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 delineate the responsibilities and requirements for requesters of data from data repositories. Please find information regarding the contents of this document below:

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THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Template Data Use Agreement

This Data Use Agreement (this "Agreement") is effective as of _____, 20[XX] (the "Effective Date") between _____ [RECIPIENT INSTITUTION NAME] ("RECIPIENT") located at [RECIPIENT INSTITUTION ADDRESS] and _____ [SUPPLYING INSTITUTION NAME] ("REPOSITORY") located at [SUPPLYING INSTITUTION ADDRESS].[1]

Background and Recitals

WHEREAS, in order to make the requested Full Data Package available to APPROVED USERS and to assure that the information contained therein is appropriately protected, [REPOSITORY] intends to provide a copy of the requested Full Data Package to [RECIPIENT] for the purpose(s) described in the Data Request Form incorporated into this Agreement by reference;

WHEREAS, [REPOSITORY] and [RECIPIENT] are committed to maintaining the privacy of research participants by protecting their identities against Deductive Disclosure;

WHEREAS, this Agreement is of mutual interest and benefit to [REPOSITORY] and [RECIPIENT] and will further the pursuit of open science;

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

I. Definitions of Terms and Parties

a. "SUPPLYING 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 worked with the data contributor to curate the Full Data Package being requested by RECIPIENT.

b. "RECIPIENT INSTITUTION" (RECIPIENT) refers to the entity that will have access to, and will conduct analyses based upon, the Full Data Package obtained through this Agreement. Those affiliated with the RECIPIENT INSTITUTION, as listed in the Data Request Form, are hereby deemed to be APPROVED USERS.

[1] We recommend that an institution always serve as the signatory of the DUA, if possible. In the event that an individual *not affiliated with an institution* requests access to a dataset, this template may be amended accordingly. The term "[RECIPIENT INSTITUTION NAME]" may be changed to "[RECIPIENT INDIVIDUAL]."

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

d. "CONTRIBUTING INDIVIDUAL OR INSTITUTION" (CONTRIBUTOR) refers to the [FUNDER] Research Awardee that initially deposited the Full Data Package in the REPOSITORY.

e. "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 and conditions of this Agreement. For THIRD PARTIES to gain access to the Full Data Package, they must enter into an assurance of compliance with the terms of this Agreement in accordance with Section IV.d. of this Agreement.

f. "Full Data Package" includes all study-specific information that [REPOSITORY] makes available to [RECIPIENT] under the terms and conditions this Agreement. Elements of the Full Data Package include the Full Analyzable Dataset, the Full Protocol, Metadata, Data Dictionary, Full Statistical Analysis Plan (including all amendments and all documentation for additional work processes), and Analytic Code (not proprietary), and a summary of the method of de-identification of Individual Participant Data (IPD).

g. "Analyzable Data Set" refers to the final cleaned, edited, and locked data set generated after the [FUNDER]-sponsored research project has been declared complete and is 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).

h. "Data Request Form" describes the research purposes for which [RECIPIENT] requests access to the Full Data Package. [RECIPIENT] provides information in the following categories: (1)general information, (2) information about the research team (including the lead researcher and key personnel), (3) research proposal, (4) dataset linkage, (5) lay summary/ public abstract, (6) statistical analysis plan, (7) project timeline, (8) dissemination and publication plan, (9) funding of the proposed research, (10) conflicts of interest, and (11) requirements and attestations.

i. "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 are the subjects of data contained within the Full Data Package is expressly prohibited.

j. "Safety Concerns" means any new information that might influence the evaluation of the risks and benefits of the product to which the Full Data Package pertains.

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

l. "New Intellectual Property" means all discoveries, developments, inventions (whether patentable or not), improvements, methods of use or delivery, know-how, or trade secrets that are made by [RECIPIENT] in connection with the use of the Full Data Package under the terms of this Agreement.

II. Relationship between Parties

a. The relationship of the Parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other, and neither party has authority to make any statement, representation, commitment, or action of any kind that purports to bind the other without the other's prior written authorization.

III. Incorporation by Reference

a. All Parties agree that the following documents are incorporated into this Agreement by reference:
    i. The Data Request Form, as defined in Section I.h.
    ii. Assurance of Compliance for Key Personnel (see Appendix A).

IV. Rights of Use of Data

a. [RECIPIENT] will only use the Full Data Package for the reasons expressly stated in this Agreement.
    i. It is prohibited for [RECIPIENT] to sell any portion of the Full Data Package to any entity for any reason;
    ii. It is prohibited for [RECIPIENT] to use or attempt to use the Full Data Package in support of litigation or to harm, marginalize, or discriminate against individuals or populations, whether in insurance, employment, or other manners.

b. If, at any point after execution of this Agreement, [RECIPIENT] seeks to conduct analyses on the Full Data Package that differ from those described in the Data Request Form, [RECIPIENT] must complete and submit a separate Data Request

Form for consideration by [REPOSITORY], which, if approved, will result in a separate Data Use Agreement;

c. If, at any point after execution of this Agreement, [RECIPIENT] wishes to link datasets for purposes not explicitly described in the Data Request Form, [RECIPIENT] must submit a formal request to [REPOSITORY] in writing, which will require that a formal amendment to the original DUA be executed. The formal request for dataset linkage must include a brief justification and/or rationale (see Appendix B).
    i. [REPOSITORY] will acknowledge receipt of formal request by contacting [RECIPIENT]. This acknowledgment will mark the first day of a fourteen-day hold placed on the Full Data Package. During this fourteen-day hold, [RECIPIENT] may not perform the requested dataset linkage. [REPOSITORY] will use this fourteen- day period to review the submitted request and discuss with [RECIPIENT] any concerns and/or objections to the requested linkages.
    ii. If [REPOSITORY] approves [RECIPIENT]'s request to perform dataset linkage, [RECIPIENT] may proceed with proposed linkage(s);

d. If, at any point after execution of this Agreement, [RECIPIENT] seeks to share any portion of the Full Data Package with THIRD PARTIES, as defined in Section I. e., [RECIPIENT] must submit a formal request to [REPOSITORY] in writing. Formal request for sharing of data package elements with THIRD PARTIES must include a brief justification and/or rationale (see Appendix C).
    i. [REPOSITORY] will acknowledge receipt of request by contacting [RECIPIENT]. This acknowledgement will mark the first day of a fourteen-day hold placed on the Full Data Package. During this fourteen-day hold, [RECIPIENT] may not transfer any elements of the Full Data Package to THIRD PARTIES. [REPOSITORY] will use this fourteen-day period to review the submitted request and to discuss with [RECIPIENT] any concerns and/or objections to the request.
    ii. If [REPOSITORY] approves [RECIPIENT]'s request to share elements of the Full Data Package with THIRD PARTIES, [REPOSITORY] will contact THIRD PARTIES in order to execute an assurance of compliance with the terms of this Data Use Agreement.

V. Data Privacy and Confidentiality

a. As stated in Section II, [RECIPIENT] is considered to be an independent contractor of [REPOSITORY]. As such, [RECIPIENT] is authorized to protect the privacy and confidentiality of the research participants who are the subjects of data contained within Full Data Package through mechanisms such as those described in Section VI.d.

b. The obligations of data privacy and confidentiality under this Section V shall not extend to any information:
    i. Which is or becomes publicly available, except through breach of this Agreement;
    ii. Which [RECIPIENT] can demonstrate that it possessed prior to, or developed independently from, disclosure under this Agreement;
    iii. Which [RECIPIENT] receives from a THIRD PARTY that is not legally prohibited from disclosing such information; or
    iv. Which [RECIPIENT] is required by law to disclose, provided that [REPOSITORY] is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement.

VI. Obligations and Activities of [RECIPIENT]

Having been granted access by [REPOSITORY] to the Full Data Package requested in the Data Request Form accompanying this Agreement, [RECIPIENT] agrees:

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

b. To comply with the Rights of Use of Data outlined in Section IV of this Agreement;

c. That use of the Full Data Package will be consistent with relevant policies regarding scientific integrity and human subjects research.
    i. [RECIPIENT] agrees to comply with all internal rules and regulations in requesting and using the Full Data Package;
    ii. [RECIPIENT] is responsible for determining whether the method of de-identification of the Full Data Package is compliant with applicable federal, state, local, and institutional laws and regulations, as further described in Section VI.h.;

d. To ensure that all APPROVED USERS will use appropriate administrative, physical, and technical safeguards to prevent Deductive Disclosure of research participants' identities. Safeguards against Deductive Disclosure include, but are not limited to, the following:
    i. Refraining from attempting, under any circumstances, to re-identify and/or contact research participants who are the subjects of data contained within the Full Data Package;
    ii. Refraining from making any attempts, other than those explicitly disclosed to and approved by [REPOSITORY] in the Data Request Form and/or formal written request(s), to link the information contained in the Full Data Package with information contained in another data set—including other

data sets provisioned by [REPOSITORY] as part of this or subsequent Agreements—in order to discern participants' identities.

e. That, upon becoming aware of Deductive Disclosure of research participants' identities, unapproved access to elements of the Full Data Package, or use of the Full Data Package that violates the terms and conditions of this Agreement, [RECIPIENT] will report such activity to [REPOSITORY] in writing within three (3) business days of discovery;

f. To inform [REPOSITORY] immediately and in writing of any Safety Concerns, as defined in Section I.j, discovered during analyses.
    i. [RECIPIENT] acknowledges that [REPOSITORY] may take action regarding such Safety Concerns, including informing regulatory authorities or healthcare providers, or otherwise making the Safety Concerns public.

g. To allow [REPOSITORY] to conduct inspections of [RECIPIENT]'s use of the Full Data Package. Inspections may consist of on-site audits during normal business hours, upon reasonable written notice, for purposes of evaluating whether [RECIPIENT] is compliant with the terms of this Agreement and all applicable privacy and confidentiality laws and regulations;

h. To comply with all applicable federal, state, and local laws or regulations, including privacy laws and regulations, in requesting and using the Full Data Package. In the event of a conflict between applicable laws and regulations, the stricter law or regulation will apply.

i. To provide a summary of all findings (including negative findings) related to the secondary use of the Full Data Package to [REPOSITORY], in accordance with Section X, which will be posted on [REPOSITORY]'s website within 12 months of the data the approval of the data request.

j. To post, or make otherwise available in an eligible repository, all derived datasets related to the secondary use of the Full Data Package.

k. To acknowledge the [CONTRIBUTOR] as a primary source of the data and [FUNDER] as a funder in all Publications, as defined in Section I.k., that result from secondary use of the Full Data Package, as specified in Section IX.

VII. Obligations and Activities of [REPOSITORY]

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

a. To fulfill its duties of preserving, managing, and providing [RECIPIENT] with access to the Full Data Package. Specifically, [REPOSITORY] is responsible for the following:
   i. Managing the costs for database management and support;
   ii. Storing, translating, copying, and/or re-formatting the Full Data Package in any way to ensure its future preservation and accessibility;
   iii. Provisioning the Full Data Package to [RECIPIENT] within a reasonable time of execution of this Agreement by appropriate [REPOSITORY] officials;
   iv. Providing support to [RECIPIENT] with respect to the Full Data Package. If [REPOSITORY] is unable to answer [RECIPIENT]'s questions related to the Full Data Package, [REPOSITORY] will communicate with the [CONTRIBUTOR] to answer [RECIPIENT]'s questions. [REPOSITORY] reserves the right to decline to address any questions;
   v. Posting a summary of all findings (including negative findings) related to the secondary use of the Full Data Package to the repository website within 12 months of the date of the approval of this data request. This summary will be provided by [RECIPIENT], as specified in Section VI.i.
   vi. Requiring [RECIPIENT] to post, or make otherwise available in an eligible repository, all derived datasets related to the secondary use of the Full Data Package.
   vii. Requiring that [RECIPIENT] acknowledge the data contributor as a primary source of the data and [FUNDER] as a funder in all Publications, as defined in Section 1.k.

b. To not use the Full Data Package for any purpose other than facilitating access to the information contained therein by APPROVED USERS. [REPOSITORY] will 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;

c. That, in the event of unintended release of data at [REPOSITORY] through either security breach or unauthorized access, [REPOSITORY] will inform [RECIPIENT] in writing in a timely manner. [REPOSITORY] will provide for reasonable correction where possible;

d. To inform the proper regulatory authorities or healthcare providers in the event of newly discovered Safety Concerns, as defined in Section I.j.

e. To conduct an inspection of [RECIPIENT]'s use of the Full Data Package, when necessary.

VIII. Data Ownership

a. [RECIPIENT] acknowledges and agrees that the Full Data Package and any rights therein are owned or controlled by the [REPOSITORY] and that, other than the limited license granted hereunder, [RECIPIENT] does not have or obtain any right, title, or interest of any kind in the Full Data Package.

b. [RECIPIENT]'s research and analyses, summary results, and Publications will belong to [RECIPIENT] and may be retained by [RECIPIENT]. [RECIPIENT] shall post the results of conducted analyses appropriately, in accordance with Section IX. Only on condition of default does [REPOSITORY] exercise its right to post results of conducted analyses after termination of this Agreement with appropriate acknowledgment of [RECIPIENT].

IX. Publication

a. [REPOSITORY] supports academic freedom and expects that [RECIPIENT] will make the results of research and/or analyses using the Full Data Package available through Publication as defined in Section I.k. in a timely and complete manner. All Publications ought to adhere to the following guidelines:[2]
   i. [RECIPIENT] shall not publish Confidential Data and/or information relating to the identities of research participants in any Publications or citations;
   ii. [RECIPIENT] shall not publish Full Data Package elements, or portions thereof, in any Publications or citations;
   iii. [RECIPIENT] shall acknowledge the data contributor as a primary source of the data and [FUNDER] as a funder in all Publications that result from secondary use of the Full Data Package.

b. [RECIPIENT] shall provide to [REPOSITORY] a copy of any proposed Publication within five (5) days of submission to a scientific congress or journal. Notice to [REPOSITORY] must be in writing and shall consist of the proposed title of the Publication and a copy of the Publication. Upon successful publication, [RECIPIENT]

[2] The MRCT Center did not decide on an appropriate time limitation re: attempts to publish results of research and/or analyses. The Office of Science Policy at the National Institutes of Health similarly acknowledges the challenge of enforcing a timeline on publications in its published Strategies for NIH Data Management, Sharing, and Citation, available at https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

shall provide [REPOSITORY] with the applicable reference citation(s). If derivative dataset(s) developed by [RECIPIENT] during secondary analyses are deposited in a repository and assigned a globally unique identifier (GUID), [RECIPIENT] shall additionally provide [REPOSITORY] with the data citation(s) of relevant dataset(s).

X. Results and Analyses Reporting

a. Upon completion of the research and analyses proposed in the Data Request Form, [RECIPIENT] must 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 the repository's website within 12 months of the data the approval of the data request.[3]

b. If [RECIPIENT] does not complete the research and analyses as proposed in the Data Request Form, [RECIPIENT] shall notify [REPOSITORY] promptly and in writing. [REPOSITORY] may terminate this Agreement in accordance with Section XII.

XI. Intellectual Property and Licensing

a. [RECIPIENT] will notify [REPOSITORY], promptly and in writing, of any New Intellectual Property. [RECIPIENT] hereby grants to [REPOSITORY] and to [REPOSITORY]'s affiliates a perpetual, non-exclusive, royalty-free, worldwide license for all purposes to each such New Intellectual Property.
    i. [RECIPIENT] agrees to obtain written agreements with employees, agents, and subcontractors who assign, without additional consideration, all rights, title and interests in New Intellectual Property to [RECIPIENT] for subsequent licensing to [REPOSITORY].

b. [REPOSITORY MAY INSERT ANY ADDITIONAL INFORMATION ON INTELLECTUAL PROPERTY AND LICENSING]

c. The obligations of this Section shall survive termination of this Agreement.

XII. Term and Termination

a. Duration of Agreement
    i. This Agreement shall be effective for 1 year from the Effective Date.
    ii. [RECIPIENT] may request an extension of the duration of this Agreement, in writing, no later than 15 days before 1 year from The Effective Date of this Agreement. If request for extension is approved by [REPOSITORY], duration of this Agreement may be extended for a finite length of time, and from

[3] Repositories have their own policies regarding the use of these summary results. Some post them publicly on their website; others keep them for archival purposes. [FUNDER] must decide whether to honor the process(es) of its partnering repositories or to establish its own re: summary results reporting.

time-to-time as agreed upon by both Parties. Neither Party is obligated to extend this Agreement.

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. After completion of the research and analyses detailed in the Data Request Form found in Appendix A of this Agreement, expiration of the Terms of this Agreement, or termination of this Agreement, whichever shall occur first, [RECIPIENT]'s access to the Full Data Package will be terminated.
        1. In addition, if applicable, [RECIPIENT] will return to [REPOSITORY] or destroy (at [REPOSITORY]'s option) all copies of the Full Data Package on whatever media they exist. If [REPOSITORY] requests that [RECIPIENT] destroy the Full Data Package, [RECIPIENT] shall provide a certification evidencing such destruction within 30 days of the expiration date.

    ii. Notwithstanding the foregoing, if [RECIPIENT]'s results and analyses are accepted for publication, as described in Section IX of this Agreement, [RECIPIENT] may retain rights to use the Full Data Package for verification of [RECIPIENT]'s Publications and to respond to inquiries regarding those Publications.
        1. During this period, [RECIPIENT] may not use the Full Data Package to conduct additional or different research and/or analyses without submitting a new Data Request Form and obtaining approval from [REPOSITORY].

    iii. Obligations relating to the Full Data Package, Confidentiality, and Publication and Citation will survive termination of this Agreement, as will any other provision that by its nature and intent remains valid after termination.

XIII. Representations and Warranties

a. [RECIPIENT] represents and warrants that [RECIPIENT INSTITUTION] does not have, and will not 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 IV and Section VI.

b. [RECIPIENT] represents and warrants that it has the authority to bind the individuals listed as Key Personnel in the Data Request Form accompanying this Agreement to the terms of this Agreement for the purposes described therein via the completion of Assurance of Compliance Addenda.

XIV. Indemnification

a. [RECIPIENT] 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 [RECIPIENT] in this Agreement, (b) any breach or violation of any material covenant or agreement of such [RECIPIENT] in or pursuant to this Agreement, and (c) the gross negligence or willful misconduct by [RECIPIENT] 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 [REPOSITORY] in or pursuant to this Agreement, or the gross negligence or willful misconduct of [REPOSITORY].

XV. 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 [RECIPIENT] 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 [RECIPIENT] and [REPOSITORY], and no further approvals are necessary to create a binding agreement.

c. The obligations and activities of [RECIPIENT], 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 [REPOSITORY]
   (name):_____
   (address):_____
   (city, state, country, zip code):_____
   (email address):_____

   ii. If to [RECIPIENT]
   (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.

[REPOSITORY INSTITUTION]

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

[RECEIVING INSTITUTION]

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

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Template Assurance of Compliance for Key Personnel

The following individuals, listed as Key Personnel in the Data Request Form incorporated into the Data Use Agreement by reference, are authorized to receive and use the Full Data Package described in the Data Use Agreement for the purposes described therein.

By signing below, we acknowledge the restrictions on our use and disclosure of the Full Data Package in accordance with the Data Use Agreement.

Name: _____
Position: _____
Employer, company, research institution, or primary affiliation: _____
Signature: _____
Date: _____

Name: _____
Position: _____
Employer, company, research institution, or primary affiliation: _____
Signature: _____
Date: _____

Name: _____
Position: _____
Employer, company, research institution, or primary affiliation: _____
Signature: _____
Date: _____

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Template Written Notification for Desire to Link Datasets

Please address the following questions when formally requesting approval from [REPOSITORY], in writing, to link datasets (as described in Section IV.d. of the Data Use Agreement):

1. Please explicitly describe all plans to link individual participant-level data from two or more sources (including datasets provisioned through execution of the initial Data Use Agreement).

2. Describe how the requested linkage of data sets will enable you to address the specific research aims outlined in the submitted Data Request Form. How is dataset linkage consistent with your initial research proposal? What added value will dataset linkage offer?

3. Are there any additional requirements that may influence successful linkage of datasets, such as information needed to match patients, selection of data elements, and definitions used? If so, how do you plan to acquire and execute such additional requirements?

4. Please explain the procedures and algorithms you will employ in linking datasets, including the success, limitations, and validation of the matching algorithm(s).

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Template Written Request to Share Elements of Data Package with Third Parties

Please address the following questions when formally requesting approval from [REPOSITORY], in writing, to share elements of the Full Data Package with THIRD PARTIES (as defined in Section I.d. of the Data Use Agreement):

1. Please provide the following information about the THIRD PARTY:
    a. Name
    b. Position
    c. Employer, company, research institution, or primary affiliation
    d. Education, professional qualifications, and memberships that are relevant to the proposed research
    e. Affiliation with company, research institute, academic institute, etc.
    f. Contact Person
        i. Name
        ii. Position
        iii. Email Address
    g. History of collaboration of THIRD PARTY with [RECIPIENT]

2. Please explicitly describe the reasoning behind your desire to share elements of the Full Data Package with the above THIRD PARTY.
    a. Which elements of the Full Data Package do you plan to share with the THIRD PARTY?
    b. How, specifically, will the THIRD PARTY be involved in the research and analyses proposed in the original Data Request Form?

3. Describe the ability of the THIRD PARTY to comply with the terms of Sections IV and V of the original Data Use Agreement (Rights of Use of Data, and Data Privacy and Confidentiality, respectively). Are you confident that the THIRD PARTY will take appropriate measures to protect against misuse of the Full Data Package?

4. Please disclose any real or potential conflicts of interest between you and the THIRD PARTY. Please discuss how these conflicts of interest will be managed.

Template Data Request Form

Please complete this Data Request Form to inform [REPOSITORY] about the research purpose(s) for which you request access to the Full Data Package. Completing this form ensures that [REPOSITORY] has an accurate understanding of the rationale underlying your data request. Your request will undergo review by an independent committee directed by a [FUNDER]-designated repository. The purpose of this review is to ensure that the research purpose(s) for which you request access to the Full Data Package has scientific merit, in that (1) the scientific purpose is clearly described; (2) the data requested will be used to create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health; (3) the proposed research can be reasonably addressed using the requested Full Data Package; and (4) that the data requestor team has the appropriate expertise to conduct the proposed research.

If your request for access is approved, please be informed that [REPOSITORY] will post a summary of this data request on its public website. This summary will include the data fields with asterisks (*) next to them (the scientific purpose of the analysis being proposed and the identity of data requestors). In making this information available to the public, [REPOSITORY] seeks to minimize the prevalence of duplicative research and maximize the utility of deposited datasets. If, for some reason, it would be detrimental and ill-advised to make this information available to the public (e.g. exploration of sensitive information would put you in jeopardy), you must submit a justification to [REPOSITORY] in writing, which will be reviewed and either approved, deferred, or not approved.

I. General Information

1. Research project title
2. Primary therapeutic area
    a. Secondary therapeutic area, if applicable
3. Research setting (single-site or multi-site)
4. Country where analysis will be conducted
5. Does your proposed research require ethics committee or IRB approval? (Y/N)
    a. If yes, please provide further details below.
6. Describe the potential for the study to improve healthcare and/or outcomes.

II. Information about the Research Team

1. Lead Researcher (*required)*: the principal investigator is responsible for the scientific or technical aspects of the proposed research. He/she assumes responsibility and accountability for research execution, organization conduct, and compliance. He/she also manages day-to-day operation of the research and project, and acts as the lead research representative of the organization/ institution.
    a. Name *

b. Position *
c. Employer, company, research institution, or primary affiliation *
d. Education, professional qualifications, and memberships that are relevant to the proposed research
e. Affiliation(s) with company, research institute, academic institute, etc.
f. ORCID ID
g. Government official identification/ disclosure

2. Key Personnel *(as applicable):* key personnel are individuals who are considered to be critical to the project's scientific development or execution in a measurable, substantive way.
    a. Name *
    b. Position *
    c. Employer, company, research institution, or primary affiliation *
    d. Education, professional qualifications, and memberships that are relevant to the proposed research
    e. Affiliation with company, research institute, academic institute, etc.
    f. ORCID ID
    g. Government official identification/ disclosure

III. Research Proposal

1. Project background and statement of project significance
2. What is the scientific purpose of the analysis being proposed? *
3. What are the specific aims/ objectives of the proposed research?
    a. Please include the specific hypotheses to be evaluated.
4. Please provide a brief description of the study design. This may include a statement of whether the study is case-control, cohort, cross-sectional, historical controlled, hybrid designed, meta-analysis, pooled analysis, etc.
5. Please provide a description of the study population or populations for the proposed research. Please explain why these subgroups are of interest, and whether subgroups will be used to test a hypothesis or for exploratory analysis.
6. Please identify specific populations and health decision(s) that you anticipate will be affected by the research.
    a. Please describe (1) the specific health decision the research is intended to inform, (2) the specific populations for whom the health decision is pertinent, and (3) how study results will inform the health decision.
7. Please describe the endpoints of the requested studies that will be analyzed.
8. Please describe the specific outcomes' elements and how they will be categorized/defined for your study, including Domain (e.g., anxiety), Specific measurement (e.g., Hamilton Anxiety Rating Scale), Specific Metric (e.g., change

from baseline), Method of Aggregation (e.g., mean), and Time-point(s) (e.g., 3 and 6 months).

a. Main Predictor/Independent Variable and how it will be categorized/defined for your study:
b. Other variables of interest that will be used in your analysis and how they will be categorized/defined in your study (i.e. genders, age groups, ethnic groups)

IV. Dataset Linkage

1. Do you plan to link the individual participant-level data contained in any of the requested datasets with individual participant-level data contained in a different dataset (including another dataset requested from [REPOSITORY])? If so, please describe the following:
    a. (1) the data sources and/or the linked data set in terms of its appropriateness, value, and limitations for addressing specific research aims
    b. (2) any additional requirements that may influence successful linkage, such as information needed to match patients, selection of data elements, and definitions used
    c. (3) the procedures and algorithm(s) employed in matching patients, including the success, limitations, and any validation of the matching algorithm(s)

V. Lay Summary/ Public Abstract

1. Please provide a lay summary of the proposed research. The lay summary should include the following elements and should be written in language that the general public will understand (at or below the 8th grade reading level).
    a. Description of the problem your project seeks to solve
    b. Outcomes you hope to achieve
    c. Brief background on why this project is important
    d. How patients and other stakeholder partners will help to make the project successful

VI. Statistical Analysis Plan

1. Specify plans for quantitative and qualitative analysis that correspond to the major aims of the proposed research. Please describe how you will analyze the requested data, including descriptive, bivariate and multivariable analyses, and any other planned advanced analyses (such as propensity score methods, Kaplan-Meier or Cox modeling approaches, non-parametric testing).
    a. Option to upload file

VII. Project Timeline

1. Target Analysis Start Date
2. Analysis duration (include any follow-up period if applicable):
3. Estimated Analysis Completion Date

VIII. Dissemination & Publication Plan

1. Provide a description of anticipated products and target audience, including expectation for study manuscripts and potentially suitable journals for submission of the completed research project
2. Provide references for all cited material (following APA guidelines):
    a. Option to upload file
3. Supplementary material
    a. Option to upload file

IX. Funding of the Proposed Research

1. Is the proposed research being funded by research grants from government agencies? (Y/N)
    a. If yes, please provide details below.
2. Is the proposed research being funded by employers through employment contracts? (Y/N)
    a. If yes, please provide details below.
3. Is the proposed research being funded by additional contracts or consultancies? (Y/N)
    a. If yes, please provide details below.
4. Is the proposed research being funded by commercial organizations? (Y/N)
    a. If yes, please provide details below.

X. Conflicts of Interest

1. Lead Researcher
    a. Please disclose any potential conflicts of interest.
    b. Please discuss how these conflicts of interest will be managed.
2. Key Personnel
    a. Please disclose any potential conflicts of interest.
    b. Please discuss how these conflicts of interest will be managed.

XI. Requirements and attestations

1. Please check the box below to acknowledge that you have read and understand the requirements of this data request form, and that it was completely truthfully and accurately.

☐

2. Please check the box below to attest that the requested data will not be used for litigious purposes and that no portion of the requested data will be sold to any entity for any reason.

☐

3. Please check the box below to attest that the requested data will be used to create or materially enhance generalizable scientific knowledge, and that it will not be used to harm, marginalize, or discriminate against individuals or populations, whether in insurance, employment, or other manners.

☐

XII. Other Information

1. Please provide any additional information or upload any files that should be considered when reviewing this proposal