ATTACHMENT 5: Form for NIH Office of Human Subjects Research Protection (OHSRP)

REQUEST FORM: OHSRP DETERMINATION FOR RESEARCH-USE OF DE-IDENTIFIED SPECIMENS OR DATA

INSTRUCTIONS

Use this form to request a review by OHSRP to determine if your research activity involves the collection or study of data, documents, records or pathological or diagnostic specimens, if these sources are, publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Note two categories not eligible for exemption are listed in the footnote below[1]. In order for a determination to be made:

A. Data/specimens **received** by NIH researchers must be either:
   (1) **Unlinked:** Specimens/data that were initially collected from humans with identifiers that, before research use, have been irreversibly stripped of all identifiers by use of an arbitrary random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the samples and/or data to the sources; OR
   (2) **Coded:** Use of coded specimens for which the link is retained by the sender; and the following conditions are met:
      (a) **FWA:** Data or specimens will be collected or were collected at an institution with a Federalwide Assurance (FWA), or certification that the specimens were collected under the laws and regulations for the protection of human subjects of the foreign country.
      (b) **De-identification Agreement:** This agreement specifies that the providing investigator will not share any identifiers or means to determine the identities of individuals who provided the data or specimens, with the recipient investigator.

B. Data and/or specimens **provided** by NIH researchers must be:
   (1) **De-identified:** NIH researchers must de-identify all data or specimens before sharing them. For more information on de-identification, see SOP 6- Appendix 1- "Information that should be removed for data or specimens to be considered de-identified."
   (2) Note that a Material Transfer Agreement[2] may also be required.

C. For **collection** of existing data by NIH researchers:
   (1) Identifiable information may be viewed by the researcher, but only de-identified data may be recorded.
   (2) An honest broker may be used to de-identify data. For more information or to obtain an Honest Broker Agreement contact OHSRP.

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[1] The following two situations are not eligible for exemption and must be reviewed by an IRB:
- Research involving specimens or data related to prisoner research
- Research involving test articles regulated by the FDA

[22] For more information contact your IC Technology Development Coordinator at http://www.ott.nih.gov/nih_staff/tdc.aspx

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For assistance completing this form, call OHSRP at (301) 402-3444. Submit a PDF of the completed form with required signatures and attachments to: by PDF and E-mail: ohsr_nih_ddir@od.nih.gov, Fax: 301-402-3443 or Interoffice mail: Building 10, Room 2C146

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REQUEST FORM: OHSRP DETERMINATION FOR RESEARCH-USE OF DE-IDENTIFIED SPECIMENS OR DATA

Date of Request: _____

Requestor's name: _____ e-mail: _____

Role: __Investigator __Administrative support __Other, explain: _____

Name of NIH Senior Investigator: _____
(*The investigator must be an NIH employee*)

IC _____ Laboratory/Branch _____

Building & Room No. _____ Tel. No. _____ FAX No. _____

Is the NIH Senior Investigator an NIH employee (FTE)? _____Yes _____No

Senior Investigator Signature: _____
(*Signature of Investigator who will conduct research*)

Supervisor Signature: _____
(*Signature of official for IC, e.g., Lab/Branch Chief*)

Name of NIH investigator conducting research if not the NIH Senior Investigator: *(i.e, junior investigator, contractor investigator, fellow, student)*
_____

Please provide the name and e-mail of any others who should receive a copy of the OHSR determination: _____

1. **What role will the NIH investigator(s) have in this research project?** *(check all that apply)*
   ___ Analyze samples/data only
   ___ Consultant/advisor to collaborator(s)
   ___ Author on publication(s)/manuscript(s) pertaining to this research
   ___ Investigator or the NIH holds an IND/IDE for this research
   ___ Other, please describe: _____

2. **Title:** _____
(Provide a short title to distinguish this activity from other projects that you may have)

3. Describe in lay terms the research activity that will be performed:
_____

4. Proposed start date ___/___/_____ **Proposed completion date** ___/___/_____

5. Specify the nature of the specimens or data: *(select all that apply)*

___ iPSC lines ___ hESC ___ Fetal Tissue
___ WES/WGS ___ GWAS
___ Other human specimens *(e.g. tissue, blood, derivatives)*, describe:
_____
___ Data *(e.g. clinical or research information or laboratory results)* describe:
_____
___ Other, describe: _____

6. Will specimens or data be? (*select all that apply*)

Collected Yes__ No__
Received Yes__ No__
Sent Yes__ No__

7. If receiving or sending, list the collaborating investigator(s):

Name	Institution/IC	Address/e-mail	FWA number*

8. Do the specimens, data or information:

Already exist? Yes__ No__

If "no", explain:_____

9. Select the best description that applies to the specimens or data:

(a) ___ Specimens, data or information will not contain any identifiable information, and cannot be linked to individual subjects by you or your collaborators.
(b) ___ Specimens, data or information will be coded, however that **code cannot be used by either the provider or the receiver** to identify specific individuals.
(c) ___ Specimens, data or information will be **coded so that the provider of the samples/data can link them to specific individuals** but the receiver will not be able to do so.

10. If c is selected above, please follow the instructions below:

Projects involving coded research specimens obtained from a non-NIH collaborator will require a de-identification agreement. Please e-mail your collaborator(s) the following agreement language modified to reflect the nature of your collaboration. Attach the completed agreement to this submission.

De-identification Agreement:

Provider of coded specimens or data:

I, [Name] of [Institution], holder of the code-key or cipher for the coded [specimens, data (*specify*)], promise not to release the identity of the subjects from whom the coded [specimens, data (*specify*)] originated, until the subjects decease to [Recipient Name] at [Recipient Institution].

Recipient of coded specimens or data:

I, [Name] of [Institution], recipient of the coded [specimens, data (*specify*)], promise not to request the identity of the subjects from whom the coded [specimens, data (*specify*)] originated, until the subjects decease from [Sender Name] at [Sending Institution].

11. If data are being extracted from existing records, who will extract the data? (*if applicable*)

(a) ___ NIH Investigator
(b) ___ non-NIH Collaborator
(c) ___ NIH Contractor
(d) ___ Other, specify_____

If b or c, will an Honest Broker or data use agreement be used? Yes__ No__

If yes, complete and attach the Honest Broker Assurance or Data Use Agreement to this submission; e-mail ohsr_nih_ddir@od.nih.gov to request the form.

12. Where are the subjects of this research activity located? _____

13. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (For example, as subject's physician, obtaining specimens directly from the subject?) Yes__ No__

14. Do the specimens, data or information come from:

___ NIH BTRIS
___ NIH Medical Records
___ Repository
If an NIH Repository, specify: _____
___ Pathological waste
___ Autopsy material
___ Publicly available source
___ Originate from an IRB-approved protocol?

___ Other_____

15. Will the results of the research be returned to the provider(s) of the specimens or data?

(a) ___ No, results will not be returned to the provider(s)
(b) ___ Yes, aggregated results will be returned to the provider(s)
(c) ___ Yes, results that are linked to identifiable individuals, will be returned to provider(s)
(d) ___Yes, the results of this project will be returned to an active NIH IRB-approved protocol? If yes, protocol ID: _____

If b or c, is the NIH project consistent with the IRB/EC-approved protocol at the collaborating institution? Yes__ No__

16. Per NIH guidance, are all conflicts of interest by NIH employees, if any, resolved?
_____Yes _____No**

**A Federalwide Assurance (FWA) is issued by the U.S. Department of Health and Human Services (DHHS)/ Office of Human Research Protections (OHRP) to institutions which receive Federal funds/support to conduct human subjects research. To search for the FWA# for domestic or international institutions go to http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc*

***If the answer is "No", note that OHSRP will be unable to make a determination and research may not proceed until all conflicts are resolved. For more information, see the October 2011, A Guide to Preventing Financial and Non-Financial Conflict of Interest in Human Subjects Research at NIH. For assistance review the list of Ethics Coordinators and find the contact for your IC: http://ethics.od.nih.gov/coord.pdf*