3/19/19

INVESTIGATOR ATTESTATION: ADDRESSING THE PROTECTION OF HUMAN SUBJECTS FOR MTAS/DTAS

Instructions:

This attestation must be completed by NIH investigators, who wish to share or receive human biospecimens and/or human data under a Material Transfer Agreement, a Data Transfer Agreement or other similar agreement and provided to the appropriate Tech Transfer contact. **If an NIH investigator plans to share human biospecimens and/or human data which were collected under an IRB approved protocol, the original consent form language cannot include a prohibition against sharing or be inconsistent with the planned research.** In either instance, the human biospecimens and/or human data cannot be shared. *If you have questions about how to complete this attestation or are uncertain whether biospecimens or data may be shared, please contact your IRB office (for NIH IRB-approved protocols) or the NIH Office of Human Subjects Research Protections.*

Please also note that if the NIH investigator is only sharing or collaborating in research involving human biospecimens and/or human data for which the NIH research team has no access to identifiers or ability to re-identify, the investigator does not need to submit for a request for determination of "not human subjects research" as in the past.

The investigator should do the following:

1. Review the entire *Attestation*
2. Determine which scenario matches the planned transfer of materials (one of three); place checkmarks in the appropriate boxes; and sign
    a. Only complete the form if he or she can attest to the veracity of the statements exactly as written and check all the required boxes under a given section
3. When unable to attest to the conditions in the document, consult the IRB Office or OHSRP about the specific case. Depending on the circumstances, the IRB or OHSRP *may* be able to sign off on the Attestation in lieu of the investigator.
    a. If the specimens or data are being shared from an NIH IRB-approved protocol, consult the IRB.
    b. Otherwise, consult OHSRP.
4. Once signed (by either the investigator or an IRB/OHSRP representative), provide the *Attestation* to Tech Transfer.

FOR COMPLETION BY TECH TRANSFER: IC Reference #:

INVESTIGATOR ATTESTATION: ADDRESSING THE PROTECTION OF HUMAN SUBJECTS FOR MTAS/DTAS

NIH Investigator Name: _____

Name of External Institution: _____

Description of human biospecimens and/or human data:

NIH Protocol # (if relevant for this attestation): _____

I, the NIH Investigator, attest to the following:

For Outgoing Human Biospecimens and/or Human Data Collected as Part of an IRB Approved Protocol Involving NIH Investigators

Check the following, if true (If you are unsure, consult with the IRB):

____ There is sharing language in the original consent form, **AND** that language is consistent with the proposed research and sharing plan.

Also check one of the following:

____ The human biospecimens and/or human data are linked to identifiers; **the NIH research team will receive research results that they can link to identifiers** as part of a research collaboration; and I have or will seek IRB review and approval prior to initiating the planned research.

____ **The NIH research team will not receive research results that they can link to identifiers** as part of a research collaboration.

For Outgoing Human Biospecimens and/or Human Data from All Other Sources

Only check one of the following:

____ **No one at NIH has access to identifiers** linked to the human biospecimens and/or human data.

____ The human biospecimens and/or human data are linked to identifiers, but **the NIH research team will not receive research results that they can link to identifiers** as part of a research collaboration.

____ The human biospecimens and/or human data are linked to identifiers, **the NIH research team will receive research results that they can link to identifiers**, and I have or will seek IRB review and approval prior to initiating the planned research.

FOR COMPLETION BY TECH TRANSFER: IC Reference #:

For Incoming Human Biospecimens and/or Human Data

Only check one of the following:

____ The human biospecimens and/or human data that will be received **will not be identifiable to the NIH research team**.

____ The human biospecimens and/or human data **will be identifiable to the NIH research team**, and I have or will seek IRB review and approval prior to initiating the planned research.

For Investigator Signature Only

Investigator Name: _____

_____ _____ _____

NIH Investigator Signature IC Date

****

For OHSRP or IRB Use (Staff or Chairs) Only

The NIH researcher is unable to attest to the conditions described above, e.g. because he or she does not have access to the original consent form. However, I have reviewed the case with the him or her and sharing is allowable under the circumstances.

Name: _____

_____ _____ _____

Signature IRB Name or OHSRP Date