USE OF RESEARCH DATA BY
FORMER DUKE STUDENTS OR FORMER DUKE EMPLOYEES
3/11/2013

The purpose of this policy is to define the conditions under which former Duke 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 generated by these individuals during their tenure at Duke ("Data"). These Data 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. The needs of current and potential research at Duke must always be considered before Data are removed from Duke.

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

For Data that have been coded and de-identified, or anonymized, the Principal Investigator (PI) of the original study(ies) under which the Data were collected must submit an amendment to the original study(ies) in eIRB 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 Data; and
c. A statement that the key to the code will not be provided to the recipient (for coded and de-identified Data only).

II. Data that contain identifiers

For Data that contain identifiers, the wording in the consent form for the study(ies) under which the Data were collected will determine whether or not the Data 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 Data.

a. When the consent form(s) under which the Data were collected contain(s) Duke’s standard language, and the Data 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 Data Transfer Agreement or other agreement as determined by Duke’s Office of Corporate Research Collaborations (‘OCRC’) to be appropriate.

An example of this scenario would be a former student or employee who wishes to finish the research project that he/she 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 Data were collected contain(s) Duke’s standard language\(^2\), and the Data 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 he/she 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 Data were collected contain(s) language that allows external use of Data 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 Data;

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 Data Transfer Agreement or other agreement as determined by OCRC to be appropriate.

An example of this scenario would be a former student or employee who wishes to use Data 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 Data were collected. An IRB Chairperson or Executive Director can provide further instruction regarding this issue.

III. Data that contain permissible identifiers (Limited Data Sets)

For Data that contain permissible identifiers\(^3\), the language in the consent form(s) under which the Data were collected is not relevant provided the requirements below are satisfied. In such cases, the PI for the study(ies) under which the Data
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 Data;
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; and
iii. A copy of the fully executed Data Use Agreement for the use of the Data.

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

FOOTNOTES

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

2 Duke’s standard consent language: “Except when required by law, you will not be
identified by name, social security number, address, telephone number, or any other direct
personal identifier in study records disclosed outside of Duke.”

3 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.