GUIDELINES FOR HUMAN SUBJECT RESEARCH COLLABORATIONS

THE JACKSON LABORATORY AND UCONN HEALTH

**BACKGROUND**

There is an expectation that UConn Health and The Jackson Laboratory (JAX) personnel will collaborate often on human subject research projects. As such, an IRB Reliance agreement has been established whereby JAX may rely upon the IRB of UConn Health.

UConn Health is a covered entity under HIPAA whereas JAX on the UConn Health campus is considered a hybrid entity under HIPAA. Within JAX, the Clinical Genomics (CLIA) Laboratory service is a revenue-generating operation and a covered entity under HIPAA. JAX will be developing Business Associate Agreements (BAAs) with various hospitals in the area to address HIPAA as related to the clinical genomics service. The research portion of JAX is not a covered entity under HIPAA. JAX will establish a firewall between the clinical portion of the company (the covered entity portion) and the research portion of the company (the non-covered entity).

UConn Health and JAX have worked together to establish the following guidelines for addressing HIPAA and other issues related to human subject research studies that are done in collaboration.

**GUIDELINES**

In all cases in which JAX is involved in any capacity with a human subject research study (e.g. providing funding and/or services)," **Jackson Labs" is to be noted in the Administrative Oversight section of the Key Study Personnel section of the IRB Application** . This designation allows for JAX administrators to maintain a listing of all studies with which JAX is involved.

**A: Collaborating with Investigators from JAX**

**1. DOCUMENTS: Informed Consent Form, HIPAA Authorization, IRB Application**

*WHEN TO USE*: **Identifiable\*** health information will be collected as part of the study and the IRB application includes JAX investigators. In most cases if informed consent is being sought from a potential subject a HIPAA Authorization will also be obtained.

*HOW TO IMPLEMEMT*:

* Consent:
  + The consent form addresses the functions that JAX will perform (e.g. your coded tissue sample will be provided to The Jackson Laboratory where a variety of genomic assays (tests) will be done to investigate whether XXXX…..).
  + The confidentiality section of the consent form accurately describes how information will be provided to JAX and that there is a chance for identification of the individual (e.g. While only coded samples will be provided to JAX, because the study team works so closely together there is a chance that as the progress of the research is discussed your identity may become known to the investigators from JAX . JAX employees are obligated to keep that information confidential.")
* Authorization:
  + The Jackson Laboratory is listed on the Authorization under the section titled "People/Offices That Will Have Access to Your Information" as an entity to which information may be disclosed
    - Listing JAX in this section does not mean that JAX has to receive all of the protected health information noted in the authorization. The protocol and consent may still note that only coded information will be sent to JAX. However, because of the close nature of the collaborations and discussions that occur among the study team, JAX is required to be listed in this section.
* IRB Application:
  + In the Key Study Personnel (KSP) section of the application, JAX investigators are named individually
  + On the KSP page in the area designated for Administrative Oversight "Jackson Labs"1 is listed. This allows for JAX administrators to maintain a listing of all studies with which JAX is involved.
  + Indicate Yes that collaborating sites are involved and then add JAX in the collaborating sites section, describing their role in the study accordingly. (Note, end user to select "Other" from the drop down list and then type in JAX where asked to describe "Other")
  + If JAX is providing any funding Jackson Laboratory1 is noted in the application as a funding source
    - If JAX is the recipient of a federal award and providing funding to UConn Health through a sub-award, both the federal agency and Jackson Laboratory are added as funding source and a copy of the federal award is attached to the IRB submission. Both the JAX award number and UConn Health sub-award number should be added to the IRB application so that both JAX and UConn Health Office of Research and Sponsored Programs can link the IRB approval to the grant award.

*OUTCOME:* If protected health information (PHI) is disclosed by UConn Health to JAX for research with an individual's written permission in the form of an Authorization, that PHI that was disclosed may no longer be covered under HIPAA. This is acceptable for JAX.

**2. DOCUMENTS: Waiver of Consent, Waiver of HIPAA Authorization, IRB Application**

*WHEN TO USE*: **Identifiable\*** protected health information is being collected for the research and it is NOT possible to obtain consent and authorization from subjects (e.g. retrospective review of clinical records)

*HOW TO IMPLEMENT*:

* Consent Waiver:
  + Form to request waiver of consent is completed and submitted to IRB
* HIPAA Waiver
  + Form to request waiver of HIPAA is completed and submitted to the IRB:
    - JAX is noted as an entity that may have access to the PHI through disclosure.
      * Listing JAX in this section does not mean that JAX has to receive all of the protected health information noted in the waiver. The protocol may still note that only coded information will be sent to JAX. However, because of the close nature of the collaborations and discussions that occur among the study team, JAX is required to be listed in this section.
    - If any identifiable data is shared with JAX, the UConn Health investigators must retain an accounting of that disclosure. (Note: Coded data is considered identifiable if the code is derived from identifiers. Coded data is also considered identifiable if the individual has the key to decipher the code.)
* IRB Application:

Same as previously noted. *OUTCOME:* Because the information was shared under a waiver of authorization the information may no longer be considered “protected” health information so this is acceptable for JAX. Use of the waiver of authorization allows for full sharing of study information.

**Note:** Limited data sets and data use agreements are not to be used because receipt of information by JAX under such agreements imposes HIPAA restrictions upon JAX.2

**B: Services Provided by JAX without Collaboration**

*WHEN APPLICABLE*: When JAX will provide services for a study that are limited to analysis of samples/data that do not contain any identifiers3 **and** no individuals from JAX are recognized as co-investigators on the study. The information may be coded providing the code is not derived from other identifiers and that JAX personnel do not have the key to decipher the code. If the UConn Health investigators are using protected health information, HIPAA is addressed per routine practice at UConn Health.

*HOW TO IMPLEMENT*:

Assuming that the study at UConn Health requires consent and authorization.

* Consent:
  + The consent form addresses the functions that JAX will perform (e.g. your coded tissue sample will be provided to JAX Labs where a variety of genomic assays (tests) will be done to investigate whether XXXX…..).
  + The confidentiality section of the consent form accurately describes how information will be provided to JAX and that there is a chance for identification of the individual (e.g. While only coded samples will be provided to JAX, there is a chance that as the research progresses your identity may become known to employees at JAX . JAX employees are obligated to keep that information confidential.")
* Authorization:
  + The Jackson Laboratory is listed on the Authorization under the section titled "People/Offices That Will Have Access to Your Information" as an entity to which information may be disclosed
    - Listing JAX in this section does not mean that JAX has to receive all of the protected health information noted in the authorization. The protocol and consent may still note that only coded information will be sent to JAX. Listing outside labs that may receive data is a standard part of the UConn Health Authorization template and as such JAX is required to be listed in this section.
* IRB Application:
  + In the Key Study Personnel (KSP) section of the application, JAX investigators are **NOT** named individually
  + On the KSP page in the area designated for Administrative Oversight Jackson Labs is listed. This allows for JAX administrators to maintain a listing of all studies with which JAX is involved, whether engaged in the research directly or providing a service to UConn Health investigators.
  + Indicate No that collaborating sites are not involved because JAX employees are providing a service but not considered co-investigators / collaborators in the research; in essence they are acting as an outside lab service
    - If JAX is providing any funding Jackson Laboratory is also noted in the application as a funding source.
      * If JAX is the recipient of a federal award and providing funding to UConn Health through a sub-award, both the federal agency and Jackson Laboratory are added as funding source and a copy of the federal award is attached to the IRB submission. Both the JAX award number and UConn Health sub-award number should be added to the IRB application so that both JAX and UConn Health Office of Research and Sponsored Programs can link the IRB approval to the grant award.

*OUTCOME:* Because the information is not identifiable when received by JAX, HIPAA is not applicable to JAX and JAX (unless providing the funding) is not engaged in the human subject research aspect of the work.

**C. WHEN APPLICABLE - REQUIRED CERTIFICATIONS FOR DATA SHARING PLANS**

The following guidance is provided for studies that involve both JAX and UConn Health and that require a data sharing plan in compliance with NIH Guidelines (i.e. NIH funded studies that are expected to generate large-scale genomic data).

The IRB form Appendix E 4 NIH Genomic Data Sharing Plans for Data Submission to an NIH Repository" must be included as part of the IRB submission packet.

* The PI of the Study completes part A
* In Part B of the form
  + the Chair of the reviewing IRB will sign in the section certifying IRB review
  + the Institutional Official from the of the institution submitting the grant application will sign the Institutional Certification section.

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**1 - Identifiers:** identifiable means the health information being shared contains one or more of the HIPAA defined identifiers listed below. De-identified therefore means none of the HIPAA identifiers are included in the data. For a code to be an identifier it must be comprised of other identifiers, and/or the recipient of the data must have the key to link the coded data back to the individual from whom it came.

**IDENTIFIERS PER HIPAA**

|  |  |  |
| --- | --- | --- |
| Names |  | Geographic Subdivision Smaller Than a State |
| Phone #s |  | All Elements of Date Except Year |
| Fax #s |  | E-mail Addresses |
| Social Security #s |  | Medical Record #s |
| Account #s |  | Health Plan Beneficiary #s |
| Certificate/License #s |  | Vehicle Identifiers and Serial #s |
| Device Identifiers and Serial #s |  | Web URLs |
| IP Addresses |  | Biometric Identifiers |
| Photographic Images |  | Any other unique identifying number, characteristic or code |

**2 - Obligations re receipt of a limited data set under a data use agreement:**

* Data Recipient agrees to not use or disclose the Limited Data Set other than as permitted or required by the Data Use Agreement (DUA) or as Required By Law.
* Data Recipient agrees to use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided for by the DUA.
* Data Recipient agrees to report to Covered Entity any use or disclosure of the Limited Data Set not provided for by the DUA of which it becomes aware.
* Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set received from Covered Entity agrees to the same restrictions and conditions that apply through the DUA to Data Recipient with respect to such information.
* Data Recipient agrees not to identify the information or contact the individuals
* Data Recipient, and any of his/her agents, including a subcontractor, to whom they provide Limited Data Set information received from Covered Entity, must agree to the restrictions and conditions that apply through the DUA with respect to such information.
* Except as otherwise limited in a DUA, Data Recipient may use or disclose Limited Data Set to perform research functions, activities, or servicesprovided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity.

3: Within the program used to make IRB submissions (IRIS) The Jackson Laboratory is referenced in different ways. The account to be used to allow JAX to be identified in the Administrative Oversight section on the application form had to be set up as an individual user account and is under the name **Jackson Labs**. In order for JAX to be able to be listed as a funding source the name has to exist on a table value within IRIS, and that value is noted as **Jackson Laboratory**.

4. If the sharing of data is not possible (i.e. criteria noted in Appendix E cannot be met), justification for why the criteria cannot be met, and a suggested alternative for sharing the data is to be included in the IRB submission, just as it is required by NIH policy for the grant submission.