HUMAN RESEARCH PROTECTIONS-RELATED TEMPLATE LANGUAGE

NIH Data Management and Sharing (DMS) Policy [link]

DMS Plans (Element 5), IRB Protocols and Consent Forms

DMS Plans (Element 5: Access, Distribution, or Reuse Considerations)

Instructions: Following the general NIH draft format for DMS plans (note the NIH recommendation to limit your plan to 2 pages or less), highlighted in yellow font below is added template language applicable to DMS Plan Element 5. Revise as appropriate to your DMS Plan particulars.

A. Factors affecting subsequent access, distribution, or reuse of scientific data:

1. *NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data.*

Factors that may affect access, distribution and reuse of shared scientific data that may result from this proposed research include the following [insert and tailor as may be applicable to your specific research, the information to be collected and the scientific data that is expected to result]:

(1) As indicated in section C below, data will be de-identified or otherwise protected before it is shared; however, this de-identification or protection may affect the usefulness of the shared data for some recipients;

(2) The IRB application for research that may be funded through this application will include language that describes the data management and sharing plan, explaining the motivation for sharing, and ensuring that personal identifying information will be removed prior to sharing; the IRB may restrict or limit our data management and sharing activities;

(3) The informed consent process and materials for research that may be funded through this application will include language that describes the data management and sharing plan, explaining the motivation for sharing, and ensuring that personal identifying information will be removed prior to sharing; the IRB may require changes to informed consent that may change what prospective subjects are told about our data management and sharing activities.

(4) [List other factors that may affect access, distribution and reuse of shared scientific data]

B. Whether access to scientific data will be controlled:

*State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).*

Select from among the following statements, and tailor the statement or develop your own statement consistent with your specific research, the information to be collected and the scientific data that is expected to result:

(1) As indicated in section C below, access to the scientific data generated by research that may be funded through this application does not include any identifiable information. For this reason access will not be controlled;

(2) Access to the scientific data generated by research that may be funded through this application does not include any information about behavior that occurs in a context in which a human research participant may reasonably expect that no observation or recording is taking place, or information that has been provided by a human research participant for specific purposes and which the human research participant may reasonably expect will not be made public. For this reason access will not be controlled;

(3) Access to the scientific data generated by research that may be funded through this application does not include any identifiable private information about behavior that occurs in a context in which a human research participant may reasonably expect that no observation or recording is taking place, or information that has been provided by a human research participant for specific purposes and which the human research participant may reasonably expect will not be made public. For this reason access will not be controlled;

(4) Given the sensitive nature of the scientific data, de-identified human subjects data will be made available in the [insert name of --] data repository, which restricts access to the data to qualified investigators with an appropriate research question who sign a data use agreement. The [insert name of --] data repository will maintain storage and access of the data for as long as it maintains scientific utility.

Then, describe data repository access methods and security measures; see sample below.

Sample Data Repository access methods and security measures

A full de-identified dataset and associated documentation may be available to users who apply for access to the [insert name of repository] dataset with a description of their research project and who sign a data use agreement that stipulates that recipients will: (1) use the data only for research purposes; (2) not identify or attempt to identify or re-identify any individual/study participant; (3) secure the data using appropriate and accepted information security methods and technology; (4) not link to other data; (5) not further disclose or redistribute the data; and (6) destroy the data after analyses are completed. Costs for making this project’s data available are include in the proposed budget and related justification.

C. Protections for privacy, rights, and confidentiality of human research participants:

*If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).*

To protect human research participants’ privacy, rights and the confidentiality of their data, shared scientific data will be de-identified by [insert a description by selecting and tailoring from the sample protections below or adding other deidentification methods that may be consistent with your specific research, the information to be collected and the scientific data that is expected to result applicable; be sure to note any other applicable laws or institutional policies such as those related to HIPAA or FERPA]:

Sample Protections

(1) Removing all direct HIPAA identifiers in accordance with 45 CFR 164.514(b)(2) (“Safe Harbor”) from a Protected Health Information;

(2) Using principles and methods determined by an expert to ensure, in accordance with 45 CFR 164.514(b)(1), that the risk of identifying a human research participant’s identification, alone or in combination with other information, is very small or unlikely;

(3) Removing all direct identifiers of individuals, including names, Social Security Numbers, email addresses, other unique identifiers [insert other unique identifier elements];

(4) Removing other extensively-used individual-level information [insert other indirect identifiers as applicable, e.g., telephone numbers, URLs, residential addresses etc.] which if linked to additional information may result in identification;

(5) Coding or pseudonymizing all direct identifiers for which no linking key is ever provided or otherwise made available;

(6) Deidentifying quasi-identifiers (indirect identifiers, e.g., birthdates, Zip codes, gender) through [insert method and explain, e.g., data suppression, generalization, perturbation, swapping].

Additionally, the following will be put into place to further protect human research participants: [insert as applicable and consistent with your specific research, the information to be collected and the scientific data that is expected to result]:

(7) A NIH Certificate of Confidentially (CoC) applies to the shared data, and human research participants are informed during the consent process and through consent materials about how the CoC serves to protect their privacy, rights and the confidentiality of their data;

(8) All recipients of the shared data must sign a data use agreement before the shared data may be accessed. The data use agreement includes the following stipulations: That shared data recipients will: (1) use the data only for research purposes; (2) not identify or attempt to identify or re-identify any individual/study participant; (3) secure the data using appropriate and accepted information security methods and technology; (4) not link to other data; (5) not further disclose or redistribute the data; and (6) destroy the data after analyses are completed;

(9) [insert any other steps to protect human research participants].