RESEARCH DATABASES, BIOSPECIMEN REPOSITORIES, AND CONTACT LISTS

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I. OVERVIEW

Databases and biospecimen repositories (sometimes called registries, banks, libraries, or contact lists) are used to store data and/or biospecimens for future use. When the use is for clinical purposes or quality improvement (QI), IRB approval is not required. However, when the use is for research purposes, the databases/biospecimen repositories (DSRs) must be approved by the IRB.

The DSRs must satisfy the requirements of the Common Rule (45 CFR 46) for protection of human research subjects and the requirements of the Health Insurance Portability and Accountability Act (HIPAA) (45 CFR 160 and 164), for protection of individually identifiable health information. Further information is available on the National Institutes of Health (NIH) website: http://privacyruleandresearch.nih.gov/pdf/research_repositories_final.pdf.

DSRs require consent and authorization (C/A) by subjects for the storage and potential future research use of their data/biospecimens, or a waiver of C/A by the IRB. Use of data or biospecimens may be declared exempt by the IRB if the data/biospecimens are coded such that the identity of the subject or associated protected health information is not readily ascertained by the research team (see policy entitled, “Coded Private Information or Human Biospecimens”).

II. RESEARCH DATABASES/SPECIMEN REPOSITORIES (DSRs)

A. Future, Specified Research

When the data/biospecimens are stored for future research related to a specific research study, a description of the storage and specified use must be included in the IRB protocol/research summary and in the C/A form for the specific study. The specific study protocol must remain open for the duration of planned use of stored data/biospecimens.

B. Future, Unspecified Research

When the data/biospecimens are stored for future research other than, or in addition to, a specific research study, IRB requirements differ based on the location of the DSR.

1. **Maintained within Duke University Health System**
   a. **Purpose of the DSR –** In the IRB submission, describe the DSR not as a research study itself, but rather as the source of data/biospecimens for future unspecified research studies. Provide a general description of the potential future research to be performed using the data/biospecimens.
   b. **Separate protocols for human subjects research studies -** The DSR protocol should include a statement that no human subjects research will occur

as part of the DSR and that a separate protocol will be submitted for IRB approval for each specific human subjects research study that uses data/biospecimens from the DSR. Each is considered to be an activity that is separate from the activity of the DSR itself.

c. **Data/specimens to be included -** Describe the data/biospecimens to be included in the DSR, their sources, and the process of acquisition. If some of the data/biospecimens have been or will be collected at sites outside of DUHS for storage at DUHS, include a recommended collection plan and C/A document for distribution to data/biospecimen collectors and possible use by their local IRBs. Confirm that documentation of local IRB approval will be provided to the DUHS IRB for each site contributing data/biospecimens to the DUHS DSR and that no data/samples will be transferred to DUHS until a Data Use Agreement (DUA) and/or Material Transfer Agreement (MTA) has been fully executed, as needed.
d. **Security and confidentiality -** Describe how and where data/biospecimens will be stored, and how the privacy of subjects and the confidentiality of their data will be protected.
e. **Access to the data/specimens -** Describe who will have access to the data/biospecimens, what the requirements for access are, and who will control access.
f. **Consent and authorization (C/A) -** Describe how C/A will be obtained from subjects, or why waiver of C/A is justified.
    i. **Written C/A -** The DSR C/A form should contain all the elements for C/A required by federal regulations. The C/A form should clearly state that subjects are giving permission for their data/biospecimens to be stored in the DSR for use in future research studies. When subsequent IRB protocols are submitted for a specific study that will utilize data/biospecimens from the DSR, the IRB will consider a request for waiver of C/A, provided that all criteria for the waiver have been met.
    ii. **Waiver of C/A -** Waiver of C/A can be granted by the DUHS IRB as follows:
        - For inclusion of data/specimens in the DSR that have been collected in the past from DUHS patients for other research studies or solely for clinical or QI purposes, the federal criteria must be met for waiver of consent (45 CFR 46.116(f)) and waiver of authorization (45 CFR 164.512(i)(1) and (2)) (See policy titled “Waivers or Alterations of Consent and HIPAA Authorization”).
        - For inclusion of data/specimens in the DSR that will be collected in the future from DUHS patients for other research studies or solely for clinical or QI purposes, the federal criteria for waiver of consent and authorization must be met, as well as all of the requirements of the policy entitled “Coded Private Information or Human Biospecimens.”
        - For inclusion of data/biospecimens in the DSR that will be collected in the future, the federal criteria for waiver of consent and authorization must be met, and both of the following conditions:
            - The data/biospecimens will be collected for purposes other than submission to this DSR (for example: solely for clinical purposes, QA/QI, or prior IRB-approved research), AND
            - The data/specimens are entered into the DSR without any identifiable private data or information and no codes or links of any sort are maintained either by the submitter or by the DSR that would permit

access to identifiable private information about the individual from whom the data/biospecimens were obtained

2. **Maintained Outside of DUHS**
   - **a.** If the DSR is maintained outside of DUHS and there is no DUHS IRB protocol for a specific related study, then a separate protocol and C/A form are required for the external DSR that follow the guidelines as described in Section II, B, 1, above.
   - **b.** If the DSR is maintained outside of DUHS and there is a specific DUHS IRB study protocol, then a separate IRB protocol is not required for the DSR. However, the following are required:
     - **i. Description –** The external DSR must be described within the IRB protocol for the specific related study. Details are required on the purpose of the DSR, the type and source of data/biospecimens, the process of acquisition, how and where data/biospecimens will be stored, who will have access to the data/biospecimens, how access will be managed, and how the privacy of subjects and the confidentiality of data will be protected.
     - **ii. Assurances –** The DUHS IRB requires either documentation of local IRB approval at the DSR site (such as at an academic institution), or written assurances from the keeper of the outside DSR (such as with an industry sponsor) that the subjects' privacy will be protected adequately. These assurances can be provided as part of a data use agreement between DUHS and the institution or sponsor maintaining the DSR, or in a separate document, such as the protocol.
     - **iii. Consent and Authorization (C/A) –** Describe how C/A will be obtained from subjects, or why waiver of C/A is justified.
       - **Written C/A –** The C/A form should contain all the elements for C/A required by federal regulations and clearly state that subjects are giving permission for their data/biospecimens to be stored in the DSR for use in future research studies relating to the stated area of investigation. In the future, when an IRB protocol is submitted for a specific study that will utilize data/biospecimens from the DSR, the IRB at the proposed site for the specific study will consider a request for waiver of C/A, provided that all criteria for the waivers have been met.
       - **Compound or separate C/A form –** C/A for an external DSR may be included within the C/A form for the specific related research study (i.e., a compound C/A form) or in separate C/A form. When a compound C/A form is used, the requirements are different for external databases than for external specimen repositories:
         - **External databases –** When only data are stored in an external DSR, there should be assurances in the C/A form that the subjects' privacy will be protected adequately (i.e., appropriate safeguards are to be used to ensure that identifiable private information, such as protected health information (PHI), is not used or disclosed inappropriately), and no attempt will be made to identify the individuals to whom the information pertains or to contact such individuals except as otherwise stipulated in the C/A form.
         - **External biospecimen repositories –** When a research study involving a therapeutic intervention includes a provision for biospecimens to be stored externally for future unspecified research,

there should be either a separate C/A form for the DSR or a compound C/A form that includes a separate section with Optional Yes/No statements. These statements should allow the subject to give separate C/A for participation in the external DSR, with the option to decline. Research-related treatment, payment, or eligibility for benefits must not be conditioned on C/A for storing data/biospecimens in a DSR for possible future unspecified research. Subjects must be given the right to participate in the study involving treatment even if they decline participation in the DSR.

- **Data from a study involving FDA regulated product –** Ordinarily, subjects have the right to decide whether their identifiable private research information or specimens may be stored for possible use in future unspecified research. However, the sponsor of a research study involving an FDA regulated product may be required by FDA in the future to analyze the research data for reasons not currently envisioned. Therefore, for research involving an FDA regulated product, regardless of where the DSR resides (within or outside of DUHS), "Opt In/Out" considerations do not apply for data stored for possible future unspecified research use by the sponsor/designee. Opt In/Out considerations do continue to apply for specimens stored for possible future unspecified research use.

iv. **Waiver of C/A -** Waiver of C/A can be granted by the DUHS IRB as appropriate.

III. CONTACT/RECRUITMENT LISTS FOR FUTURE RESEACH

Contact or recruitment lists (e.g., names, telephone numbers, addresses, email addresses) are essentially databases that store information for possible future use. When stored for clinical purposes or quality improvement (QI), IRB approval is not required. However, when such a database is stored for research purposes and contains identifiable private information, it is a DSR that must be approved by the IRB and satisfy the requirements of the Common Rule (45 CFR 46) and HIPAA, if applicable. Investigators have the following options for establishing and maintaining a contact or recruitment DSR:

A. Future, Specified Use within a Specific Study

When the contact information is to be maintained in relation to a specific research study, a description of the storage and specified use of the contact information (e.g., enrollment in a follow-up study, long-term outcome evaluation) must be included in the IRB protocol/research summary and in the C/A form for the specific study. The specific study protocol must remain open for the duration of planned used of the contact information.

B. Future Specified Research in Addition To or Unrelated To a Specific Study

When the contact information is to be maintained for use in addition to or unrelated to a specific study, a separate DSR for possible use in future research must be submitted. If the DSR is maintained at DUHS, a separate IRB DSR protocol and C/A form are required. If the specific study closes and the DSR is maintained at DUHS, the contact information in the separate DSR may continue to be used as long as the DSR protocol remains open. If the DSR is maintained outside of DUHS, the main study compound C/A form must describe where the DSR will be maintained and include Opt In/Out signature lines for storage of identifiable private information in the external DSR.

C. Future Research Requiring No Identifiable Private Information or PHI

Investigators may establish and maintain a contact list database without obtaining C/A or IRB approval when the information associated with the list does not contain identifiable private information or PHI, such as medical diagnosis codes, disease states or medical conditions by which individuals on the Contact List are categorized. While such a contact database without private information may be maintained for research purposes without IRB approval, investigators must obtain IRB approval to contact individuals from the database for research purposes.

IV. CONVERSION OF AN EXISTING CLINICAL OR QA/QI DSR TO A RESEARCH DSR

Data/specimens that have been stored in a DSR solely for clinical or QI purposes in the past can be moved into a research DSR under an IRB waiver of C/A. Ordinarily, this would occur only once per research use because care must be taken to ensure that the continued collection of such data/specimens occurs solely for non-research purposes.

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