IRB and the Relying Institution any changes in financial conflicts of interest and to abide by the applicable Conflict of Interest Management Plan, including additional restrictions as determined by the Designated IRB, if applicable.
	4. Investigator agrees not to implement any changes to the Research (including any applicable informed consent forms) without prior approval from the Designated IRB, except where necessary to eliminate an immediate risk of harm to participants. Any such change and the perceived risk shall be promptly reported to the Designated IRB and the Relying Institution.
	5. Investigator agrees to maintain human subjects protection education in accordance with the Relying Institution’s policies and procedures.
	6. Investigator agrees to report unanticipated problems to the Designated IRB promptly, in accordance with the Designated IRB’s policies.
8. Compliance with SOPs. The Relying Institution and its researchers shall comply with the SOPs.
9. Obligation to Update Information. The Relying Institution will provide written notification to the Designated IRB promptly upon any material changes to the information provided as part of its participation in the Research or otherwise about its site, its human research program, or the local research context in connection with this Agreement or any Research. The Relying Institution will require its research personnel to provide any information about the conduct of the Research that the UM IRB requires for continuing review, in accordance with the UM IRB’s policies and procedures.
10. Complaints. The Relying Institution is responsible for investigating all research subject complaints related to the Research. Complaints that meet the criteria of an unanticipated problem involving risks to subjects or others or serious or continuing noncompliance must promptly be reported to the Designated IRB.
11. Notices and Primary Contacts.

Any notices that are sent to the undersigned institutional officials or correspondence regarding IRB review and oversight, or any other notices required under this Agreement, must be addressed as follows:

Designated Institutional Review Board Primary Contact:

Name: Evelyne Bital, MA, CIP

Title: Associate Director, Regulatory Affairs and Reliance

Address: 1531 Brescia Avenue, Casa Bacardi, Coral Gables, Fl. 33146

email ebital@med.miami.edu

Phone: 305-243-9977

Relying Institutions Primary Contact:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Termination

1. Term. This Agreement shall become effective on the last date signed below and shall continue as set forth in Section III above, or until the Agreement is terminated as provided in Section VI.2 below.

2. Termination. The Designated IRB may terminate this Agreement for any reason upon sixty (60) days prior written notice to the Relying Institution. Further, any parties to this Agreement may terminate this Agreement for cause upon fourteen (14) days prior written notice to the other party(ies). Cause may include, but is not limited to, breach of the Agreement by a party that is not cured to the reasonable satisfaction of the non-breaching party(ies) within said fourteen (14)-day notice period; and to the extent the Designated IRB discovers evidence of material changes in any information provided by the Relying Institution under this Agreement. In the event that any party’s FWA is threatened, terminated, or expires, the other party(ies) may terminate this Agreement immediately.

1. Effect of Expiration or Termination; Survival. In the event of any termination of this Agreement, the parties will work together to determine the effect of such termination on any Research and associated activities being conducted under the Agreement at the time of termination. In the event of any expiration or termination of this Agreement, the Relying Institution will remove the Designated IRB from the list of designated IRBs on its FWA (if it had included the Designated IRB on this list) and will notify the Designated RB (via the Coordinating Center) that this has been done.
2. Indemnification

Each party to this Agreement will be responsible (“Responsible Institution”) for any third-party claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney’s fees and court costs related thereto) (“Claims”), and shall defend, indemnify, and hold harmless, the other party hereunder (“Other Institution”), and its trustees, officers, faculty, IRB members, students, volunteers, and employees (“Other Institutional Representatives”), to the extent such Claims arise out of: (i) any breach of the Agreement by the Responsible Institution; and/or (ii) the negligent acts and omissions made by the Responsible Institution, Responsible Institution’s IRB, as applicable, or any trustees, directors, officers, representatives, employees, or other agents of the Responsible Institution in their performance of this Agreement.

1. Miscellaneous.
	1. This Agreement may be amended only by a written agreement signed by authorized representatives of all parties. If any provision of this Agreement shall be held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected thereby. All the titles and headings contained in the Agreement are inserted only as a matter of convenience and reference and do not define, limit, extend, or describe the scope of this Agreement or the intent of any of its provisions. This Agreement is not assignable in whole or in part, and any attempt to do so shall be void.
	2. Relationship of the Parties. This Agreement is not intended to create nor shall be construed to create any relationship between the parties other than that of independent entities contracting for the purpose of effecting the provisions of this Agreement. Other than as expressly set forth in this Agreement, no third persons or entities are intended to be or are third party beneficiaries of or under this Agreement. Nothing in this Agreement shall be construed to create any liability on the part of the parties or their respective directors, officers, trustees, faculty, employees or agents, as the case may be, to any such third parties for any act or failure to act of any party hereto.
	3. No Waiver. The failure of a party to insist upon the performance of any of the terms of this Agreement shall not be construed to be a waiver or relinquishment by such party of any of the terms of the Agreement or of the whole Agreement.
	4. Audit Notification. The Designated IRB and the Relying Institution agree to notify each other when a federal regulatory agency has conducted or will conduct an audit or review of a study subject to this Agreement and will notify each other of the outcome of such review.
	5. Change in Law: This Agreement is intended to comply with existing federal, State and local laws, rules and regulations.  However, the parties acknowledge that the existing law and regulations may change and that the courts, or federal or State agencies with appropriate jurisdiction, may change their interpretation of existing law.  Upon the enactment or amendment of any federal, State or local law or regulation, or upon the issuance of any judicial or administrative ruling or interpretation that a party believes affects the interpretation or validity of this Agreement, either party may notify the other party of such event.  The parties shall use their best efforts during a sixty (60) day period after such notice is sent to mutually agree to such amendments to this Agreement as to permit its valid and legal continuation.  If after such sixty (60) day period, the parties are unable to agree to amend this Agreement, this Agreement shall automatically terminate.

**Signature of Signatory Official (Designated IRB Institution):**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_

Print Full Name:  Evelyne Bital, MA, C.I.P

Institutional Title: Associate Director, Regulatory Affairs and Reliance

**Signature of Signatory Official (Relying IRB Institution):**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_

Print Full Name:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_