Biospecimen Transfer Information (BTI) Form
Johns Hopkins Medicine Transfer of Human Biological Materials
VERSION 6/11/2024

The Johns Hopkins School of Medicine (JHM) is committed to ethical stewardship of the biospecimens obtained during both routine clinical care and through research protocols. Although it is not possible to know or describe all possible future uses of biospecimens at the time of collection, the primary purpose of future use of these biospecimens is the improvement of human health through research and discovery.

The Johns Hopkins Medicine policy ADMIN015 includes a description of how human biospecimens obtained through clinical or research procedures at JHM should be managed to comply with applicable regulatory, ethical, and privacy standards, in order to ensure that they are utilized for the highest and best purpose.

The Principal Investigator initiating the transfer request should complete the form below.

SECTION 1 – Application to Request Transfer of Human Biospecimens		
1.1	Principal Investigator (PI) initiating transfer request:	
1.2	JHM IRB Application number where transfer request is initiated:	
1.3	JHM IRB Application title where transfer request is initiated:	

SECTION 2 – Recipient Information		
2.1	Name of Proposed Recipient:	
2.2	Recipient Institution and Location:	
2.3	Recipient Institution Type **Please note: a collaborative research project is required in order to request biospecimen transfer to an entity external to Hopkins.*	☐ Commercial/Industry ☐ Nonprofit/Academic *If selected and the research at the receiving institution qualifies as human subjects research, please include a copy of the receiving institution's IRB approval or IRB exemption determination in the attachments uploaded in eIRB application Section 23, Item 4.*
2.4	Describe any unique technologies/expertise (used to process or analyze biospecimens) of the recipient entity and explain whether these technologies/expertise are also available at Hopkins.	

In Section 3, please complete a separate table for each source of biospecimens. Two tables are provided below for two sources of biospecimens, (Source 1, Items 3.1-3.8 and Source 2, Items 3.1.2-3.8.2). Please remove Source 2 or add additional tables, as needed.

Section 3 - Specimen Description and Source		
Source 1:		
3.1	IRB application under which the biospecimens were collected / derived	
3.2	• Type of biospecimen • Estimated Number of biospecimens to be transferred (including cell line name, if applicable) • Number of participants from whom the biospecimens were obtained	
3.3	List data (e.g., MRN, date of collection) that will be sent along with the biospecimens. Could this lead to identification of the person from whom the biospecimens were obtained?	
3.4	Confirm that the PI of the protocol under which the biospecimens were collected / derived has been made aware of the transfer and does not object.	☐ Confirmed ☐ Not confirmed (Please *explain*):
3.5	If the biospecimen is a cell line or hPSC line derived at JHM AND it was derived after September 2016, was the derivation consistent with JHM Policy BIO001?	☐ Yes ☐ No (Please *explain*): ☐ N/A ☐ Cell line was derived prior to September 2016
3.6	Please confirm whether there is documentation of consent, (clinical or research) for each biospecimen to be transferred:	☐ The Principal Investigator of the **collection/derivation** protocol has a signed copy of the consent form from each donor of biospecimens to be transferred. ☐ The Principal Investigator of the **transfer** protocol has a signed copy of the consent form from each donor of biospecimens to be transferred. ☐ There is an IRB waiver of consent for the planned research use. Completion of Section 7 is required for the proposed transfer of unconsented biospecimens
3.7	Describe the consent language allowing the requested use and transfer (please also attach a	

	copy of the relevant consent with relevant language highlighted). Include whether any language might limit the sharing, (e.g., opt-in/opt-out option, specific to disease not to be studied) and how this will be addressed:	
3.8	Have any research participants/patients contacted you and expressed disagreement with use of any of the biospecimens collected in the protocol(s) relevant to this proposed sharing?	☐ Yes (Please *explain*): ☐ No

Source 2:		
3.1.2	IRB application under which the biospecimens were collected / derived	
3.2.2	• Type of biospecimen, • Estimated Number of Biospecimens to be transferred (including cell line name, if applicable) • Number of participants from whom the biospecimens were obtained	
3.3.2	List data (e.g., MRN, date of collection) that will be sent along with the biospecimens. Could this lead to identification of the person who donated the specimens?	
3.4.2	Confirm that the PI of the protocol under which the biospecimens were collected / derived has been made aware of the transfer and does not object.	☐ Confirmed ☐ Not confirmed (Please *explain*):
3.5.2	If the biospecimen is a cell line or hPSC line derived at JHM AND it was derived after September 2016, was the derivation consistent with JHM Policy BIO001?	☐ Yes ☐ No (Please *explain*): ☐ N/A ☐ Cell line was derived prior to September 2016

3.6.2	Please confirm whether there is documentation of consent for each biospecimen to be transferred:	☐ The Principal Investigator of the **collection/derivation** protocol has a signed copy of the consent form from each donor of biospecimens to be transferred. ☐ The Principal Investigator of the **transfer** protocol has a signed copy of the consent form from each donor of biospecimens to be transferred. ☐ There is an IRB waiver of consent for the planned research use. Completion of Section 7 is required for the proposed transfer of unconsented biospecimens
3.7.2	Describe the consent language allowing the requested use and transfer. Include whether any language might limit the sharing, (e.g., opt-in/opt-out option, specific to disease not to be studied) and how this will be addressed:	
3.8.2	Have any research participants/patients contacted you and expressed disagreement with use of any of the biospecimens collected in the protocol(s) relevant to this proposed sharing?	☐ Yes (Please *explain*): ☐ No

Section 4 - Purpose and Description of the Research/Collaboration		
4.1	Briefly describe the purpose of the proposed biospecimen transfer, including the JHM researchers' role in contributing substantially to the design of the research:	
4.2	Who will be responsible for analyzing the data? (*Select all that apply*.)	☐ Sender ☐ Recipient ☐ Sender and Recipient ☐ Other *(Please explain)*:
4.3	What (new) data, if any, will you receive back from the entity to which you are transferring the biospecimens? How will this sharing contribute to your research? (e.g., DNA sequencing)	

4.4	Please describe your participation in the planned publications: (*Transfer of human biospecimens requires a written agreement with the recipient, which should address the respective publication rights of JHU and your collaborators / recipient before transferring biospecimens*.)	
4.5	What is the anticipated scientific value of transferring specimens to the other entity and how might this lead to improving human health?	
4.6	By transferring the material, will you substantially affect your – or other JHM investigators' – ability to complete additional research projects in the future? (e.g., will biospecimen supply be depleted)	☐Yes *(Please explain)*: ☐No
4.7	Are there any anticipated social or cultural issues associated with the biospecimens or transfer of these biospecimens? (e.g., a tribe or family unit could be identified and object to this research being conducted even if not personally identified.)	☐Yes *(Please explain)*: ☐No

Section 5 - Related Agreements and Commercialization		
5.1	What is the agreement for the use of the data after the project? *(Select all that apply.)*	☐ No data will be retained by recipient ☐ Data will be retained by recipient If the above was selected, please provide individual data elements/variables to be retained and confirmation that data will not be used for unspecified future use here: ☐ New data will be returned to sender ☐ Other *(Please clarify)*:

5.2	What is the agreement for the return or disposal of the biospecimens after use?	☐Destruction upon completion of the research ☐Biospecimens will be completely used up in the assays described above ☐Return of samples (*unused/partially used*) ☐Other *(Please explain)*:	
5.3	Will any additional documents or agreements, other than the anticipated MTA affect how these biospecimens may or may not be used?	☐Yes *(If yes, please attach)* ☐No	
5.4	Do you think the transfer of these biospecimens will directly lead to any commercial use? Why or why not?	☐Yes ☐No *Please explain:*	
5.5	In order to facilitate the transfer process, please select what best describes the funding for this transfer.	☐ Federal grant (*Please identify)*: ☐ Commercial support (*Please identify):* ☐ Other (*Please identify, e.g., no funding, internal gift account, foundation, material support)*:	
5.6	Will there be a contract covering this biospecimen transfer that will include funding beyond the cost of preparing and shipping the biospecimens?	☐Yes *(Please explain)*: ☐No	
5.7	Confirm whether a contract, MTA or research agreement has been initiated.	☐ Clinical Research Contracting ☐Office of Research Administration ☐Has not yet been initiated	Please provide Fibi PD/My RAP/JAWS number:
5.8	If available, provide the name of the contact person in the research office who will negotiate the agreement.		
5.9	Confirm that you have notified the recipient investigator of their responsibility to obtain appropriate approvals/acknowledgments in order to perform research with Hopkins specimens.	☐Yes ☐No *(Please explain)*:	

Section 6 – Conflicts of Interest		
6.1.	To the best of your knowledge, is there an institutional conflict of interest?	☐Yes *(Please provide documentation of review from Office of Policy Coordination)* ☐No

6.2	Does any faculty or staff member from the collection **OR** transfer protocol have a financial conflict of interest related to the use of these biospecimens?	☐Yes: ☐Collection Protocol ☐Transfer Protocol *(Please explain the relationship between the proposed use and the reported conflict of interest and provide the eDisclose reference number)* *Explanation:* ☐No
6. 3	Does the proposed recipient of the transferred biospecimens have a conflict of interest related to the proposed use of these biospecimens? **Please note, this question is only applicable to non-commercial recipients*.	☐Yes ☐No ☐N/A *If yes, please provide a copy of any conflict of interest management plan and an explain the relationship between the proposed use and the reported conflict of interest.*

If you indicated that there is an IRB waiver of consent for the planned research use in Section 3, please complete Section 7 below.

Section 7 – Unconsented Specimens		
7.1.	Is consent/reconsent practicable?	☐Yes - *Please provide a plan for recontact/reconsent of participants:* ☐No – *Please explain why:*
*If you responded "Yes" to Question 7.1, please **stop here**.* *If you responded "No" to Question 7.1, please continue by responding to the below questions designed to assist the committee in weighing the risk/benefit ratio of sharing unconsented biospecimens outside of Hopkins*.		
7.2	Use of a **consented** source of biospecimens is required where such a source exists. Please confirm there is not an alternate consented source available and explain your reasoning.	
7.3	How will the knowledge gained by transferring unconsented biospecimens specifically benefit Hopkins/our patient community, or address a local clinical need?	
7.4	Confirm that no germline genomic data will be generated by the recipient.	

I attest to the accuracy of information provided on this form and agree to limit the use of biospecimens as described therein:

Name of PI initiating transfer	Date of attestation

*** PLEASE SUBMIT THIS FORM WITH COPIES OF RELEVANT DOCUMENTATION, INCLUDING HIGHLIGHTED CONSENT FORM(S), IRB APPROVAL LETTER(S), COEUS PD in eIRB APPLICATION SECTION 23, ITEM 4.***