**CHECKLIST: Sharing of Participant Data and/or Biospecimens**

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| **TRANSFER OVERVIEW** | | | |
| **U-M Principal Investigator** |  | | |
| **Name of Outside Entity** |  | | |
| **HUM#** |  | | |
| **PAF#** |  | | |
| **Investigator or U-M Conflict of Interest?** | Yes  No | **If yes, is there a management plan in place?** | Yes  No  N/A |
| **Were data/specimen collected as part of a sponsored project?** | Yes  No | **If yes, do the terms of the sponsor agreement permit transfer?** | Yes  No  N/A |
| **Type of Transfer** | Retrospective  Prospective | | |
| **Project Summary**  **(brief description of the purpose of the transfer and original project under which data/biospecimens were collected, if applicable)** |  | | |
| **Quantity being Transferred** |  | | |
| **What does U-M receive in return, if applicable?** |  | | |
| **What does the outside entity receive/retain?** |  | | |

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| **Biospecimens and/or Data to be Transferred** | |
| Yes  No | Biospecimens will be collected, stored, and distributed to Outside Entity  Source(s) of specimens: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Yes  No  N/A | Biorepository Oversight Committee approval granted |
| Yes  No | Patient/Participant health data will be collected, stored, and distributed to Outside Entity  Source(s) of data: |
| Yes  No  N/A | Patient/Participant health data is only at the aggregate, summary-level |
| Yes  No  N/A | Patient/Participant health data is at the individual-level |
| Yes  No  N/A | Individual patient/participant level data verified to be  De-Identified  Limited Data Set  Coded |
| Yes  No  N/A | Coded data crosswalk maintained by honest broker (DOCTR)  If no, by whom (specific name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Honest broker attestation signed?  Yes  No |

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| **IRB Protocol and Consent Form** | |
| Yes  No | Type of data/biospecimens and transfer use consistent with permissions in  IRB application  Consent |
| Yes  No  N/A | Outside Entity to receive biospecimens/data explicitly named *OR* language about potential of for-profit commercial entity to receive data/biospecimens **in consent** (Select N/A if waiver of consent) |
| Yes  No  N/A | Collection occurred under waiver of consent |
| Yes  No | Explanation of provisions in place for protecting the privacy and confidentiality of participants |
| Yes  No  N/A | Explanation of whether research participants will be re-contacted by U-M investigator |
| Yes  No  N/A | A statement is included in the **consent** that the participants do not retain any property rights to their materials/data nor receive any financial benefits (Select N/A if waiver of consent) |
| Yes  No  N/A | All versions of the **consent** used in the collection are attached and have been reviewed (Select N/A if waiver of consent) |
| If using waiver of consent, include regulatory and legal provisions which permit these activities. |  |

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| **COST RECOVERY/VALUATION** | |
| Yes  No  N/A | Full-cost budget to recover project expenses and study team effort discussed (prospective data/specimens) or provided and reviewed (retrospective data/biospecimens) |
| Yes  No  N/A | Full-cost recharge rate of central units (DOCTR and/or Central Biorepository) included in budget, if applicable |
| Yes  No  N/A | Institutional data/biospecimen transfer fee included |
| Yes  No  N/A | Valuation/licensing consultation by Business Development, Office of Technology Transfer, or ORSP |
| Summary of any other financial terms |  |

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| **DRAFT AGREEMENT** | |
| Agreement Type | DUA  MTA  Research Agreement  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Central Unit Responsible for Contract | ORSP  OTT  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **For retrospective, does the draft agreement provided by the Outside Entity include the following require Medical School terms?** | |
| Yes  No | Statement that ownership remains with U-M, |
| Yes  No | Statement that derivatives, secondary use, sale, or redistribution is prohibited |
| Yes  No | Statement that Outside Entity may not, under any circumstances, attempt to re-identify participants and if identifiers detected U-M to be notified |
| Yes  No | Statement that once data and/or biospecimen are used for specific purpose of transfer described in the agreement, they are destroyed or returned.  If no, what happens to the data/biospecimens: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **DOCTR Notes** |
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**Prepared/Reviewed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*Data Office for Clinical & Translational Research*

**Committee Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: ­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*Data & Biospecimen Release Committee*

**Committee Recommendation:**  Approve  Approve with Contingencies  Decline

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| **Committee Notes** |
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**Medical School Decision:**  Approve  Decline

**Dean’s Office: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: ­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**