Additional Information/Reference Guide/General Information

All DUAs require review and approval by the Sponsored Project Office, UNM HSC Privacy Office and Information Technology Security Office (where unapproved or custom solutions are required). The UNM HSC University Counsel may be consulted to review the negotiation of applicable terms. Please allow additional time for review and negotiation.

If data is publicly available, a data use agreement IS NOT required. **"Publicly Available"** refers to data and/or biospecimens that are accessible to anyone in the general public, without the need for special qualifications, permissions (certifications or electronic signatures to access the data), or privileges. Examples include data/biospecimens available for public purchase, searchable online, or available at a library.

Examples of types of identifiable data/biospecimens that are not considered "public" are:

- Date in electronic medical record
- Social media data labeled as "private" by the data owner, or not readily available without permission of this site Owner/Administrator under the Terms of Service of the site;
- Data protected by copyright, such as databases or other unique or original ways of gathering data, or licensed data, such as library databases; and
- Data or Biospecimens that have access restrictions (e.g. are only available to clinicians or qualified researchers or may only be accessed on a secure server.

After completing this form, to initiate the DUA request, you will need to create a record in Click Agreements (https://hsc.unm.edu/about/finance/sponsored-projects/ under Quicklinks/ClickERA Agreements). If you do not have an account, please contact HSC-Preaward@salud.unm.edu in order to receive the steps to obtain an account. If you have a Click account but have not used Click Agreements, please contact HSC-PreAward@salud.unm.edu to request the appropriate role (i.e. PI).

DUA CONTACTS:

SPONSORED PROJECTS OFFICE: HSC-DUASPO@salud.unm.edu

PRIVACY OFFICE: HSC-Privacy@salud.unm.edu

INFORMATION SECURITY OFFICE: HSC-ISO@salud.unm.edu

To expedite the process, please provide all requested information and direct any questions to HSC-DUASPO@salud.unm.edu for assistance. ***Please allow at least 5 business days to hear from us.***

Reference Guide / Questions Assistance

(Question 1) Information:

Please provide complete contact information for self and collaborators. This information assists the SPO with information that must be required on a data agreement and provides collaborator contact information for executing the agreement.

(Question 2) Short Description:

Please provide as much summarized information as possible about this project. This should include information such that each party understands the project that the Recipient will perform using the Data. For example: I am looking into submitting a grant to NIH. I require (data from...) to compare against my current analysis to provide as part of my submission. You might include other pertinent information such as

- Whether the data is obtained from human subjects and, if so, a description of the population included in the data.
- If the data is from animal subjects, the species of animal the data was obtained using.
- If not from human or animal subjects, a description of the focus of the data.
- The number of subjects and/or experiments included
- Name of the study that the data was obtained under

(Question 3) Receiving/Outgoing/Mutual:

Please provide whether you will be -

- Receiving the data from another company/institution (this would include accessing their systems to obtain the data)
- Sending data based off research findings and/or that is accessible from UNM specific systems
- Mutually sending data and receiving data

This question helps determine the DUA template that will be used.

(Question 4) Data Repository Upload:

Will the data be uploaded to a repository by you, your team, or the recipient? If so. Please specify whether the repository is federally or privately managed, and provide its full name.

(Question 5) Data Transmission/Access:

If data is being accessed on a web site, such as a virtual data enclave, a proprietary system, a data repository, or other means of access where **data is not transferred out of the system**, please provide sufficient details on the location of the data (e.g., web address, data set name, etc), the name of the provider, any contact information for the data owner, and information about or links to information on security, maintenance, and access controls.

If data is transferred to or from HSC, there are currently two approved options, Secure File Transfer System (SFTP) and REDCap. These are usually for transferring secure data sets (SFTP) and for external parties entering clinical data into our REDCap data collection forms. Qualtrics is a UNM-sponsored survey tool that can also be used for non-clinical data collection. If none of these options is viable, due to data set size, restrictions from the data provider, or other reasons, the HSC Information Security Office (HSC ISO) will need to review your proposed data transmission

solution. To work with them on options prior to review, contact the office at HSC-ISO@salud.unm.edu. For this form, provide as much information as possible to help HSC ISO understand your proposed solution, provide sufficient details on the proposed data transfer method, including the name of the provider, any contact information for the data owner, and information about or links to information on security, maintenance, and access controls.

(Question 6) Human Subject Data:

If human subject data, please provide the approved IRB protocol number. If you have submitted your protocol to the IRB for review but it has not yet been approved, please select "Pending." If this is not Human Subject research, please select "not applicable."

If human subject data and you have not started developing your IRB protocol, we encourage you to start that process now. The DUA agreement can be negotiated/executed congruently with your IRB submission being reviewed. However, you will not be able to send/receive data without an approved IRB protocol.

(Question 7) Examples/Definitions for Completion of Data Descriptions:

***De-identified Human Subjects*:** This data has been stripped of all "direct identifiers" or all information that can be used to identify the patient from whose medical record the health information was derived. Examples of these identifiers are referenced under Question 7 above.

The de-identified data may include health statistics, general demographic information (without specific geographical indicators below the state level), and aggregate age categories (such as "90+").

Limited Data Set (LDS): A Limited Data Set refers to a subset of identifiable patient information, as defined under HIPAA's Privacy Regulations, that excludes certain direct identifiers but can still be used for research, public health, or healthcare operations (with a Data Use Agreement in place).

An LDS contains health information and one or more of the following:

- Dates such as admission, discharge, service dates, and dates of birth (DOB) or death (DOD)
- City, state, and five-digit ZIP code
- Age (in years, months, days, or hours)

For data to qualify as an LDS, the following identifiers must be removed for the patient, their employer, relatives, and household members:

- Names
- Street addresses (other than city, state, ZIP code)
- Phone and fax numbers
- Email addresses
- Social Security numbers
- Medical record and account numbers
- Health plan beneficiary numbers
- Web URLs and IP addresses
- Vehicle identifiers and serial numbers (e.g., license plates)
- Device identifiers and serial numbers
- Biometric identifiers (fingerprints, voiceprints)
- Full-face photographic images or comparable images

A Data Use Agreement (DUA) must be in place before disclosing an LDS to ensure proper privacy

safeguards.

Protected Health Information (PHI) - HIPAA: PHI is information that is created or received by a health care provider and that relates to the physical or mental health condition of an individual; the provision of health care to the individual; and the payment information for the individual's receipt of health care.

HIPAA, the Health Insurance Portability and Accountability Act does the following:

- Requires the protection and confidential handling of protected health information
- Mandates industry-wide standards for health care information on electronic billing and other process
- Provides the ability to transfer and continue health insurance coverage for millions of American workers and their families when they change or lose their jobs; and
- Reduces health care fraud and abuse

Personally Identifiable Information

Personally identifiable information (PII) is human subjects data that does not include health information, but does include one or more data elements that would allow subjects to be re-identified. This includes name, email address, address, and other elements that are listed in Question 7. This category is appropriate for many types of social science, behavioral, and educational research, such as, but not limited to, surveys, interviews, focus groups, educational test information, etc.

More information on PII, adapted from: https://ria.princeton.edu/human-research-protection/data/what-kind-of-data-protect

PII can be benign information about individually identifiable people, such as data on human subjects who have been given an assurance of confidentiality. Benign data files do not contain sensitive information but need some protection due to the assurance of confidentiality. Accidental or unintended disclosure is unlikely to result in harm to the study subjects. The risks to the research subject may be considered no greater than those associated with everyday life.

PII can also contain sensitive information about individually identifiable people, that, if disclosed, could reasonably be expected to present a non-minimal risk of civil liability, moderate psychological harm, or material social harm to individuals or groups. The risks to the research subject may be considered greater than those associated with everyday life.

PII can also include very sensitive information about individually identifiable people that could cause significant harm to an individual if exposed, including, but not limited to, serious risk of criminal liability, serious psychological harm or other significant injury, loss of insurability or employability, or significant social harm to an individual or group. The risks to the research subject may be considered greater than those associated with everyday life. This can include genetic information.

Other:

This can include data from animal research, basic sciences research, and any other research type not meeting the standards of the options above. Please describe the data in detail and indicate whether it includes any data elements that are considered confidential or proprietary.

(Question 8) Examples/Definitions for Completion of Data Descriptions:

Please check all boxes that apply regarding the data that will be analyzed and shared. These selections assist with determining the data description.

(Question 9) Certificate of Confidentiality:

Please note if the data provided/received is covered under a Certificate of Confidentiality.

(Question 10) Instructions for Completion of Data Description:

This section should provide enough information so that each party understands the information transmitted under this DUA. Please reference Question 7 for examples of data elements for human subject research.

(Question 11) Instructions for Data Ownership:

You will indicate data ownership. If you created the data, you/UNM would be considered the owners. If another company/institution created the data, they would be the owners.

(Question 12) Material Transfer Requirement:

An MTA may be required if you need to receive/send material related to the data being exchanged. A material transfer agreement governs the transfer of tangible research property for research use. It is important to note that although the DUA can be executed prior to an IRB protocol being approved, an MTA cannot be executed without confirmation of an approved IRB protocol. A SPO representative would reach out to you with further direction if you selected "yes" to this question.

Please note: If you have already created a Click Agreements record for your MTA, and it has not yet been executed, please reach out to the SPO Specialist assigned to the agreement and let them know that there is a data use share accompanying the material transfer.

(Question 13/14) Covered Entity/Honest Broker:

A **covered entity** under HIPAA refers to organizations or individuals that must comply with HIPAA regulations concerning the privacy and security of Protected Health Information (PHI). If human subject data is being sent to or received from a company or institution that falls under HIPAA, they are considered a "covered entity." Examples of covered entities include:

- **Healthcare Providers**: Any provider who transmits health information electronically in connection with HIPAA-covered transactions. Examples are doctors, dentists, chiropractors, psychologists, clinics, hospitals, pharmacies, and nursing homes.
- **Health Plans**: This includes health insurance companies, health maintenance organizations (HMOs), government programs like Medicare and Medicaid, and military and veterans' health programs.
- **Healthcare Clearinghouses**: Entities that process or facilitate the processing of health information between providers and payers, such as billing services.
- **Researchers**: Researchers are considered covered entities if they are also healthcare providers who electronically transmit health information in connection with HIPAA-covered transactions. If researchers don't meet these criteria, they may need agreements, such as a Business Associate Agreement (BAA), to handle PHI.

An **honest broker** is a neutral third party, typically an individual or a system, who collects sensitive patient data, removes all identifying information (de-identifies it), and then provides

anonymized data to researchers. This ensures patient privacy while allowing access to the necessary information for research purposes. Honest brokers are not part of the research team and are not directly involved in the study's analysis. Examples of honest brokers include:

- A hospital’s approved data management team acting as an honest broker by providing de-identified patient records to researchers studying a specific disease.
- A biorepository uses an honest broker to distribute tissue samples for research, ensuring that patient identities are not revealed.

(Question 15) Additional Information:

Please share any other details or instructions that may assist in the review and processing of the DUA.