** Data Use Agreements and Material Transfer Agreements

for ALL Human-related data and Human-derived samples **

(Review, Negotiation & Execution of Document)

Work with CWRU Technology Transfer Office and Institutional Review Board

This process is required when:

 CWRU faculty want to send human-related data or human-derived samples or specimens out of CWRU. CWRU faculty must have an approved IRB protocol or determination that includes a provision for the transmission of the human data and/or materials. In addition, they must have an appropriate contract, a Data Use Agreement (DUA) for data or a Material Transfer Agreement (MTA) for specimens, drafted and sent to the relevant outside entity. It is then negotiated with the outside entity and executed by an authorized signatory for the university and the outside entity.

or

 CWRU faculty want to receive human-related data or human-derived samples from another institution and that institution has provided their DUA or MTA for review and execution by CWRU.

The faculty member will work with:

- Work with the Technology Transfer Office (TTO) for the data use or material transfer agreement contract.
- Submit to the Institutional Review Board (IRB) a protocol to obtain the IRB determination or approval for use of the human data or human specimen.
- UTech (if the data is identifiable) to create a Data Safety Plan for transfer, storage and use of data or to satisfy the terms of the DUA.

Please note that this process applies to all human derived data or material including deidentified, Limited Data set (LDS) or full Protected Health Information (PHI). The IRB is the authority that will make a determination regarding the nature of the data or material and whether it is de-identified, LDS, or full PHI.

Turn-around time from submission:

The processing time depends on a number of factors, including:

- what the contract from an outside institution looks like (how standard is it)
- how responsive the other institution is to CWRU's questions or suggested revisions to their contract
- the number of submissions being processed by the IRB and TTO
- whether the IRB submission is a new protocol or an approved protocol requiring modification
- other external factors

After submission of completed MTA or DUA review form, you should receive confirmation of receipt and follow-up questions within a number of days. Review of the contract following approval of the IRB protocol and Data Security Plan can take at least one week after all approvals have been received.

Always needed for DUAs and MTAs:

Complete and sign the appropriate review form and submit to TTO

- For data use agreements: <u>DUA Review Form</u>
- For material transfer agreements: MTA Review Form

Obtain IRB approval or determination letter. The information submitted to the IRB must be consistent with the information provided to TTO, including the data security plan.

Who can help:

TTO:

Courtney Pokorny at 216.368.0336 or cxp395@case.edu for assistance with DUAs. Walid Jalabi at 216.368.2151 or wxj68@case.edu for assistance with MTAs. Amanda Tonelli at asa11@case.edu

UTech IT Security Office:

Cal Frye at 216.368.3769 or cxf244@case.edu

CWRU IRB Office

Kim Volarcik at 216-368-0134 or cwru-irb@case.edu Ginger Pomiecko at 216-368-4514 or cwru-irb@case.edu