**IRB Reliance Agreement**

**Between**

**Texas A&M University-Corpus Christi**

**And**

**Institution Name**

THIS IRB RELIANCE AGREEMENT (“Agreement”) is between **Texas A&M University-Corpus Christi**, a member of The Texas A&M University System, an agency of the State of Texas, having a place of business at 6300 Ocean Drive, Corpus Christi, Texas, hereinafter referred to as (“TAMU-CC”) and **Institution Name**, having a place of business at address, hereinafter referred to as (“IRB of Record”), each of the aforementioned being referred to individually as the (“Party”) or collectively as the (“Parties”).

**Name of Organization Providing IRB Review** (hereinafter, “IRB of Record”): **Institution Name**

|  |  |
| --- | --- |
| OHRP Federalwide Assurance  (FWA) #, if applicable |  |
| IRB Registration Number: |  |
| Name of Institutional Official |  |
| Street Address |  |
| City |  |
| State (if US) |  |
| Zip/Postal Code |  |
| Country |  |

|  |  |
| --- | --- |
| Name of Individual Responsible for  Administration of the HRPP |  |
| Title of Individual |  |
| Phone Number |  |
| Email address |  |

**Name of TAMU-CC Relying on the Reviewing IRB** (hereinafter, “TAMU-CC”): Texas A&M University-Corpus Christi

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| --- | --- |
| OHRP Federalwide Assurance  (FWA) #, if applicable | [FWA00011281](javascript:__doPostBack('ctl00$MainContent$gvLnkList$ctl03$btnIrbName','')) |
| IRB registration Number | I[ORG0000876](javascript:__doPostBack('ctl00$MainContent$btnIdent','')) |
| Name of Institutional Official | Dr. Ahmed Mahdy |
| Street Address | 6300 Ocean Drive, Room 177 |
| City | Corpus Christi |
| State (if US) | Texas |
| Zip/Postal Code | 78412 |
| Country | United States |

|  |  |
| --- | --- |
| Name of Individual Responsible for  Administration of the HRPP | Rebecca Ballard |
| Title of Individual | Director, Research Compliance |
| Phone Number | 361-825-2497 |
| Email address | rebecca.ballard@tamucc.edu |

1. ***Scope of the Agreement****:* 
   1. The Officials signing below agree that TAMU-CC shall rely on IRB of Record for review and continuing oversight of human subject research for collaborative human subjects research projects.
   2. This Agreement applies to: (i) any human subject research within the meaning of the Federal

Policy or within the meaning of any other federal human subjects research regulations or policies; (ii) any clinical investigation within the meaning of the Food and Drug Administration (“FDA”) IRB regulations; and (iii) any other research for which any Participating Institution(s) seek or are required to rely upon a Reviewing IRB (“Research”). As used in this Agreement, Research may reference a specific study or protocol in which there will be a Reviewing IRB and Relying Institution operating pursuant to the terms of this Agreement, or collectively the studies reviewed under the Agreement. The Participating Institutions may also rely on one another under this Agreement for determinations and documentation of exemption from IRB review pursuant to the Federal Policy.

* 1. Elective Use. Each Participating Institution shall have the right to elect, on a case-by-case basis, whether to cede or provide IRB review of any Research under this Agreement.
  2. Non-Exclusivity. This Agreement does not preclude any party from participating in any other IRB authorization agreements that it may have or enter with other entities for human subject research other than the study or studies for which review is ceded to the IRB of Record under this Agreement (“Study,” or collectively the “Studies”).
  3. This Agreement must be kept on file by all parties and shall be provided to FDA, OHRP, and/or other applicable regulatory agencies upon request. This Agreement may be executed in any number of counterparts, either in original, emailed or faxed form.
  4. TAMU-CC will follow IRB of Record’s policies and procedures pertaining to documentation and review. For the purposes of conducting the IRB review, IRB OF RECORD will identify and interpret the requirements of applicable state or local laws, and regulations. TAMU-CC shall have the ability to discuss these interpretations with the IRB OF RECORD.

1. ***Responsibilities of the IRB of Record***
   1. The review performed by IRB OF RECORD will meet the human subject protection requirements of the Common Rule (e.g., 45 CFR 46) and applicable FDA regulations (e.g., 21 CFR Parts 50, 56, 312, 812). IRB OF RECORD will follow written procedures for reporting its findings and actions to the Principal Investigator (“PI”), Sponsor, and appropriate officials at the TAMU-CC and federal agencies as appropriate. Relevant minutes of IRB meetings may be made available to the TAMU-CC by IRB OF RECORD upon request.
   2. IRB OF RECORD services shall include, but not be limited to:
      1. review and approval or disapproval of new protocols;
      2. review and approval, disapproval or modification of consent forms or waivers of informed consent;
      3. review and approval of modifications to protocols;
      4. review and approval or disapproval of the investigator(s) and changes in research;
      5. collection of reports of unanticipated problems and serious or continuing noncompliance;
      6. maintenance of required IRB records pursuant to applicable federal regulations; and
      7. continuing review of certain new research studies appropriate to the degree of risk in such studies. IRB OF RECORD agrees to conduct at least an annual review of each non exempt study.
   3. IRB OF RECORD shall promptly notify the PI(s) of the ceded studies as designated on the IRB protocol submission of all IRB decisions and shall make available all applicable study-related documents including but not limited to approved protocols, consent forms, surveys, and decision letters.
   4. IRB OF RECORD shall notify the TAMU-CC promptly:
      1. if there is ever a suspension or restriction of IRB OF RECORD’s authorization to review the Studies;
      2. of any changes in IRB OF RECORD operating procedures or practices that might affect the TAMU-CC ’s reliance on IRB OF RECORD reviews;
      3. of complaints from human subjects enrolled in Studies at the TAMU-CC ;
      4. of unanticipated problems involving injury or risks to subjects or others in a Study;
      5. if the IRB OF RECORD determines that serious or continuing non-compliance has occurred, and any steps the IRB OF RECORD deems necessary for remediation of non-compliance;
      6. of suspension or termination of IRB approval;
      7. of any communication with the FDA, OHRP or funding agency of matters relevant to human subject protections and relating to the TAMU-CC ’s Studies; or
      8. changes in accreditation status.
   5. IRB OF RECORD shall provide relevant minutes of the IRB meetings upon request by TAMU-CC.
   6. The Parties shall comply with all applicable federal and state laws, rules, and regulations, including but not limited to, all laws and regulations relating to the maintenance, uses, and disclosures of protected health information, including but not limited to, the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder and Subtitle D of the Health Information Technology for Economic and Clinical Health Act, which is Title XIII of the American Recovery and Reinvestment Act of 2009 (Public Law 111-5), and any regulations promulgated thereunder (collectively, “HIPAA”). The Parties agree to enter into any further agreements with each other or other appropriate entities as may be necessary to facilitate compliance with HIPAA.
   7. HIPAA. IRB of Record will perform those determinations required by the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, “HIPAA”) and Texas H.B. 300 with respect to the mechanisms for permitting the use and disclosure of Protected Health Information (“PHI”) for the research protocol in this Agreement, including authorization and waivers of authorization for use and disclosure of PHI. If it becomes necessary for the parties to access and share PHI in any way not covered by the existing authorization or waiver of authorization, then the parties will work together to determine any additional steps necessary to ensure that the required information is shared in a HIPAA-compliant manner.
2. ***Responsibilities of the TAMU-CC*** 
   1. The TAMU-CC shall ensure investigator compliance withthe protocol, IRB OF RECORD determinations, applicable federal and state regulations, sponsor requirements, and if applicable with the terms of its OHRP-approved FWA.
   2. The TAMU-CC shall ensure prompt reporting to the IRB OF RECORD of proposed changes in a research activity, and ensure that such changes in approved research, during the period for which IRB OF RECORD approval has already been given, may not be initiated without IRB OF RECORD review and approval except when necessary to eliminate apparent immediate hazards to the subject.
   3. TAMU-CC shall provide all information reasonably required by IRB OF RECORD in order to conduct its reviews and will facilitate IRB OF RECORD access to TAMU-CC expertise when needed. TAMU-CC cannot approve any research Study that has been disapproved by the IRB OF RECORD. TAMU-CC may, however, disapprove any Study approved by the IRB OF RECORD. TAMU-CC agrees to abide by the decisions of the IRB OF RECORD and shall use its best efforts to ensure that the human subject research performed by TAMU-CC shall be conducted in accordance with those decisions.
   4. TAMU-CC shall ensure that investigators and other Study personnel at the TAMU-CC are qualified and have appropriate resources to conduct the research, including but not limited to education and training in human research protection regulations. The TAMU-CC shall provide documentation of training and education, as requested by the IRB OF RECORD.
   5. TAMU-CC shall implement a process by which complaints about Studies can be made by Study participants or others. Complaints that meet criteria as a potential unanticipated problem involving risks to subjects or others or serious or continuing noncompliance must be reported to the IRB OF RECORD in accordance with the timeframe specified by the IRB OF RECORD.
   6. TAMU-CC shall cooperate with any IRB OF RECORD investigation regarding serious or continuing noncompliance or an unanticipated problem involving risk to subjects or others related to Studies at the TAMU-CC . Nothing in this Agreement shall prevent either Party from conducting its own investigation. However, IRB OF RECORD shall have primary authority to determine whether serious or continuing noncompliance or unanticipated problems involving risks to subjects or others have occurred.
   7. TAMU-CC shall notify the IRB OF RECORD promptly:
      1. if there is ever a suspension or restriction of the TAMU-CC ’s authorization or ability to conduct Studies;
      2. of any changes in TAMU-CC ’s operating procedures or practices that might affect the IRB OF RECORD’s ability to review for the TAMU-CC ;
      3. of complaints from human subjects enrolled in Studies that involve potential unanticipated problems involving risks to subjects or others;
      4. of unanticipated problems involving injury or risks to subjects or others in a Study reviewed by the IRB OF RECORD;
      5. if the TAMU-CC believes that serious or continuing non-compliance has occurred in a Study, and any steps the TAMU-CC deems necessary for remediation of non-compliance;
      6. of suspension or termination of TAMU-CC approval; or
      7. of any communication with the FDA, OHRP or funding agency relating to Studies
   8. **Federally Funded Studies:** TAMU-CC will maintain a current, approved Federalwide Assurance (FWA) with OHRP for the duration of this Agreement. The TAMU-CC will notify the IRB OF RECORD promptly in writing if its FWA is suspended or expires for any reason.
3. ***Joint Responsibilities***
   1. **Confidentiality.** The Parties recognize that it may be necessary to exchange information pursuant to this Agreement that is confidential in nature and the Parties agrees to treat such information as confidential (“Confidential Information”). No Party shall disclose Confidential Information received pursuant to this Agreement to any individual or entity other than the other Party without prior written approval. Notwithstanding the foregoing, nothing in this Agreement shall be construed to restrict a Party from disclosing Confidential Information as required by law, subpoena, court order, or other governmental order or request. TAMU-CC shall cause Principal Investigator and all other research personnel to comply with the terms and conditions of this section in the same manner as such terms and conditions apply to TAMU-CC. This section shall survive the termination of this Agreement.
   2. **Record Keeping.** IRB OF RECORD and TAMU-CC agree to maintain records in compliance with all applicable federal, state, and TAMU-CC regulations regarding record retention and agree to make to records available when reasonably requested by a Party or a regulatory agency and as required by law.
   3. **Federal Regulatory Agency Review.** IRB OF RECORD and TAMU-CC agree to notify the other Party when a federal regulatory agency has or will conduct an audit or review of a Study applicable to this authorization agreement and will notify the Party of the outcome of the review.
   4. **Inspection.** IRB OF RECORD or its authorized representatives shall be permitted upon request to: (1) examine and inspect TAMU-CC ’s facilities used for the performance of its research, including storage and use of any investigational products; (2) observe the conduct of the research performed at the TAMU-CC ; (3) inspect and copy all documents relating to its studies, including study records and informed consent documents, investigational product logs, required licenses, certificates and accreditations; and (4) interview all necessary personnel involved in the research conduct of its studies. Likewise the TAMU-CC shall be permitted upon request to (1) obtain copies of all applicable IRB correspondence pertaining to activities hereunder; (2) review IRB OF RECORD’s policies, procedures, roster and other information pertinent to board functions; and (3) inspect and copy all documents relating to its studies, including but not limited to protocols and informed consent documents, investigational drug brochures, reports, unanticipated problems, reports of noncompliance, required licenses, certificates and accreditations.
   5. **Reporting to Sponsor, Federal Agencies, or other oversight entities.** If the IRB OF RECORD determines that it must report the findings of an investigation to a sponsor, OHRP, the FDA and/or other oversight entities, it will notify the TAMU-CC in advance. If either Party determines a report must be made, the Party making the report will share the report with the other Party before it is sent to the sponsor/oversight authority, and will copy the other Parties’ Institutional Official(s) and designees. Nothing in this Agreement shall be construed to prevent prompt reporting, or either Party from making its own report to OHRP, the FDA, in accordance with its written procedures, or from taking additional remediation steps.
   6. **Conflict of Interest Review.** The TAMU-CC may perform its own investigator conflict of interest analysis under its relevant policies. Any applicable conflict of interest and associated management plan shall be communicated to the IRB OF RECORD. The IRB OF RECORD will apply its standard policies regarding confidentiality of review of information and disclosures submitted to it regarding potential investigator conflicts of interest. IRB OF RECORD will implement TAMU-CC ’s conflict of interest management plans to the extent that they involve human subject protection considerations, such as mandated language in informed consent forms once this information is communicated to the IRB OF RECORD. If the IRB OF RECORD determines the management plan is not acceptable, the IRB OF RECORD will promptly inform the PI and the TAMU-CC ’s responsible individual.
4. ***Term and Termination*.** 
   1. The term of this Agreement shall commence upon execution of this Agreement by both parties, and shall continue for five (5) years (“Term”) or until such time as either party gives thirty (30) days written notice of termination, whichever comes first.
   2. Notwithstanding the foregoing, in the event that either Party is in default in the performance of any of its obligations under this Agreement, and the default has not been remedied within thirty (30) days after the date of notice in writing of such default, the Party not in default may terminate this Agreement immediately by written notice.
   3. Notwithstanding the immediately preceding Section 5.1.2, the Parties specifically recognize that 45 CFR 46.109(e) and 21 CFR § 56.109(f) requires that, “An IRB shall conduct continuing review of research . . . not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.” Therefore, termination of this Agreement shall not affect the IRB OF RECORD’s obligations of continuing review for Studies approved hereunder or TAMU-CC ’s payment responsibilities until such Studies are appropriately transferred to a new IRB.
5. ***Insurance***
   1. IRB OF RECORD acknowledges that, because TAMU-CC is an agency of the state of Texas, liability for the tortious conduct of employees of TAMU-CC or for injuries caused by conditions or use of tangible state property is provided solely by the provisions of the Texas Tort Claims Act (Texas Civil Practice and Remedies Code Chapters 101 and 104); and that Workers’ Compensation Insurance coverage for employees of TAMU-CC is provided by the A&M System as mandated by the provisions of Chapter 502, Texas Labor Code. TAMU-CC shall have the right, at its option, to (a) obtain liability insurance protecting TAMU-CC and its employees and property insurance protecting TAMU-CC's buildings and contents, to the extent authorized by Section 51.966, Texas Education Code, or other law, or (b) self-insure against any risk that may be incurred by TAMU-CC as a result of its operations under the Agreement.
6. ***Indemnification*** 
   1. TAMU-CC shall indemnify and hold harmless A&M System, Texas A&M, TAMU-CC, and their regents, employees and agents (collectively, the “A&M System Indemnities”) from and against any third-party claims, damages, liabilities, expense or loss asserted against A&M System Indemnities arising out of any acts or omissions of TAMU-CC or its employees or agents pertaining to the activities and obligations under this Agreement, except to the extent such liability, loss or damage arises from an A&M System Indemnitee’s gross negligence or willful misconduct.
7. ***Public Information***
   1. IRB OF RECORD acknowledges that TAMU-CC is obligated to strictly comply with the Texas Public Information Act, Chapter 552, Texas Government Code (the “PIA”), in responding to any request for public information pertaining to this Agreement, as well as any other disclosure of information required by applicable Texas law.
8. ***Use of Name***
   1. Each Party agrees not to use the name, service mark or logo of the other Party without the other Party’s prior written consent.
9. ***Miscellaneous***
   1. Independent Contractor. The Parties hereto are independent contractors, and neither Party nor any employee of such Party shall be deemed to be an agent or employee of the other Party. Both Parties agree that neither shall have the power or right to bind or obligate the other, nor shall either hold itself out as having such authority. Neither Party will have any responsibility to provide transportation, insurance or other fringe benefits normally associated with employee status. TAMU-CC shall observe and abide by all applicable laws and regulations, policies and procedures, including but not limited to those of TAMU-CC relative to conduct on its premises.
   2. Entire Agreement. This Agreement constitutes the sole agreement of the Parties and supersedes any other oral or written understanding or agreement pertaining to the subject matter of this Agreement. This Agreement may not be amended or otherwise altered except upon the written agreement of both Parties.
   3. Severability. If any provisions of this Agreement are rendered or declared illegal for any reason, or shall be invalid or unenforceable, such provision shall be modified or deleted in such manner so as to afford the Party for whose benefit it was intended the fullest benefit commensurate with making this Agreement, as modified, enforceable, and the remainder of this Agreement and the application of such provision to other persons or circumstances shall not be affected thereby, but shall be enforced to the greatest extent permitted by applicable law.
   4. Headings. Headings appear solely for convenience of reference. Such headings are not part of this Agreement and shall not be used to construe it.
   5. Non-Assignment. Neither Party shall assign its rights nor delegate its duties under this Agreement without the prior written consent of the other Party.
   6. Force Majeure. Neither Party will be in breach of its obligations under this Agreement (other than payment obligations) or incur any liability to the other Party for any losses or damages of any nature whatsoever incurred or suffered by that other Party if and to the extent that it is prevented from carrying out those obligations by, or such losses or damages are caused by, a Force Majeure, except to the extent that the relevant breach of its obligations would have occurred, or the relevant losses or damages would have arisen, even if the Force Majeure had not occurred.  Force Majeure is defined as: 1) acts of God; 2) war; 3) act(s) of terrorism; 4) fires; 5) explosions; 6) natural disasters, to include without limitation, hurricanes, floods, and tornadoes; 7) failure of transportation; 8) strike(s); 9) loss or shortage of transportation facilities; 10) lockout, or commandeering of materials, products, plants or facilities by the government or other order (both federal and state); 11) interruptions by government or court orders (both federal and state); 12) present and future orders of any regulatory body having proper jurisdiction; 13) civil disturbances, to include without limitation, riots, rebellions, and insurrections; 14) epidemic(s), pandemic(s), or other national, state, or regional emergency(ies); and 15) any other cause not enumerated in this provision, but which is beyond the reasonable control of the Party whose performance is affected and which by the exercise of all reasonable due diligence, such Party is unable to overcome.  Such excuse from performance will be effective only to the extent and duration of the Force Majeure event(s) causing the failure or delay in performance and provided that the affected Party has not caused such Force Majeure event(s) to occur and continues to use diligent, good faith efforts to avoid the effects of such Force Majeure event(s) and to perform the obligation(s).  Written notice of a Party’s failure or delay in performance due to Force Majeure must be given within a reasonable time after its occurrence and which notice must describe the Force Majeure event(s) and the actions taken to minimize the impact of such Force Majeure event(s). Notwithstanding the foregoing, a Party’s financial inability to perform its obligations shall in no event constitute a Force Majeure.
   7. Governing Law. The validity of this Agreement and all matters pertaining to this Agreement, including but not limited to, matters of performance, non‑performance, breach, remedies, procedures, rights, duties, and interpretation or construction, shall be governed and determined by the Constitution and the laws of the State of Texas.
   8. Venue. Pursuant to Section 85.18, Texas Education Code, venue for any suit filed against TAMU-CC shall be in the county in which the primary office of the chief executive officer of TAMHSC is located, which is Nueces County, Texas.
   9. Non-Waiver. TAMU-CC is an agency of the state of Texas and under the Constitution and the laws of the state of Texas possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has authority as is granted to it under the Constitution and the laws of the state of Texas. TAMU-CC expressly acknowledges that TAMU-CC is an agency of the State of Texas and nothing in this Agreement will be construed as a waiver or relinquishment by TAMU-CC of its right to claim such exemptions, privileges, and immunities as may be provided by law.
   10. Conflict of Interest. By executing this Agreement, TAMU-CC and each person signing on behalf of TAMU-CC certifies, and in the case of a sole proprietorship, partnership or corporation, each Party thereto certifies as to its own organization, that to the best of their knowledge and belief, no member of the A&M System or the A&M System Board of Regents, nor any employee, or person, whose salary is payable in whole or in part by the A&M System, has direct or indirect financial interest in the award of this Agreement, or in the services to which this Agreement relates, or in any of the profits, real or potential, thereof.
   11. Prohibition on Contracts with Companies Boycotting Israel. To the extent that Texas Government Code, Chapter 2271 applies to this Agreement, TAMU-CC certifies that (a) it does not currently boycott Israel; and (b) it will not boycott Israel during the term of this Agreement. TAMU-CC acknowledges this Agreement may be terminated and payment withheld if this certification is inaccurate.
   12. Certification Regarding Business with Certain Countries and Organizations. Pursuant to Subchapter F, Chapter 2252, Texas Government Code, TAMU-CC certifies it is not engaged in business with Iran, Sudan, or a foreign terrorist organization. TAMU-CC acknowledges this Agreement may be terminated if this certification is or becomes inaccurate.
   13. Notices. Any notice required or permitted under this Agreement must be in writing, and shall be deemed to be delivered (whether actually received or not) when deposited with the United States Postal Service, postage prepaid, certified mail, return receipt requested, and addressed to the intended recipient at the address set out below. Notice may also be given by regular mail, personal delivery, courier delivery, facsimile transmission, email or other commercially reasonably means and will be effective when actually received. TAMU-CC or TAMU-CC can change their respective notice address by sending to the other party a notice of the new address. Notices should be addressed as follows:

If to TAMU-CC:

Attention: Rebecca Ballard

Title: Director, Research Compliance

Address: 6300 Ocean Drive, Unit 5843

City: Corpus Christi State: TX Zip: 78412-5843

Email: Rebecca.Ballard@tamucc.edu Phone: 361-825-2497

If to IRB OF RECORD:

Add contact info

***Signature Page to Follow***

IN WITNESS WHEREOF, each party accepts the terms herein as evidenced by their authorized signatures below.

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| --- | --- | --- | --- | --- |
| Texas A&M University-Corpus Christi | |  | IRB OF RECORD | |
|  | |  |  | |
|  | |  |  | |
| (Authorized Signature) | |  | (Authorized Signature) | |
|  | |  |  | |
| Name: | Ahmed Mahdy, Ph.D. |  | Name: |  |
|  |  |  |  |  |
| Title: | Vice President for Research and Innovation |  | Title: |  |
|  |  |  |  |  |
| Date: |  |  | Date: |  |