USE OF RESEARCH DATA/SAMPLES BY FORMER DUKE STUDENTS OR FORMER DUKE FACULTY AND EMPLOYEES

12/19/2023

The purpose of this policy is to define the conditions under which former Duke faculty/employees, former Duke students, or external personnel conducting research at Duke, whether through appropriate written agreements or in fulfillment of academic requirements, may continue to have access to research data/samples generated or obtained by these individuals during their tenure at Duke (collectively, "Materials"). These Materials are owned solely by Duke University and may not be taken or accessed by these individuals without completion of the applicable requirements described in this policy and approval provided by the Department Chair, Division Chief, CRU Director, or their authorized designee. All appropriate transfer agreements must be finalized before transfer of the Materials. The needs of current and potential research at Duke must always be considered before Materials are removed from Duke.

I. Materials that are coded and de-identified, or anonymized

For Materials that have been coded and de-identified, or anonymized, the Principal Investigator (PI) of the original study(ies) under which the Materials were collected must submit an amendment to the original study(ies) in iRIS containing:

a. A brief description of the intended research by the external recipient;
b. A brief description of the process used to code and de-identify, or anonymize, the Materials; and
c. A statement that the key to the code will not be provided to the recipient *(for coded and de-identified Materials only).*
d. There is nothing in the original consent form(s) under which the Materials were collected to prohibit the intended transfer.

II. Materials that contain permissible identifiers (Limited Data Sets)

Materials that contain permissible identifiers[2], may be transferred provided the requirements below are satisfied. In such cases, the PI for the study(ies) under which the Materials were collected must submit an amendment to the original study(ies) containing the following:

i. A brief description of the external recipient's intended use of the Materials;
ii. A copy of the external recipient's site IRB approval or a copy of the fully executed IAA or IIA for the intended use, OR documentation that the institution considers a limited data set; and
iii. A copy of the fully executed Data Use Agreement for the use of the Data.
iv. There is nothing in the original consent form under which the Materials were collected to prohibit the intended transfer.

An example of this scenario would be a former student or employee who wishes to use Materials to conduct a new unrelated research project that requires interventional dates.

III. Materials that contain identifiers

For Materials that contain identifiers[1], the wording in the consent form for the study(ies) under which the Materials were collected will determine whether or not the Materials can be used externally without a request for waiver of consent and HIPAA Authorization ('Waiver'). The Waiver must be approved by the DUHS IRB prior to transfer of the Materials and the investigator must notify the Privacy Section of OARC (privacy@duke.edu).

a. When the consent form(s) under which the Materials were collected contain(s) Duke's standard language, and the Materials will be used in a manner consistent with the objectives of the original study(ies) under which they were collected, the PI must submit an amendment to the original study(ies) containing the following:
   i. A brief description of the specific activities to be conducted by the external recipient;
   ii. A copy of either the external recipient's site IRB approval or a copy of the fully executed IRB Authorization Agreement ('IAA') or Individual Investigator Agreement ('IIA') for the intended use;
   iii. A Waiver for the disclosure of identifiers; and
   iv. A copy of a fully executed transfer agreement or other agreement as determined by Duke's Office of Research Contracts (ORC) to be appropriate.

   An example of this scenario would be a former student or employee who wishes to finish the research project that they originally began at Duke. The PI is encouraged to consider the practicability of sending coded and de-identified or anonymized data in this scenario.

b. When the consent form(s) under which the Materials were collected contain(s) Duke's standard language, and the Materials will NOT be used in a manner consistent with the objectives of the original study(ies) under which they were collected, the PI must submit an amendment to the original study(ies) containing the elements (i)-(iv) above, except that the Waiver must be requested not only for the disclosure of identifiers but also for the intended use by the external recipient.

   An example of this scenario would be a former student or employee who wishes to initiate additional research based upon the research project that they originally began at Duke. In such a case, the Duke PI is encouraged to consider the practicability of sending coded and de-identified or anonymized data.

c. When the consent form(s) under which the Materials were collected contain(s) language that allows external use of Materials with associated identifiers, then the PI must submit an amendment to the original study(ies) containing the following:

i. A brief description of the external recipient's intended use of the Materials;
ii. A Waiver for the intended use (if the intended use is not specifically described in the consent form(s));
iii. A copy of the external recipient's site IRB approval or a copy of the fully executed IAA or IIA for the intended use; and
iv. A copy of a fully executed transfer agreement or other agreement as determined by ORC to be appropriate.

An example of this scenario would be a former student or employee who wishes to use Materials to conduct a new research project that may be unrelated, or only partially related, to the objectives of the original study(ies) under which the Materials were collected. An IRB Chairperson or Executive Director can provide further instruction regarding this issue.

Previous version(s): 5/16/2016, 3/11/2013, 8/31/2016, 9/28/2021

FOOTNOTES

[1] For a listing of HIPAA identifiers, see 45 CFR 164.514(b)(2)(i)(A-R)

[2] Permissible identifiers that may be included in a Limited Data Set are: admission/discharge dates, service dates, intervention dates, dates of birth or death, city, state, zip code up to 5 digits, age in years up to 89. The Limited Data Set may include a link field to allow the provider to re-identify individuals. See 45 CFR 164.514(b)(2)(i)(A-R) and 45 CFR 164.514(e)(2)(i-xvi) for a list of identifiers that may be included in a Limited Data Set.