HUMAN RESEARCH PROTECTION PROGRAM (HRPP) MTA/DTA REVIEW AND SIGNATURE APPROVAL PROCESS GUIDANCE DOCUMENT

Introduction and Purpose

The scope and purpose of this Guidance Document is to establish the process for reviewing and approving material and data transfer agreements (MTA/DTA) in clinical research projects involving the University of Utah. This Guidance should be used to direct the initiation, review, approval, and monitoring of a MTA/DTA to promote compliance with University policies and to meet Good Clinical Practice standards.

Definitions and Acronyms

Clinical Research: Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

EMMA: Electronic Agreement System with the HRPP. It manages the submission and review process for Reliance Agreements, Material Transfer Agreements, etc.

Office of Foreign Influence: manages and mitigates the risk of potential undue foreign influence associated with the University's ongoing commitment to advancing research and discovery on the local, national, and global levels.

AVPRIC: Associate VP for Research Integrity & Compliance
DTA: Data Transfer Agreement
HRPP: Human Research Protection Program
IRB: Institutional Review Board
MTA: Material Transfer Agreement
OQC: Office of Quality Compliance
OSP: Office of Sponsored Projects
PIVOT: Partners for Innovation, Ventures, Outreach & Technology
RGE: Resource for Genetic and Epidemiological Research
UPDB: Utah Population Database
VPR: Vice President for Research

MTA/DTA Review and Signature Approval Process

1. **IRB Receipt:** Institutional Review Board (IRB) front desk receives a Material Transfer Agreement (MTA) / Data Transfer Agreement (DTA) via email from the Partners for Innovation, Ventures, Outreach & Technology (PIVOT) Center or Office of Sponsored Projects (OSP) reviewer.
2. **Foreign Influence Considerartion:** Any MTA/DTA involving a foreign entity that returns results, and/or potential results, from the restricted party screening performed by PIVOT/OSP will be sent from PIVOT/OSP to the Office or Foreign Influence within 7

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calendar days for further review and determination.

3. **EMMA Entry:** IRB front desk enters the MTA/DTA into "EMMA", the Electronic Agreement System within the Human Research Protection Program (HRPP) implemented to manage the submission and review process for MTAs/DTAs.
4. **IRB Reviewer Assignment and RGE Consideration:** IRB front desk assigns the MTA/DTA for review to an IRB new study administrator and, if needed, contacts the Resource for Genetic and Epidemiological Research (RGE) Director.
5. **IRB Administrator Review:** IRB administrator reviews the MTA/DTA, comparing it to the IRB application(s).
   - 5.1. If changes are needed to the IRB application or the MTA/DTA-Exhibit A, the IRB administrator emails the PI(s), study team members, and the PIVOT or OSP reviewer. The IRB administrator adds this email as an internal comment in EMMA.
   - 5.2. The IRB administrator follows up within 30 calendar days of that first email to ensure the requested changes are being made.
     - 5.2.1 The IRB has a 30-calendar day response policy. If there are revisions needed to an MTA/DTA and the study team does not respond to the revision request in the 30 calendar days, their application will not move forward. The IRB reviewer will send a follow-up email to the study team within 25 calendar days. If no response is received within 5 calendar days, the MTA/DTA application will be withdrawn by the IRB, PIVOT, or OSP.
     - 5.2.2 If PIVOT/OSP have given the MTA/DTA to the IRB and the IRB is requiring revisions, the reviewer at PIVOT/OSP should be copied on the email.
     - 5.2.3 If Utah Population Database (UPDB) data are involved, the MTA/DTA is routed to the RGE Director for review and possible revisions before sending for signatures.
6. **Routing for Signature:** When the IRB administrator determines that the MTA/DTA and IRB application(s) are consistent and accurate, the IRB administrator gives the MTA/DTA to the IRB front desk to route for signatures in DocuSign.
   - 6.1. If the IRB administrator determines that an amendment to the IRB application(s) is needed, the IRB administrator can send the MTA/DTA for signatures once the amendment is submitted. The amendment does not have to be fully approved.
   - 6.2. Signature order:
     - 6.2.1 IRB Director
     - 6.2.2 RGE Director (when applicable)

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6.2.3 Associate VP for Research Integrity & Compliance (AVPRIC)
6.2.4 Vice President for Research (VPR) (as determined by AVPRIC)

7. **EMMA Activation:** After all signatures have been obtained, the IRB front desk scans the final copy of the MTA/DTA and attaches it to the MTA/DTA application in EMMA.

   7.1. The IRB front desk moves the EMMA application for the MTA/DTA into the "Active" state.

8. **PIVOT/OSP Notification:** The IRB front desk sends a copy of the completed MTA/DTA back to the PIVOT or OSP reviewer, as well as the study team.

9. **OQC Notification:** The IRB front desk notifies the Office of Quality Compliance (OQC) of the active MTA/DTA.

10. **OQC Review:** The MTA/DTA, and any associated data and/or documentation, are subject to review by the OQC at any time.

Materials Required

- PIVOT Center **Material/Data Transfer Agreement Request Form**

References

- Human Research Protection Program (HRPP)
- Institutional Review Board (IRB)
  - **IRB Transfer Agreement Guidelines**
- Office of Foreign Influence
- Office of Quality Compliance (OQC)
  - **MTA/DTA Checklist**
- Office of Research Integrity and Compliance (ORIC)
- Office of Sponsored Projects (OSP)
- PIVOT Center
- Resource for Genetic and Epidemiologic Research (RGE)
- Utah Population Database (UPDB)

Document Approval

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DocuSigned by:

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4/18/2022 | 2:36 PM MDT

Ann Johnson, PhD, MPH — DATE
Director, Human Research Protection Program (HRPP), University of Utah
Director, Institutional Review Board (IRB), University of Utah

Revision History

Version Date	Change Summary
22/FEB/2022	Origional Version
15/APR/2022	Formatting updated to follow standardized layout for Guidance Documents

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