National Clinical Trials Network (NCTN)
NCI Community Oncology Research Program (NCORP)

NCTN/NCORP Data Archive

Data Use Agreement (DUA) for Trials Under Collaborative Agreements

Green <Brackets> note where data would be imported from Data Request Form.

Definitions

For the purpose of this agreement:

"APPROVED USERS" are all individuals from the same ENTITY (defined below) specifically identified in the Data Request Form, including the Principal Investigator (PI). Only individuals listed in this Data Use Agreement (DUA) may have access to the DATA.

"CLINICAL TRIAL" is the clinical study(ies) that collected the DATA described in this DUA.

"DATA" are the requested data covered by this DUA and may include CLINICAL TRIAL data, defined as but not limited to clinical trial participant data, "omic" data, which may include genomics, proteomics, transcriptome, metabolomics, and epigenomic data, or images/imaging data, obtained through The Cancer Imaging Archive.

"ENTITY" is any organization/institution/employer which the Principal Investigator (PI, defined below) is employed by or representing, and the research being conducted with the DATA is within the scope of the PI's employment or affiliation. By this definition, the ENTITY is the organization/institution/employer that is officially seeking access to the DATA.

"Principal Investigator (PI)" is an individual who assumes responsibility to lead the scientific investigation proposed in the Research Plan using the DATA, and is judged by the ENTITY (if applicable) to have an appropriate level of authority and expertise to do so. Responsibilities of the PI include oversight of the supporting staff who are provided access to the DATA and contribute to the analytic effort, and responsibility for all team members' compliance with the terms and conditions of this DUA.

"RECIPIENT(S)" refers to the PI, APPROVED USERS, and the ENTITY, individually or collectively.

Introduction

The National Cancer Institute (NCI), and RECIPIENT(S), hereby enter into this Data Use Agreement (DUA) as of the effective date specified on the final signatures page.

The data (DATA) and Research Plan covered by this DUA are:

<Import all information from the Data Request Form here (Requestor information, including city/state/country, Other Approved Users, and Research Plan, including clinical trials).**>**

The DATA are provided through the NCTN/NCORP Data Archive, and, in some cases, The Cancer Imaging Archive. The NCTN/NCORP Data Archive database was established by the NCI and the National Clinical Trials Network (NCTN) to develop and maintain the infrastructure necessary to facilitate and maximize access to data from NCI-sponsored NCTN/NCORP clinical trials in accordance with NCI approved procedures.

The RECIPIENT(S) agree that nothing herein will be deemed to constitute, by implication or otherwise, the grant of any license or other rights under any patent, patent application or other intellectual property right or interest. NCI reserves the right to distribute the DATA to others and to use it for NCI's own purposes.

The DATA were collected as part of the above clinical study(ies); hereafter referred to as "CLINICAL TRIAL." They constitute a unique scientific resource and the NCI is committed to making them available in a timely manner, on appropriate terms and conditions, to the largest possible number of investigators who wish to analyze the data in a secondary study designed to enhance the public health benefit of the original work. The RECIPIENT(S) acknowledge responsibility for ensuring the review of and agreement to the terms within this DUA and the appropriate research use of the DATA, subject to applicable laws and regulations. Note that any scientific collaborators, including contractors**,** who are not in the same ENTITY as the RECIPIENT(S) must submit their own Data Request Form (DRF) and DUA, subject to applicable laws and regulations.

The RECIPIENT(S) acknowledge that other researchers who have approved DUAs are entitled to access to the DATA on the same terms as the RECIPIENT(S) so that duplication of research may occur. The RECIPIENT(S) also recognize that the CLINICAL TRIAL investigators have made a substantial long-term contribution in establishing the DATA. Proper acknowledgment of their contributions (see Section 6 below) is required. Although NCI encourages appropriate collaborative relationships by outside investigators with the CLINICAL TRIAL investigators, such collaborations are not mandatory and are left for the RECIPIENT(S) and CLINICAL TRIAL investigators to define. Receipt of DATA does not entitle RECIPIENT(S) to assistance from the CLINICAL TRIAL investigators, for example with data processing or interpretation. Rather, if the RECIPIENT(S) feel they need such assistance, they can seek to establish a collaboration with the CLINICAL TRIAL investigators.

The NCI believes that the confidentiality and privacy of the CLINICAL TRIAL participants can best be assured by requiring all who are interested in accessing the DATA to acknowledge their review of this DUA and to agree to adhere to its provisions. Violation of its confidentiality provisions could lead to legal action on the part of CLINICAL TRIAL participants, their families, or the U.S. Government.

Terms of Access

1. Research Use

The RECIPIENT(S) agree that they will use the DATA solely in connection with the research project described in this DUA.

2. Recipient Responsibilities

The RECIPIENT(S) agree to report promptly to the NCI any unanticipated problems involving risks to trial participants or others, inadvertent data release, and/or unauthorized data sharing. If there is a change in the RECIPIENT(S), the RECIPIENT must submit a new DRF and DUA to the NCI.

The RECIPIENT(S) acknowledge that they will follow the appropriate human subjects protections and regulatory requirements pertaining to clinical research with respect to the Research Plan. This DUA is made in addition to, and does not supersede, any of the RECIPIENT(S)'s internal policies or any local, state, and/or Federal laws and regulations that provide additional protections for trial participants. If any RECIPIENT investigator seeks data that could unintentionally result in re-identification, RECIPIENT is aware that federal regulations may require Institutional Review Board (IRB) review.

If the DATA are the subject of a Freedom of Information Act (FOIA) request received by the RECIPIENT(S), RECIPIENT(S) intend to follow applicable federal disclosure laws and regulations.

3. Non-Identification

The RECIPIENT(S) agree to ensure that none of the APPROVED USERS will use the DATA, either alone or in combination with any other information, to attempt to identify or contact individual CLINICAL TRIAL participants. Moreover, they agree not to present or publish any information that would allow identification of CLINICAL TRIAL participants.

4. Non-Transferability of DATA

The RECIPIENT(S) agree to retain control over the DATA, and further agree not to release or distribute DATA in any form to any entity or individual unless required by the NCI or it is required to be disclosed by law or court order. The RECIPIENT(S) agree to store the DATA on a computer with adequate security controls (see Section 5), and to maintain appropriate control over the DATA at all times. DATA containing individual-level information, in whole or in part, may not be sold to any entity or individual at any point in time for any purpose.

The PI agrees that if his or her relationship with the ENTITY terminates and a relationship with a different ENTITY is established during the period of the DUA, a new DRF and DUA from the second ENTITY will need to be submitted and approved before the PI resumes use of the DATA. Any versions of the DATA stored at the first ENTITY must be destroyed. However, if advance written notice and approval by the NCI is obtained to transfer responsibility for the approved Research Plan to a different PI with a relationship with the first ENTITY (if applicable), the DATA may not need to be destroyed.

5. Security of DATA

The RECIPIENT(S) agree to store the DATA on a computer with security controls adequate to protect sensitive or identifiable information, to ensure that only approved, supervised persons have access to the DATA, and to maintain appropriate control over the DATA at all times. Hard copies of any DATA must similarly be stored under conditions sufficiently secure to avoid inappropriate access, and must be shredded prior to discarding.

This DUA will be in effect for a period of three (3) years from its effective date for the requested CLINICAL TRIAL data. At the end of the three (3) year period, the RECIPIENT(S) agree to destroy all copies of the CLINICAL TRIAL data, and all derivatives that contain individual-level information. An extension of this DUA can be made by submitting a new DRF and DUA to the NCI.

6. Intellectual Property (IP)

The RECIPIENT(S) understand that some or all of the DATA may have been collected under a binding clinical collaborative agreement between NCI and/or the NCTN/NCORP Group and a pharmaceutical company ("NCI Collaborator"). Therefore, the RECIPIENT(S) agree to abide by and provide the applicable licensing rights described in the most current "Intellectual Property Option Policy" found at the following link, with respect to any inventions generated using the DATA:

https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm

In addition, any NCI Collaborator whose DATA are provided under this agreement is hereby designated as an intended third party beneficiary of this DUA and is entitled to independently enforce all rights and obligations under this Agreement.

7. Publication Review and Acknowledgment of NCI and NCTN/NCORP Research Resources

Before a manuscript is submitted for publication, NCI and Collaborator will have thirty (30) days to review the proposed manuscript to determine if there is patentable subject matter subject to the IP Option and to review and provide informational comments. Collaborator may also contact Recipient to discuss the manuscript if there are concerns related to the manuscript. Recipient agrees to email a copy of each manuscript, including revised manuscripts being submitted to a different journal, arising from the RECIPIENT's use of the DATA to NCINCTNDataArchive@mail.nih.gov, so that NCI may send them to the NCI Collaborator for a thirty (30) day comment period prior to RECIPIENT's submission for publication. Abstracts and other public releases or public presentations should also be sent three (3) business days prior to submission or release for forwarding to the NCI Collaborator for review and comment. In addition, Collaborator has the right to use the data or algorithm generated under this agreement for internal research and regulatory purposes related to its proprietary agent(s).

The RECIPIENT(S) agree to acknowledge the contribution of the CLINICAL TRIAL in all oral and written presentations, disclosures, or publications resulting from any analyses conducted on the DATA.

The RECIPIENT(S) will acknowledge the source of the DATA by including language similar to the following either in the acknowledgment or in the text of the manuscript:

> *"This manuscript was prepared using data from Datasets [insert Dataset ID numbers for the specific datasets you used] from the NCTN/NCORP Data Archive of the National Cancer Institute's (NCI's) National Clinical Trials Network (NCTN). Data were originally collected from clinical trial NCT number [insert NCT number(s)] [insert trial title(s)]. All analyses and conclusions in this manuscript are the sole responsibility of the authors and do not necessarily reflect the opinions or views of the clinical trial investigators, the NCTN, the NCORP or the NCI."*

Within 60 days after publication of a manuscript resulting from use of the DATA, the RECIPIENT agrees to report the PubMed ID of the publication and a copy of the publication to NCI at NCINCTNDataArchive@mail.nih.gov.

8. Non-Endorsement, Indemnification

The RECIPIENT(S) acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of the DATA, the NCI and CLINICAL TRIAL investigators do not and cannot warrant the results that may be obtained by using any DATA included therein. The NCI and all contributors to these DATA disclaim all warranties as to performance or fitness of the DATA for any particular purpose.

No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that the NCI, as an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 et seq.

9. Termination and Violations

The NCI may terminate this agreement if the RECIPIENT(S) are in default of any of its conditions and such default has not been remedied within 30 days after the date of written notice of such default by an authorized representative of the NCI. Past violations will be taken into consideration by the NCI for future requests from the RECIPIENT(S) to access NCI data.

10. Representations and Certifications

The RECIPIENT agrees that it will use the Data in compliance with all applicable anti-terrorist financing and asset control laws, regulations, rules and executive orders, including but not limited to, the USA Patriot Act of 2001, Executive Order 13224, and The Department of the Treasury's Office of Foreign Assets Control's (OFAC) economic and trade sanctions.

The RECIPIENT hereby agrees that he/she is not located in, ordinarily resident in, or controlled by any entity or person located in a country that is, at any time that RECIPIENT uses the DATA, subject to sanctions by the U.S. government or, to the best of its knowledge, is not identified on any list of restricted parties maintained by the United States government, including, but not limited to, the Specially Designated Nationals List administered by the U.S. Treasury Department's Office of Foreign Assets Control or the Denied Persons List,

Debarment List maintained by the U.S. Food and Drug Administration, or the Unverified List or Entity List maintained by the U.S. Commerce Department's Bureau of Industry and Security.

The RECIPIENT further represents and certifies that the DATA will not be published or posted on any public site.

11. Supplemental DATA

The RECIPIENT(s) understand and agree that any supplemental DATA obtained through the NCTN/NCORP Data Archive, The Cancer Imaging Archive, or directly from the Network Group are subject to the terms and conditions contained within this agreement.

Signatures Page

By submission of this DUA, the RECIPIENT(S) attest to the APPROVED USERS' qualifications for access to and use of the DATA and certify their agreement to the NCI principles, policies, and procedures for the use of the DATA as articulated in this document.

READ AND ACKNOWLEDGED BY PRINCIPAL INVESTIGATOR:

NOTE: If the PI is a US resident and is not affiliated with an ENTITY, the PI may sign this agreement as an authorized signatory with the understanding that he/she will be personally liable in the event of a breach. If the PI is employed or affiliated with an ENTITY, he/she should contact the offices described below* to determine the appropriate signatory.

Name: *<NAME OF MAIN REQUESTOR>*

E-Mail Address: *<EMAIL OF MAIN REQUESTOR>*

Signature: _____

Date: _____ Country: _____

BY ENTITY (if applicable)**:**

Name of ENTITY: _____

Name and Title of Authorized Representative*:

_____

E-Mail Address: _____

Signature: _____

Date: _____ Country: _____

*An Authorized Representative is someone who is delegated signature authority to bind the ENTITY to the legal terms of the DUA. The representative is usually located in a Technology Transfer Office, Sponsored Research Programs, Office of General Counsel, or Business Development Office. NCI policy is such that the signatory for the DUA must be associated with the ENTITY of the PI and APPROVED USERS (if applicable under the definition of ENTITY provided on page 1). The data request will not be processed until your Authorized Representative signs the DUA, if applicable.

BY NCI Authorized Representative: *(This section for NCI use.)*

Name and Title: _____

Signature: _____

Effective Date: _____