11/12/21

INSTRUCTIONS FOR COMPLETING THE INVESTIGATOR ATTESTATION

The Investigator Attestation must be completed by an NIH investigator who plans to share or receive human biospecimens and/or human data for **research purposes** using a Material Transfer Agreement (MTA), Data Transfer Agreement (DTA) or Research Collaboration Agreement (RCA). **When the NIH investigator is sharing specimens and data from multiple IRB-approved protocols as part of an agreement, the investigator must complete a separate Attestation for each protocol.** If the investigator is unsure about how to complete the form, is unable to attest to the conditions listed in the form or is uncertain whether biospecimens or data may be shared, he or she should contact OHSRP for help at IRB@od.nih.gov. After completing and signing the form, the investigator should provide the Investigator Attestation to his or her IC Tech Transfer contact. This form is for internal NIH use only and does not need to be shared with outside, collaborating institutions.

If an investigator plans to share biospecimens and/or data which were collected under an IRB approved protocol, the original consent form must not have included language:

- That pledged that the applicable specimens or data would not be shared or used for future research (or had "opt out" boxes for sharing or future research selected); or
- That is inconsistent with the specific sharing or research plan (e.g., the consent form stated that the specimens or data would be shared solely with a specific institution(s) or for a certain type(s) of research); or
- That the specimens or data would be destroyed at the completion of the original research.

If any of this language was included, the human biospecimens and/or human data most likely may not be shared for the planned research without re-consenting the original subjects. If the investigator still wishes to share the materials, he or she should contact the IRB to discuss.

In completing the Attestation, the investigator should do the following:

1. Review the entire Attestation from.
2. Determine which of the three sources of specimens and/or data applies to the transfer (more than one can be chosen).
3. Review the language in the original consent forms (including different versions when applicable), when the specimens or data originated from a protocol.
4. Place checkmarks in the applicable boxes and sign, if it is determined that sharing for the planned research is allowable.
    a. The investigator may only fill out the Attestation when he or she can attest to the veracity of the statements exactly as written and check all the required boxes within a given section.
    b. If the investigator is unable to attest to the required statements or if the consent form was silent on sharing or future research, they should not sign the form. Instead, please contact Julie Eiserman, julie.eiserman@nih.gov (and cc: IRB@od.nih.gov), for guidance. Depending on the circumstances, an OHSRP representative may be able to sign off on the form in lieu of the investigator.
5. Email the signed Attestation (without this page) to his or her IC Tech Transfer contact once it is signed by either the investigator or an OHSRP representative.

Please refer to the Presentation Archive and Do I Need to Submit to the IRB? on the OHSRP website for additional information about using and sharing specimens and data; what counts as an identifier; and when IRB review and approval is required.

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FOR COMPLETION BY TECH TRANSFER: IC Reference #: _____

INVESTIGATOR ATTESTATION: ADDRESSING THE PROTECTION OF HUMAN SUBJECTS FOR MTAs/DTAs/RCAs

NIH Investigator Name: _____

Name of External Institution: _____

Description of human biospecimens and/or human data being shared and/or received:

Protocol # or ID (Source of the specimens or data being shared), if applicable: _____

Please complete a separate Attestation for each protocol when specimens or data are leaving NIH.

I, the NIH Investigator, attest to the following: *(Only check off the option(s) which apply to the Agreement.)*

OPTION #1, Outgoing Human Biospecimens and/or Human Data Collected as Part of an IRB-Approved Protocol Involving NIH Investigators:

Check the following, if true:

☐ There is sharing language in the original consent form, **AND** that language is consistent with the proposed research and sharing plan. *(If the consent form had no language about sharing or future research or the original consent language is not consistent with the sharing and research plan, consult with OHSRP; do not check this box.)*

Also check one or more of the following, as applicable:

☐ 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 for the planned research prior to initiating it (or IRB review and approval is not necessary as all the original subjects are now deceased).

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

OPTION #2, Outgoing Human Biospecimens and/or Human Data from All Other Sources (i.e., not collected as part of an IRB-approved protocol involving NIH investigators):

Check one or more of the following, as applicable:

☐ **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 for the planned research prior to initiating it (or IRB review and approval is not necessary as all the original subjects/patients are deceased).

FOR COMPLETION BY TECH TRANSFER: IC Reference #:

OPTION #3, Incoming Human Biospecimens and/or Human Data *(This section is not applicable to the return of results from a collaboration addressed in OPTION #1 or 2.)***:**

Check one of the following:

☐ All of the human biospecimens and/or human data that will be received by NIH **will not be identifiable to the NIH research team**.

☐ Some or all 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 for the planned research prior to initiating it (or IRB review and approval is not necessary as all the original subjects/patients are deceased).

****

For NIH Investigator Signature Only

Investigator Name: _____

_____ _____ _____

NIH Investigator Signature IC Date

****

For OHSRP Signature Only

The NIH researcher is unable to attest to the conditions described above, e.g., due to the specific content of the original consent form(s) or because he/she does not have access to the original consent form(s) used to collect the specimens or data. However, I have reviewed the case and sharing is allowable under the circumstances.

Name: _____

_____ _____

Signature Date