ORD Draft Guidance on Material Transfer Agreements

DRAFT GUIDANCE

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ORD welcomes any comments or suggestions regarding this draft guidance document that will represent the current position of the VHA Office of Research & Development (ORD) on this topic when the guidance is finalized. This guidance when finalized will not be binding as ORD policy. Please submit electronic comments or questions within the next 45 days by email to ORD tissue banking at offsite.tissuebanking@va.gov.

For questions regarding this DRAFT document, contact Ms. Kristina Hill at Kristina.hill@va.gov.

SCOPE: This guidance is an informational guidance document regarding Material Transfer Agreements (MTAs). MTAs are not required by ORD policy, but MTAs are commonly used for sharing and/or transferring biospecimens. This guidance provides basic information on MTAs, including why an MTA is used in addition to its critical components. This guidance applies to the sharing or transfer of human biological specimens collected or obtained as part of a VA research activity for another research activity.

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1. What is an MTA?

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

2. Does the VHA ORD require the use of MTAs for sharing or transferring of VA biospecimens?

No. ORD does not have policies in VHA Handbook 1200.05 or any other ORD Handbooks or Directives which mandate the use of MTAs. However, there may be protocol specific
requirements for use of an MTA. There may also be biorepository specific requirements for use of an MTA. For example, a VA Biorepository may require the use of an MTA for sharing/transferring VA biospecimens when investigators request access to biospecimens housed in the biorepository.

3. Why is an MTA important?

Although MTAs are not required by current ORD policies, MTAs document a chain of custody for any VA biospecimens which are shared or transferred. VA is entrusted with ensuring that 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 an MTA when VA research biospecimens are shared or transferred to another non-VA entity or institution, such as a university or the National Institutes of Health (NIH).

4. Can an 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. In addition, 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 an 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 applicable Privacy requirements.

5. What should be in an MTA?

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At a minimum, the following should be included in an 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 (blood, tissue, etc.) 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](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.
- A statement that biospecimens will not be labeled with any individually identifiable information, when possible, 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 or shipping fees, 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 should be signed by the appropriate signatory authorities for the institutions and the Recipient Investigator should sign as an acknowledgement.

6. **Can an 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.

7. **What if I am transferring biospecimens to a diagnostic testing laboratory? Do I still need to implement an MTA?**
No. ORD does not recommend use of an MTA for transferring biospecimens to a diagnostic testing laboratory unless there is a specific circumstance requiring an MTA or your facility requires it; however it is advisable to have a document of the transfer.

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

If you are sending biospecimens to a for-profit company who is sponsoring the study, a Cooperative Research and Development Agreement or CRADA must have been established between the VA and the company. This contractual agreement specifies what the company may do with the biospecimens, often designated as CRADA materials. An 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.