MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Overview and Contents of Document

This document contains materials that clarify data contributors' responsibilities, institutional safeguards, and requirements for the deposition of data in a data repository. Please find information regarding the contents of this document below:

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Template Data Contributor Agreement

This Data Contributor Agreement (this "Agreement") is effective as of _____, 20[XX] (the "Effective Date") between _____ [CONTRIBUTING INDIVIDUAL OR INSTITUTION NAME] ("CONTRIBUTOR" located at [CONTRIBUTING INDIVIDUAL OR INSTITUTION ADDRESS] and _____ [RECIPIENT INSTITUTION NAME] ("REPOSITORY") located at [RECIPIENT INSTITUTION ADDRESS].

Background and Recitals

WHEREAS, [REPOSITORY] preserves, manages, and provides access to datasets in an effort to facilitate and encourage secondary research for the public good;

WHEREAS, [CONTRIBUTOR] has rights in the research-related information more fully described in the Data Deposition Form, attached hereto and incorporated herein, generated during [FUNDER-SPONSORED] research;

WHEREAS, [FUNDER] and [REPOSITORY] have specified the method and degree of de-identification required for deposition of data in the Data Deposition Form accompanying this Agreement;

WHEREAS, [CONTRIBUTOR] seeks to deposit a copy of the de-identified Full Data Package in [REPOSITORY];

WHEREAS, [REPOSITORY] seeks to provide access to the Full Data Package to Approved Users who have entered into a Data Use Agreement with [REPOSITORY] that may be updated from time to time;

NOW, THEREFORE, in consideration of the mutual terms and conditions set forth herein, the receipt and sufficiency of which are hereby acknowledged, [CONTRIBUTOR] and [REPOSITORY] (each, a "Party" and collectively the "Parties") agree as follows:

I. Definitions of Terms and Parties

a. "CONTRIBUTING INDIVIDUAL OR INSTITUTION" (CONTRIBUTOR) refers to the [FUNDER] Research Awardee that seeks to deposit its Full Data Package in the Repository.

b. "RECIPIENT INSTITUTION" ([FUNDER] -Designated Repository) (REPOSITORY) refers to an entity that preserves, manages, and provides access to many types of digital materials in a variety of formats. [REPOSITORY] will work with [CONTRIBUTOR] to curate the Full Data Package for release, pursuant to the terms of this Agreement,

and will make the Full Data Package available for third-party requests and secondary research use(s) thereafter.

c. "APPROVED USERS" are all individuals identified as Lead Researcher(s) and Key Personnel in a Data Request Form who have requested, and have been granted, access to the Full Data Package by the independent review committee of the [REPOSITORY] under the terms and conditions of a Data Use Agreement.

d. "THIRD PARTIES" are all individuals, organizations, and institutions that have not been identified in the Data Request Form as Lead Researcher(s) and Key Personnel and have therefore not been granted access to the Full Data Package by the terms of the Data Use Agreement. For THIRD PARTIES to gain access to the Full Data Package, they must enter into an assurance of compliance with the terms of the DUA, which shall be incorporated as an exhibit to the DUA.

e. "Hosting Service" is a Third-Party service provider that facilitates access to the Full Data Package by Approved Users and assists in the establishment, administration or maintenance of the Repository. The Hosting Service is not permitted to use the Full Data Package for any purpose other than this.

f. "Data Deposition Form" describes the substantive and technical characteristics of the Full Data Package. [CONTRIBUTOR] provides information in four categories: (1) Catalog Metadata Elements, (2) Data Package elements, (3) additional information, and (4) contact information. [REPOSITORY] will use the Data Deposition Form to assist with curation of the Full Data Package, as described in Section VII.a.i.

g. "Full Data Package" includes all study-specific information that [CONTRIBUTOR] provides to [REPOSITORY] under the terms and conditions of this Data Contributor Agreement and which [REPOSITORY] will make available to APPROVED USERS under the terms and conditions of a separate Data Use Agreement. Preparation of the Full Data Package must be in accordance with the [FUNDER] standards. Elements of a Full Data Package include the Full Analyzable Data Set, Full Protocol, Metadata, Data Dictionary, Full Statistical Analysis Plan (including all amendments and all documentation for additional work processes), Analytic Code (not proprietary), and a summary of the method of de-identification of Individual Participant Data from a [FUNDER]-sponsored research project.

h. "Analyzable Data Set" refers to the final cleaned, edited, and locked data set that is generated after the [FUNDER]-sponsored research project has been declared complete. Analyzable Data Sets must be de-identified in accordance with the HIPAA Privacy Rule (45 C.F.R. § 164.514(b)). It includes derived variables and consists of

various components (e.g., participant characteristics and primary outcome, pre-specified secondary and tertiary outcomes, adverse event data, and exploratory data.

i. "Catalog Metadata Elements" are metadata elements provided by [CONTRIBUTOR] in the Data Deposition Form that describe the contents of the Full Data Package, as defined in Section 1.g.

j. "Publication" refers to any dissemination of findings (including negative findings) related to the secondary use of the Full Data Package by APPROVED USERS in printed form, on the internet, or in a presentation in a learned forum.

k. "Deductive Disclosure" refers to the process of discerning a research participant's identity through the use of known characteristics of that individual. Deductive disclosure of research participants who are the subjects of data contained within the Full Data Package is expressly prohibited.

II. Relationship between Parties

a. This Agreement does not create a partnership, joint venture, or any other relationship or obligation whatsoever between the Parties, save the relationship and obligations specifically set out herein before, and solely for the limited purposes described herein.

III. Incorporation by Reference

a. All Parties agree that the following document is incorporated into this Agreement by reference:
    i. The Data Deposition Form, as defined in Section I.f.

IV. Licensing and Rights of Use of Data for Research and Educational Purposes

a. Subject to the terms of this Agreement, [CONTRIBUTOR] hereby grants to [REPOSITORY] a royalty-free, worldwide, non-exclusive, irrevocable license to store, host and otherwise use and exploit the Full Data Package for the purposes of this Agreement.

b. The license granted in the preceding sentence includes the right of [REPOSITORY] to grant sublicenses to the following entities:
    i. APPROVED USERS, pursuant to the terms and conditions of a Data Use Agreement;

    ii. Hosting Service, or any other third party, which assists in the establishment, administration or maintenance of the Repository;

iii. Any other parties whose participation is reasonably necessary in furtherance of the purposes of this Agreement (such as a party who performs curation and annotation of the Catalog Metadata Elements provided by [CONTRIBUTOR] in Section I of the Data Deposition Form).

c. The Full Data Package will be used only for the reasons expressly stated in this Agreement. [REPOSITORY] will take necessary measures to ensure that no portion of the Full Data Package is either sold to any entity for any reason, used in support of litigation, or used to harm, marginalize, or discriminate against individuals or populations, whether in insurance, employment, or other manners.

V. Data Privacy and Confidentiality

a. In order to ensure the confidentiality of human study participants, [CONTRIBUTOR] will only provide to [REPOSITORY] as part of the Full Data Package data that has been de-identified in accordance with the HIPAA Privacy Rule (45 CFR § 164.514(b)), as specified in Section I.h.

b. Neither APPROVED USERS nor [REPOSITORY] will use the Full Data Package, alone or in conjunction with any other information, in any effort to establish the individual identities of or to make contact with any of the individuals who are the subjects of data contained within the Full Data Package.
   i. Elements of the Full Data Package must be collected and submitted in accordance with applicable laws, regulations, and standards, including—without limitation—all national, state/provincial, local, and institutional laws and regulations regarding (i) patient/ subject privacy, (ii) the collection, storage, processing, disclosure, and use of personally identifiable information, and (iii) other uses and disclosures of data.

c. In order to ensure the confidentiality of human study participants, individual investigators or teams of investigators seeking access to the Full Data Package must complete and submit a data request form to the [REPOSITORY]. [REPOSITORY] will independently review requests for data based on qualifications of the data requestors and the scientific merit of the request. If the data request is approved by the [REPOSITORY]'s independent review panel, the requestor's institution must enter into a Data Use Agreement with the [REPOSITORY] before being deemed an APPROVED USER, as defined in Section I.c.

VI. Obligations and Activities of [CONTRIBUTOR]

Having been granted permission by relevant [REPOSITORY] officials to deposit the Full Data Package, [CONTRIBUTOR] agrees:

a. That the Data Deposition Form accompanying this Agreement was completed truthfully and accurately;

b. To allow [REPOSITORY] to fulfill its duties of preserving, managing, and providing access to the Full Data Package for secondary research use(s), as outlined in Section VII.a.

c. That all elements of the Full Data Package meet the standards of Privacy and Confidentiality outlined in Section V of this Agreement, so as to diminish risk of Deductive Disclosure of research participants' identities.
    i. [CONTRIBUTOR] acknowledges that [REPOSITORY] reserves the discretionary right to reject, delete, or quarantine from its public access database any submitted Full Data Packages, in whole or in part, that contain any information that does not comply with the standards of Privacy and Confidentiality outlined in Section V of this Agreement.

d. That the research project and its findings, to which the Full Data Package pertains, have been registered on the appropriate platform, e.g. clinicaltrials.gov, in accordance with the requirements of [FUNDER].

e. To the extent required by applicable law, that there is appropriate documentation of participant informed consent that permits data collected as part of the research project to which the Full Data Package relates, to be de-identified and for such de-identified data to be used for secondary research purposes and shared with researchers not affiliated with the institution conducting the research project.
    i. If obtaining express consent as described above is not required by applicable law, that there is an appropriate waiver of any such consent requirement by a body empowered under applicable law to waive such a requirement. In the event that there are prohibitions on the use of any Full Data Package elements by APPROVED USERS (e.g., data are proprietary, contractual and/or legal barriers are in place, or the study informed consent form does not allow for data sharing), [CONTRIBUTOR] must notify [FUNDER]. [FUNDER] will determine if a complete or partial exemption from the requirements of Full Data Package deposition, as specified in Section 1.g, should apply.

VII. Obligations and Activities of [REPOSITORY]

In consideration of the promises made by [CONTRIBUTOR] in Section VI of this Agreement, [REPOSITORY] agrees:

a. To fulfill its duties of preserving, managing, and providing access to the Full Data Package for third party requests and secondary research use(s) by Approved Users. Specifically, [REPOSITORY] is responsible for the following:
   i. Working with [CONTRIBUTOR] to curate the Full Data Package for release
   ii. Describing, validating, and documenting the Full Data Package;
   iii. Creating an authoritative citation (such as a globally unique identifier (GUID)) for the Full Data Package;
   iv. Managing the costs for database management and support;
   v. Storing, translating, copying, and/or re-formatting the Full Data Package in any way to ensure its future preservation and accessibility;
   vi. Provisioning the Full Data Package to APPROVED USERS after review of data request(s) by an independent review committee;
   vii. Notifying [CONTRIBUTOR] in the event that a request for their Full Data Package has been approved. Notifications will occur within five (5) business days of the approval.
   viii. Requiring APPROVED USERS to provide a summary of all findings (including negative findings) related to the secondary use of the Full Data Package to [REPOSITORY], which will be posted on [REPOSITORY]'s website within 12 months of the date of the approval of the data request.
   ix. Requiring APPROVED USERS to post, or make otherwise available in an eligible repository, all derived datasets related to the secondary use of the Full Data Package.
   x. Requiring that APPROVED USERS acknowledge the [CONTRIBUTOR] as a primary source of the data and [FUNDER] as a funder in all Publications, as defined in Section I.j., that result from secondary use of the Full Data Package.

b. To employ reasonable technical and administrative measures to prevent unauthorized or unlawful access or use of the Full Data Package, or the accidental loss, destruction of, or damage to the Full Data Package.
   i. [REPOSITORY] will follow all applicable [REPOSITORY], local, state, and federal policies and procedures for data and computer security.
   ii. When applicable, [REPOSITORY] will obligate the Hosting Service to use reasonable security precautions in order to protect the Full Data Package against unauthorized access or use;

c. To reject, delete or quarantine from its public-access database any submitted Full Data Packages, in whole or in part, that contain any information that does not

comply with the standards of Privacy and Confidentiality outlined in Section V of this Agreement.

i. Upon any such rejection, deletion, quarantine or denial of access, [REPOSITORY] shall take reasonable efforts to notify [CONTRIBUTOR] of the problems that led to the rejection, deletion or denial of deposition;

d. To not transfer any elements of the Full Data Package to individuals or organizations who are not APPROVED USERS of the Full Data Package

i. [REPOSITORY] reserves the right to modify the Data Use Agreement at any time without consultation with or without notice to [CONTRIBUTOR]; however, when the change involves a material alteration to the rights and responsibilities of the parties to the Data Use Agreement, [REPOSITORY] will notify [CONTRIBUTOR] promptly and in writing;

e. To provide support to APPROVED USERS with respect to the Full Data Package. If [REPOSITORY] is unable to answer APPROVED USER questions, [REPOSITORY] will communicate with [CONTRIBUTOR] to answer APPROVED USER questions. [REPOSITORY] reserves the right to decline to address any question(s);

f. That, in the event of unintended release of data at [REPOSITORY] through either security breach or unauthorized access, [REPOSITORY] will inform [CONTRIBUTOR] in writing in a timely manner. [REPOSITORY] will provide for reasonable correction where possible and reserves the right to take action against a breaching THIRD PARTY.

VIII. Data Ownership and Intellectual Property

a. [REPOSITORY] does not claim any rights of ownership or intellectual property in the Full Data Package, and [CONTRIBUTOR] will maintain any pre-existing ownership and intellectual property rights that it has in the Full Data Package.

i. Notwithstanding the foregoing, in order to allow [REPOSITORY] to fulfill its purpose of facilitating and encouraging secondary research and open science, [REPOSITORY] and APPROVED USERS may use and disclose the Full Data Package, pursuant to the terms and conditions of this Agreement and the Data Use Agreement.

ii. This Agreement does not preclude the release of the Full Data Package by [CONTRIBUTOR] in other instances;

b. Subject to [CONTRIBUTOR]'s ownership rights to the Full Data Package, [REPOSITORY] shall own all right, title, and interest (including all intellectual property rights) in and to its public-access database and nothing herein shall be construed as granting any rights in that database to [CONTRIBUTOR].

IX. Term and Termination

a. Duration of Agreement

i. This Agreement shall commence on the Effective Date and continue until [CONTRIBUTOR] directs [REPOSITORY] to remove Full Data Package from its public access database.

b. Termination of Agreement

i. Termination for Breach: Either Party may terminate this Agreement if the other Party materially breaches a provision of this Agreement and fails to cure such breach within thirty (30) days of receipt of written notice describing the breach in reasonable detail.

ii. Termination without Cause: Either Party shall have the right to terminate this Agreement without cause upon 30 days' advance written notice to the other Party.

c. Effect of Termination

i. Upon termination for any reason whatsoever, [REPOSITORY] shall notify [CONTRIBUTOR] that the Full Data Package will be removed from its public-access database. If, after ninety (90) days, [CONTRIBUTOR] has not made arrangements to export and store Full Data Package in another repository, the Full Data Package will be removed from the public-access database and destroyed. If requested by [CONTRIBUTOR] in writing, [REPOSITORY] will provide written confirmation of destruction.

ii. Notwithstanding the foregoing, either Party may elect to terminate this Agreement with respect to a specific element of the Full Data Package by providing thirty (30) days' advance written notice to [CONTRIBUTOR].

1. In the event that this Agreement is terminated only with respect to a specific portion of the Full Data Package, this Agreement will remain in effect with respect to the portion of the Full Data Package for which the Agreement was not terminated.

iii. Notwithstanding the termination of this Agreement for any reason, to the extent that APPROVED USERS have entered into Data Use Agreements related to the use of the terminating Full Data Package prior to termination of this Agreement (whether in its entirety or only for a specific portion of the data), such APPROVED USERS shall be entitled to continue to use the Full Data Package until the termination of such Data Use Agreement, unless continued use of Full Data Package is otherwise restricted by applicable law or regulations.

X. Representations and Warranties

a. [CONTRIBUTOR] represents and warrants that it does not have, nor will it enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement, including, without limitation, the obligations of Section VI.

b. [CONTRIBUTOR] represents and warrants that the Full Data Package provided under this Agreement is compliant with the standards of Data Privacy and Confidentiality described in Section V.

XI. Indemnification

a. [CONTRIBUTOR] shall indemnify and hold harmless [REPOSITORY] and its respective directors, officers, employees, and agents from and against any and all claims, suits, losses, liabilities, damages, costs, fees, and expenses (including reasonable attorney fees) (collectively, "Losses") arising out of or resulting from, directly or indirectly, (a) any material breach of, or inaccuracy in, any representation or warranty made by [CONTRIBUTOR] in this Agreement, (b) any breach or violation of any material covenant or agreement of such [CONTRIBUTOR] in or pursuant to this Agreement, and (c) the gross negligence or willful misconduct by [CONTRIBUTOR] and its respective directors, officers, employees and agents, except to the extent that such Losses arise out of or result from directly or indirectly, any material breach of, or inaccuracy in, any representation or warranty in this Agreement made by [REPOSITORY], or any breach or violation of any covenant or agreement of [CONTRIBUTOR] in or pursuant to this Agreement, or the gross negligence or willful misconduct of [CONTRIBUTOR].

b. This obligation to indemnify is conditioned upon [REPOSITORY] taking the following actions:
    i. Promptly notifying [CONTRIBUTOR] of any such claim;
    ii. Reasonably cooperating with Data Contributor to facilitate the settlement or defense of the claim; and
    iii. Granting [CONTRIBUTOR] sole control of the defense of any such claim and of all negotiations for its settlement or compromise, provided that no such settlement or compromise shall impose any monetary or other obligations on [REPOSITORY] (except for potential restrictions on use of the Full Data Package).

c. In no event shall [REPOSITORY] be liable to [CONTRIBUTOR] for any lost profits, loss of data, loss of business, or loss of opportunity or any indirect, incidental, special, consequential, or punitive damages, whether based on breach of contract, negligence, or any other theory regardless of whether [REPOSITORY] has been

advised of the possibility of any such damages. In addition, [REPOSITORY] will not be liable for any breach or other misuse of the Full Data Package by any Approved Users or Third Parties.

XII. Severability

a. If any provision of this Agreement is found to be illegal, void, or invalid, that fact shall not affect the legality and validity of other provisions of the Agreement.

XIII. Miscellaneous

a. This Agreement, and all documents incorporated into this Agreement by reference, may be amended and modified by the mutual written consent of the authorized representatives of [CONTRIBUTOR] and [REPOSITORY]. Both Parties agree to amend this Agreement to the extent necessary to comply with the requirements of any applicable regulatory authorities.

b. The persons signing this Agreement have the right and authority to execute this Agreement on behalf of [CONTRIBUTOR] and [REPOSITORY], and no further approvals are necessary to create a binding agreement.

c. The obligations and activities of [CONTRIBUTOR], as outlined in Section VI of this Agreement, may not be assigned or otherwise transferred without the express written consent of [REPOSITORY].

d. This Agreement shall be governed and interpreted in accordance with the laws of [INSERT CHOICE OF LAW JURISDICTION.]

e. This Agreement represents the entire and integrated agreement between the Parties and supersedes all prior negotiations, representations, or agreements, either written or oral, regarding its subject matter.

f. All notices and correspondence required by this Agreement shall be in writing and shall be delivered either by mail delivery or by email. If delivered by mail, notices shall be sent by overnight mail delivery or by certified or registered mail, with return receipt requested, and with all postage and charges prepaid. All notices and other written communications under this Agreement shall be addressed as indicated below, or as specified by subsequent written notice delivered by the party whose address has changed:

i. If to [CONTRIBUTING INDIVIDUAL OR INSTITUTION]
(name):_____
(address):_____
(city, state, country, zip code):_____
(email address):_____

ii. If to [RECIPIENT INSTITUTION]
(name):_____
(address):_____
(city, state, country, zip code):_____
(email address):_____

In witness whereof, each of the Parties hereto has duly executed this Agreement as of the date set forth above by its duly authorized signatory.

[CONTRIBUTING INDIVIDUAL OR INSTITUTION]

By: _____
Print Name: _____
Title: _____
Date: _____

[RECIPIENT INSTITUTION]

By: _____
Print Name: _____
Title: _____
Date: _____

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Template Data Deposition Form

Please complete this Data Deposition Form to inform [REPOSITORY] about the substantive and technical characteristics of your Full Data Package. Completing this form ensures that your Full Data Package will be accurately and thoroughly described to third party requestors. [REPOSITORY] will use the information provided in this Form to fulfill its duties of preserving, managing, and providing access to the Full Data Package for third party requests and secondary research use by Approved Users, as well as to assist you with curation of the Full Data Package and to create an authoritative citation of the Full Data Package.

In addition to the information that you provide in this form, you will need to submit relevant data files to [REPOSITORY] as part of the Full Data Package. [REPOSITORY] standards for de-identification of Individual Participant Data are as follows:

- Compliance with the HIPAA Safe Harbor Method of De-Identification[1] by removing 18 specific identifiers from all files containing Individual Participant Data.

  or

- Compliance with the Expert Determination Method of De-Identification

I. General Information

1. Research project title
2. Primary therapeutic area
    i. Secondary therapeutic area, if applicable
3. Research setting (single-site or multi-site)
4. Country where analyses will be conducted

II. Data Contributor Contact Information

1. Name
2. Position
3. Employer, company, research institution, or primary affiliation
4. Education, professional qualifications, and memberships
5. Affiliation(s) with company, research institute, academic institute, etc.
6. Email Address
7. Phone Number
8. Mailing Address

[1] Full requirements for the HIPAA Safe Harbor method of de-identification may be found on HHS.gov at https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html

III. Catalog Metadata Elements[2]

[REPOSITORY] will incorporate these Catalog Metadata Elements into its public-access database for viewing by potential data requestors.

1. NCT ID (study ID assigned by ClinicalTrials.gov, if study was registered)
2. Study Title
3. Secondary IDs (any study identifiers assigned by other publicly available trial registries, grant agencies, and funding agencies)
    a. Registry identifier
    b. US NIH Grant/ Contract Award Number
    c. [FUNDER] Grant/ Funding Number
    d. Other Grant/ Funding Number
    e. Other Identifier
4. Sponsor name and type (the name of the entity or the individual who is the sponsor of the clinical study)
5. Collaborators (other organizations or individuals providing study support in funding, design, implementation, data analysis, or reporting)
6. Study start date
7. Study completion date
8. Actual enrollment
9. Age limits (minimum and maximum age of potential participants)
    a. Minimum age
    b. Maximum age
10. Sex (sex of the participants eligible to participate in the clinical study)
11. Study accepts healthy volunteers?
    a. Y/N
12. Location of study sites (countries)

IV. Required Full Data Package Elements (please upload as file attachments)

1. Full Analyzable Dataset (includes derived variables and consists of various components, e.g., participant characteristics and primary outcome, pre-specified secondary and tertiary outcomes, adverse event data, and exploratory data).
2. Full Study protocol (the initial and final study protocols from the [FUNDER]-sponsored research project, including all amendments, e.g., changes in analytic strategy, changes in endpoint, etc.)
3. Data Dictionary

[2] [FUNDER]'s partnering repositories may surface different catalog metadata elements. Additionally, the list of catalog metadata elements may differ for observational studies and studies with qualitative data. We therefore recommend that this list of Catalog Metadata Elements be adjusted in accordance with partnering repositories' practices.

4. Full Statistical Analysis Plan (including all amendments and all documentation for additional work processes)
5. Analytic Code (not proprietary)
6. Summary of the method of de-identification of Individual Participant Data

V. Additional Full Data Package Elements (please upload as file attachments)

1. Original informed consent form
2. Final informed consent form
3. Appropriate extracts from Clinical Study Reports

VI. Conflicts of Interest

1. Please disclose any conflicts of interest for the Data Contributor. Conflicts of interest arise when an individual's commitments and obligations to his/her research are likely to be compromised by a person's other interests or commitments—particularly financial. Examples of Conflicts of Interest include, but are not limited to, the following: giving remunerated lectures on behalf of companies whose economic interests are affected or perceived to be affected by an investigator's scholarly work; a paid consultancy with a company that has an interest in the investigator's work; equity holding in a company by an inventor who is evaluating technology licensed to that company; and holding an office in a company whose interests would reasonable appear to be affected by the conducted research.

VII. Study Bibliography

1. Please list all accepted presentations and peer-reviewed publications related to your study. Please include the full title, full names of author(s), place of publication/ publisher, journal name/ volume/ issue, full date, and page numbers as applicable.

VIII. Requirements and Attestations

1. Compliance with ethical standards: please check one of the two boxes below.

☐ I attest that, to the extent required by applicable law, there is appropriate documentation of participant informed consent that permits data collected as part of the research project to which the Full Data Package relates to be de-identified, and for such de-identified data to be used for secondary research purposes and shared with researchers not affiliated with the institution conducting the research project.

☐ I attest that, because obtaining express consent (as described above) is not required by applicable law, there is an appropriate waiver of any such

consent requirement by a body empowered under applicable law to waive such a requirement.

2. Compliance with data privacy and confidentiality standards
    i. Please check the box below to attest that all files containing Individual Participant Data have been de-identified in accordance with [REPOSITORY] standards, as defined on Page 1 of this Form.

☐