Reliance Acknowledgement Between

National Aeronautics and Space Administration (NASA)

And

For Institutional Review Board (IRB) Review

1. AUTHORITY AND PARTIES

1.1 Name of Institution Ceding IRB Review (Relying Institution): National Aeronautics and Space Administration

NASA IRB Registration Number	IORG0007525
NASA FWA Number	FWA00019876
Street Address	2101 E NASA Pkwy
City	Houston
State (if US)	TX
Zip/Postal Code	77058

Name of Individual Responsible for Administration of this Acknowledgment	Marisa Covington, Ph.D., CIP
Title of Individual	Director, OCHMO Office of Research Assurance
Phone Number	281-244-8277
Email address	marisa.d.covington@nasa.gov

1.2 Name of Institution Providing IRB Review (IRB of Record):

Institution's OHRP FWA #	
Name of Institutional Official	
Street Address	
City	
State (if US)	
Zip/Postal Code	

Name of Providing Site Investigator	
Title of Individual	
Phone Number	
Email address	

2. Scope of the Acknowledgement

2.1 The Officials signing below agree that the NASA IRB shall rely on [name the IRB of IRB for review and continuing oversight of the following research protocol:

Title of Research Project*	
NASA eIRB Number	
Name of NASA Principal Investigator	
Name of Sponsor	
Name of Funding Agency	
Award Number, if any	

*If more than one research project, attach an addendum to this form.

- 2.2 The review performed by [name the IRB of Record] IRB will meet human subject protection requirements [14 CFR 1230, NPR 7100.1A, HHS 45 CFR 46, and FDA 21 CFR 50, 56, 312, and 812], as applicable. [name the IRB of Record] IRB will follow written procedures for reporting its findings and actions to the appropriate officials at the NASA IRB.
- 2.3 The NASA IRB remains responsible for ensuring compliance with [name the IRB of IRB's determinations and with the terms of its OHRP-approved FWA. The NASA IRB will notify the [name the IRB of Record] IRB promptly, and in writing, of any suspension, restriction, termination, or expiration of its FWA.
- 2.4 The [name the IRB of Record] 's Human Research Protection Program is accredited by an independent accrediting body or has documented an equivalent level or standards for protection of human rights.
- 2.5 This document must be kept on file by both parties and provided to the FDA, OHRP, and/or other applicable regulatory agencies upon request.
- 2.6 This acknowledgement is limited to the review and continuing administration of the protocol as outlined in the responsibilities located in the corresponding SOP.

3. RESPONSIBILITIES OF IRB OF RECORD, [NAME THE IRB OF RECORD]

- 3.1 Maintain an FWA;
- 3.2 Maintain a Board membership that satisfies the requirements of 14 CFR 1230.107, 45 CFR 46, and 21 CFR 56.107, as applicable.
- 3.3 Comply with all applicable Federal, State, and Local Laws and regulations;
- 3.4 Make available to the NASA IRB the [name the IRB of Record]. IRBs Standard Operating Procedures;

- 3.4.1 Include any standardized language required for Informed Consent documents;
- 3.5 Submit any recent FDA warning letters or OHRP determination letters within the previous year to the NASA IRB.

4. RESPONSIBILITIES OF THE RELYING INSTITUTION, NASA IRB

- 4.1 Maintain an FWA;
- 4.2 Comply with all applicable Federal, State, and Local laws and regulations and inform the IRB of Record when State and Local laws may affect the research and its oversight.
 - 4.2.1 The Relying Institution must ensure organizational compliance with all HRPP. For example, if the Relying Institution requires approval by other internal review committees prior to IRB or EC approval (e.g. Institutional Biosafety, Radiation Safety), the Relying Institution must include that information and approval letters in the IRB application.
 - 4.2.2 The IRB of Record shall confirm receipt and compliance with HRP 100 SOP Establishing Reliance Acknowledgements and HRP 102 SOP: NASA IRB Reliance on an External IRB by checking the appropriate boxes and signing this document.

5 LIABILITY

5.1 Each Party agrees to assume liability for its own risks arising from or related to activities conducted under the scope of this Acknowledgment.

6 TERM OF AGREEMENT

6.1 The term of this Acknowledgement shall commence upon execution of this Acknowledgement by both parties, and shall continue until closure of the research protocol.

7 POINTS OF CONTACT

The following personnel are designated as the Points of Contact between the Parties in the performance of this Acknowledgement and shall serve as the contacts for further communication.

Relying Institution, NASA IRB	IRB of Record, [name IRB of Record]
Name: Arturo Garza Jr.	Name:

Management Points of Contact:

Title: IRB Coordinator	Title:
Email: Arturo.Garza@nasa.gov	Email:
Telephone:	Telephone:
Cell: 202-999-5815	Cell:
Fax:	Fax:
Mailing Address: 2400 NASA Parkway, Houston TX 77058	Mailing Address:

By checking the boxes below, confirm receipt* and compliance with:

- 1. HRP 100 SOP: Establishing Reliance Acknowledgements
- 2. HRP 102 SOP: NASA IRB Reliance on an External IRB

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

The Relying Institution: NASA IRB

The IRB of Record: [name IRB of Record]

(Authorized Signate	ure)	(Authorized Signature)	
Print Full Name:	Marisa Covington, Ph.D., CIP	Print Full Name:	
Institutional Title:	Director, OCHMO Office of Research Assurance	Institutional Title:	
Date:		Date:	