

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

RGE: Resource for Genetic and Epidemiological Research

TLO: Technology Licensing Office

UPDB: Utah Population Database

VPR: Vice President for Research

MTA/DTA Review and Signature Approval Process

1. MTA/DTA Creation:

1.1. MTA/DTAs are handled by either TLO or OSP. OSP drafts, reviews and negotiates incoming and outgoing MTA/DTAs associated with an active or anticipated sponsored project; TLO handles all other MTA/DTAs. For OSP, a Document Summary Sheet (DSS) number is required to process each request.

1.2. TLO: University faculty and staff can initiate the process for creating a MTA/DTA by securely signing into the [Technology Licensing Office's Faculty & Staff Portal](#)

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and completing the MTA or DTA request through the “Submit Agreement Request” link in the top page menu.

1.3. OSP: University faculty and staff can initiate the process for creating a MTA/DTA by signing into the Office of Sponsored Project’s MTA/DTA submission portal at: <https://osp.utah.edu/resources/agreement/cda.php>

- 2. MTA/DTA Negotiation:** The MTA/DTA language is reviewed and negotiated by TLO or OSP with the partner entity. Once the MTA/DTA has been negotiated by TLO or OSP, TLO or OSP will obtain party signatures on the agreement. TLO or OSP then submits the agreement to the Institutional Review Board (IRB) with a list of contact persons/email addresses so IRB may send out the fully executed agreement after IRB sign off.
 - 3. IRB Receipt:** IRB front desk receives the MTA/DTA via email from the TLO or OSP reviewer.
 - 4. Foreign Influence Consideration:** Any MTA/DTA involving a foreign entity that returns results, and/or potential results, from the restricted party screening performed by TLO/OSP will be sent from TLO/OSP to the Office of Foreign Influence within 7 calendar days for further review and determination.
 - 5. 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.
 - 6. IRB Reviewer Assignment and RGE Consideration:** IRB front desk assigns the MTA/DTA for review to an IRB administrator and, if needed, contacts the Resource for Genetic and Epidemiological Research (RGE).
 - 7. IRB Administrator Review:** IRB administrator reviews the MTA/DTA, comparing it to the IRB application(s).
 - 7.1. 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 TLO or OSP reviewer. The IRB administrator adds this email as an internal comment in EMMA.
 - 7.2. The study team is responsible for confirming and initiating any changes to the MTA/DTA-Exhibit A with TLO/OSP. The study team is also responsible for submission of any changes to the IRB application via an amendment in ERICA.
 - 7.3. 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

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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, TLO, or OSP.

5.2.2 If Utah Population Database (UPDB) data are involved, the MTA/DTA is routed to the RGE for review and possible revisions before sending for signatures.

8. **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.
 - 8.1. If the IRB administrator determines that an amendment to the IRB application(s) is needed, the IRB administrator may send the MTA/DTA for signatures once the amendment is submitted. It is the discretion of the IRB administrator whether the MTA/DTA signature needs to await amendment approval.
 - 8.2. Signature order:
 - 6.2.1 IRB Director
 - 6.2.2 Associate VP for Research Integrity & Compliance (AVPRIC)
 - 6.2.3 Vice President for Research (VPR) (as determined by AVPRIC)
9. **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.
 - 9.1. The IRB front desk moves the EMMA application for the MTA/DTA into the "Active" state.
10. **TLO/OSP Notification:** The IRB front desk sends a copy of the completed MTA/DTA back to the TLO or OSP reviewer, as well as the study team.
11. **OQC Notification:** The IRB front desk notifies the Office of Quality Compliance (OQC) of the active MTA/DTA.
12. **OQC Review:** The MTA/DTA, and any associated data and/or documentation, are subject to review by the OQC at any time.

References

- [Human Research Protection Program \(HRPP\)](#)
- [Institutional Review Board \(IRB\)](#)
 - [IRB Transfer Agreement Guidelines](#)
- [Office of Foreign Influence](#)
- [Office of Quality Compliance \(OQC\)](#)

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- [MTA/DTA Checklist](#)
- [Office of Research Integrity and Compliance \(ORIC\)](#)
- [Office of Sponsored Projects \(OSP\)](#)
- [Technology Licensing Office \(TLO\)](#)
- [Resource for Genetic and Epidemiologic Research \(RGE\)](#)
- [Utah Population Database \(UPDB\)](#)

Document Approval

DocuSigned by:



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DATE

Revision History

Version Date	Change Summary
22/FEB/2022	Original Version
15/APR/2022	Formatting updated to follow standardized layout for Guidance Documents
13/MAY/2024	Revised to reflect change from PIVOT to TLO and new process for initiating MTA/DTAs.

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