

**OFFICE OF RESEARCH AND DEVELOPMENT (ORD)
VETERANS HEALTH ADMINISTRATION (VHA)**

DRAFT ORD Guidance on Material Transfer Agreements

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Draft Guidance

This draft guidance document is being distributed for comment purposes only.

Document originally issued on July 28, 2018.

This draft guidance is a new ORD guidance document.

Please submit comments and suggestions regarding this draft document within 120 days of the date of issue. Submit comments and suggestions to the VHA Office of Research and Development at VHACOORDRegulatory@va.gov.

SCOPE: This guidance is an informational guidance document regarding Material Transfer Agreements (MTAs). This guidance provides basic information on MTAs, including why a MTA is used and the critical components of a MTA.

1. What is a MTA?
2. Does the VHA Office of Research and Development require the use of Material Transfer Agreements (MTAs) for sharing or transferring of VA biospecimens?
3. Why is a MTA important?
4. Can a MTA be used solely for VA research biospecimens obtained from consented VA subjects?
5. What should be in a MTA?
6. Can a MTA be used as a Data Use Agreement?
7. What if I am transferring biospecimens to a diagnostic testing laboratory? Do I still need to implement a MTA?
8. Do I need a separate MTA if I am sending biospecimens to a for-profit company who is sponsoring the study?
9. Does VA have a template for MTAs?

1. What is a MTA?

A Material Transfer Agreement, or MTA, is a legally binding agreement that is used when biospecimens are shared or transferred. A MTA defines the rights and obligations of the providers and recipients of the biospecimens.

Release Date: 07-28-2018

DRAFT ORD Guidance on Material Transfer Agreements

Page 1

March 31, 2021

2. Does the VHA Office of Research and Development (ORD) require the use of Material Transfer Agreements (MTAs) for all sharing or transferring of VA biospecimens?

No. ORD policy requiring the use of MTAs applies to collaborative research activities. VHA Directive 1200.01 paragraph 10c requires the use of an MTA when transferring biospecimens from VA as part of collaborative research, unless the biospecimens' transfer is addressed in another agreement executed between VA and the collaborating institution or party. Alternative agreements include CRADAs, subawards, MOUs, or other appropriate agreements. ORD Technology Transfer has published a VA MTA template that can be found on the Technology Transfer webpage:

https://www.research.va.gov/programs/tech_transfer/model_agreements/default.cfm.

While ORD does not require use of the VA MTA template, its use is encouraged because it simplifies the review process, particularly when VA is the provider.

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3. Why is a MTA important?

MTAs document a chain of custody for any VA biospecimens which are shared or transferred. VA is entrusted with ensuring that these VA biospecimens are used in a manner that respects the preferences and wishes of Veterans. The MTA serves as a documentation of a chain of custody for any VA specimens that are shared or transferred by documenting the authority required for use of those biospecimens as well as describing how the biospecimens may be used (e.g., the purpose of the use). The MTA also describes the stewardship of the shared or transferred biospecimens. Stewardship is a care-taking responsibility for the biorepository from the time the biospecimen is collected (when possible) through its use, distribution and destruction (when applicable). ORD recommends the use of a MTA when VA research biospecimens are shared or transferred to another non-VA entity or institution, such as a university.

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4. Can a MTA be used solely for VA research biospecimens obtained from consented VA subjects?

An MTA can involve sharing or transferring of identifiable, coded, or de-identified VA biospecimens which were initially collected or obtained with the subject's informed consent as approved by an IRB. The use of the VA biospecimens must be consistent with the subject's informed consent and the approved research activity. For example, if the subject's IRB-approved informed consent document stated that only de-identified biospecimens would be shared with other researchers as part of future research studies, an MTA cannot be used to share or transfer the subject's identifiable VA biospecimens. Such a use would be in direct conflict with the subject's IRB-approved informed consent document and what the subject

consented to when the biospecimens were initially obtained as part of the research study.

An MTA can also involve sharing or transferring of VA biospecimens that were obtained with a waiver of informed consent as approved by an IRB. Also, an MTA could involve sharing or transferring of VA biospecimens collected or obtained by a VA Investigator as part of an exempt human subjects research activity or a non-human subject research activity. For example, a VA Investigator requested de-identified biospecimens from a University's biorepository using a MTA to document the transfer and use. The VA Investigator had no access to the key or link which would allow the VA Investigator to associate the biospecimen with the subject's identity. The research activity consists solely of analyzing the specimens for a specific biomarker. The VA Investigator's activity would constitute non-human subject research.

Please note that an MTA does not create authority for use of the VA biospecimens; the use must be consistent with the approved research activity. Any use of identifiable biospecimens must also meet the applicable Privacy requirements.

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5. What should be in a MTA?

At a minimum, the following should be included in a MTA:

- A statement defining who the contributor and recipient of materials (biospecimens) are, including the Primary Investigator, laboratory director, pathologist, etc. and their institution or facility.
- A statement regarding what biospecimens will be transferred. This may be easier to reference in an appendix to the agreement.
- A statement that biospecimens will only be used for the specified research purposes.
- A statement that biospecimens will not be used in human subjects.
- A statement that biospecimens may carry infectious agents such as bacteria, viruses, etc. and should be handled by trained personnel following biohazard universal precautions. Refer to <http://www.cdc.gov/niosh/topics/bbp/universal.html> for more information.
- A statement that biospecimens must be destroyed or returned to the VA after a specific retention period. The MTA should specify which will be required by the recipient.
- A statement that biospecimens will not be labeled with any individually identifiable information and that no effort will be made to re-identify the participants they were collected from when sharing or transferring de-identified VA research biospecimens.
- A statement that the recipient will not make any attempt to sell, share or transfer any biospecimens unless permitted by the agreement. *NOTE: Selling does not include a "fee for service" arrangement that some biobanks utilize as part of their business model, but this should be documented in the MTA.*
- A statement that any publications will acknowledge the contribution or the source of the biospecimens. This may not be applicable to all situations.

- A statement that all relevant laws and regulations be followed. These may include federal and local regulations such as the Health Insurance Privacy and Portability Act or HIPAA and 38 CFR 16 and 45 CFR Part 46, where applicable.
- A statement regarding any patents or intellectual property that may be produced from the research on the biospecimens. *NOTE: You should refer to your Technology Transfer Office or legal affairs team for specific language.*
- The agreement must be signed by the appropriate signatory authorities for the institutions. The Recipient Investigator should sign as an acknowledgement.

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6. Can a MTA be used as a Data Use Agreement?

No. Biospecimens are not data. However, if data is also being sent with biospecimens, a combined Material Transfer Agreement/Data Use Agreement can be used. See *VHA Handbook 1200.12 for information on Data Use Agreements.*

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7. What if I am transferring biospecimens to a diagnostic testing laboratory? Do I still need to implement a MTA?

It depends upon the situation. The issue is what authority exists for the biospecimen to travel to the testing laboratory and if an agreement is needed to allow the biospecimens to go to the diagnostic testing laboratory.

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8. Do I need a separate MTA if I am sending biospecimens to a for-profit company who is sponsoring the study?

VA has created a guidance document called, "Guidance on Selection of the Appropriate CRADA Model" that describes when a Material Transfer CRADA is used and when a MTA is used. In some clinical studies requiring a clinical trial study CRADA, sending biospecimens to the for-profit collaborator is part of the IRB-approved protocol for which subjects are consented. In those types of studies, it is not necessary to have a separate MTA. A MTA would not apply in this case. Refer to the Tech Transfer website, http://www.research.va.gov/programs/tech_transfer/default.cfm, for more information on CRADAs.

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9. Does VA have a template for MTAs?

Yes. The MTA templates are located at https://www.research.va.gov/programs/tech_transfer/model_agreements/default.cfm. In addition, VA often receives other MTAs from other non-VA entities which are reviewed by OGC STAR for legal compliance. Also, VA also can use the Uniform Biological Material Transfer Agreement (UBMTA) published in the Federal Register.

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