

DISPOSITION OF MATERIALS FROM CASES IN THE DEPARTMENT OF VETERINARY PATHOLOGY

This document addresses the protocol for release of reports or materials (our medical records) from the Department of Veterinary Pathology (VPTH). It is the policy of Iowa State University (ISU) that ISU is the owner of all materials at this University. As per that policy, original materials are retained by the Department of Veterinary Pathology to support our reporting results as representatives of Iowa State University. Transfer of materials is addressed below and must comply with University policy.

General

Reports are only released to the submitter (our client, the referring DVM). If anyone requests a report from our Department and the requester is not the original submitter, the original submitter must give written permission. This also includes permission to give results from our service to the ISU Veterinary Medical Center (VMC) from an external veterinarian. Therefore, for any submitting veterinarian external to the CVM (non-ISU, our client), they must give written permission to release any report to anyone other than themselves. This policy is posted on our departmental website. In addition, reports submitted by DVMs in the VMC go to the DVM submitter, veterinarians of record (electronic medical record), and/or the designated responsible veterinary clinician. In addition, the VMC reports are available to all clinicians in the VMC via VetStar and the electronic medical record.

Case reports are available to VMC via VetStar. Only Veterinary Pathology Departmental personnel will have access to VADDS.

Clinical or Clinical Research Cases

If there are requests to release materials that are normally retained longer term within the Department, such as slides and paraffin blocks, the below applies. If possible, permission should be obtained from the submitter; but this is not always possible in retrospective studies. Original case materials are retained at ISU- CVM- VPTH. These materials support our departmental reporting, and in some cases, the reporting of the VMC. It is in the best interest of ISU, CVM, and VPTH to retain materials in one central location, the Department of Veterinary Pathology, for storage and retrieval for VMC case reporting and potential studies.

Blood smears: A duplicate slide may be sent to the requester if available. Alternate: a photograph may be sent. A minimum of one original slide has to be retained.

Cytology: A duplicate slide may be sent to the requester if available. Alternate: a photograph may be sent. A minimum of one original representative slide has to be retained.

Fluids (whole blood, serum, urine, cytology fluids). These are generally retained for a short period of time, 24-48 hours, but are retained longer on clinician request.

Histopathology slides: All original histopathology, including special stains, and immunohistochemical stains are retained. Representative slides may be cut and sent. Unstained slides may be cut and sent.

Paraffin blocks: Blocks are to be retained in VPTH storage, but additional slides may be cut and sent. Exceptions for research and/or studies will be reviewed by the Department Chair. If blocks are loaned, this is temporary and they will be returned. While loaned, the responsible party will sign a document stating the location of the block and document the use of the block, including if the block will be “used up” or destroyed in the process of obtaining the requested sampling. This will follow a Chain of Custody reporting to maintain the materials for the University. Any blocks loaned from ISU-CVM- VMC cases, must also have approval of the VCS Department Chair. If the blocks are to be sent to locations other than ISU, a Materials Transfer Agreement will need to be implemented. All requests would be reviewed and approved by the VPTH Department Chair.

Non- clinical cases

If research is performed on non-clinical, non-VMC cases, exceptions to materials retention may occur after reviewed by the Veterinary Pathology Department Chair. Prior to testing, a specific protocol/statement must be made regarding the disposition of samples.

Fee for service testing for research

The results of our testing/ service shall become the sole property of the company that is seeking our services and these results are deemed confidential. However any improvements of testing methodology, discoveries, inventions, copyrightable work, equipment, or processes developed solely by the University during the course of providing the service, and which can be used independently of the service, are the sole property of the University. In some cases, we (the Department of Veterinary Pathology) may need to keep portions of samples for our purposes to document the testing/service that we (VPTH) completed with the agreement of the company.

In the case where a pathologist is involved, with the agreement of the company, the materials may be signed out to the pathologist engaged in the research project and/or returned to the company.

Material Transfer Agreement (MTA)

Material Transfer Agreements:
Office of
Biotechnology, ISU
Industry Tip Sheet - Volume 1:3

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Collaborative research projects with industrial or university partners often involve an exchange of physical or biological materials between the parties. These exchanges typically warrant a material transfer agreement (MTA). MTA's are designed to prevent misuse and preserve the history of the materials. Different situations that warrant or require material transfer agreements are described below:

ISU Materials Transferred To Industry

Materials related to an invention disclosure. This MTA required and is signed by ISURF, ISU faculty/staff member(s) and an industry representative. Once the agreement is signed, use of the materials is governed by the restrictions/requirements stated in the agreement. Transfer of materials does not affect ownership. Transfer of materials without an MTA may affect the ability to protect the invention. For more information, please contact ISURF. This agreement is arranged by ISURF.

Materials not related to an invention disclosure. This MTA is signed by the Contracts and Grants Office, ISU faculty/staff member(s) and an industry representative. Once the agreement is signed, use of the materials is governed by the restrictions/requirements stated in the agreement. Transfer of materials does not affect ownership of the materials per se. This agreement is arranged by the Contracts and Grants Office.

Industry Materials Transferred To ISU

This MTA is required and signed by a Contracts and Grants Officer, ISU faculty/staff member(s) and an industry representative(s). Once the agreement is signed, use of the materials is governed by the restrictions/requirements stated in the agreement, including the restriction that the materials can not be transferred to another PI or laboratory within ISU. Transfer of materials does not affect the industry's ownership of the materials per se. This agreement is arranged through the Contracts and Grants Office.

ISU Materials Transferred To Another University

The Association of University Technology Managers (AUTM) administers the NIH standard MTA agreement (UBMTA) for transfer of biological materials. Many research institutions have agreed to the terms of the UBMTA. ISU and ISURF are among those institutions. If an institution is on this list, the signing of a simple implementation letter is all that is required to transfer biological material. This greatly simplifies transferring materials between these universities, as the language and conditions do not need to be negotiated.

Materials related to an invention disclosure. This MTA required and the implementing letter is signed by ISURF, ISU faculty/staff member(s) and an institution representative. Once the agreement is signed, use of the materials is governed by the restrictions/requirements stated in the agreement. Transfer of materials does not affect ownership. Transfer of materials without an MTA may affect the ability to protect the invention. For more information, please contact ISURF. This implementing letter is arranged by ISURF.

Materials not related to an invention disclosure. This implementing letter is signed by the Contracts and Grants Office, ISU faculty/staff member(s) and an institution representative. Once the agreement is signed, use of the materials is governed by the restrictions/requirements stated in the agreement. Transfer of materials does not affect ownership of the materials per se. This implementing letter is arranged by the Contracts and Grants Office..

ISU Materials Transferred Between ISU Principal Investigators

Transfer of materials between PIs at ISU does not require an MTA. However, due to the sensitive nature of some materials, or other unusual circumstances, an MTA might be recommended or requested by a PI. This MTA is signed by a Contracts and Grants Officer, and the ISU faculty/staff members exchanging the material. This contract is arranged through either the Contracts and Grants Office or the Biotechnology Industrial Liaison.

*It is important to remember that ISU faculty/staff member(s) sign the MTAs personally, and on behalf of their laboratory, but NOT on behalf of the university. If more than one faculty member/laboratory will be receiving the material(s), each will need to sign the agreement. Note: These are general guidelines and are sufficient for most material transfer agreements between Iowa State and a third party. However, some situations may have special requirements. If you have any questions, or would like assistance with this process (including initial preparation of any MTA agreement), please contact:
Lisa Lorenzen*

Biotechnology Industrial Liaison
1210 Molecular Biology Building
Phone: (515) 294-0926
Email: llorenze@iastate.edu

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Research Materials: The Source Matters

Most research involves the use of materials, both biological and non-biological. In addition to the compliance regulations that govern proper physical handling and storage of materials, the source of the materials and the source of funding also indicate proper and improper uses. All transfer of materials should be conducted under a Material Transfer Agreement (MTA) that clearly defines your rights and responsibilities.

Materials received from a third party

All materials received from a third party for research use should be accompanied by an MTA. This MTA will typically state that the material remains the property of the provider, prohibit the ISU faculty/staff member that received the materials from further distributing the materials without written permission from the provider, define intellectual property terms, and other legal considerations.

Materials are provided only to the ISU faculty/staff member requesting the materials and NOT everyone at ISU. Therefore, it is inappropriate for ISU faculty/staff members to transfer the materials outside of his/her laboratory to a third party, which in this case, is also considered another ISU faculty/staff member.

Another important consideration is the funding source. For example, materials received from a company should not be used in a project funded by another company. Use of materials from companies is generally permissible with federal funding sources, but it is always best to check with OSPA before proceeding.

Finally, personnel should also be considered. Materials are transferred to an ISU lab for use only by personnel of that laboratory. Generally, laboratory personnel are considered to be people whose salary is paid by the lab. It is not appropriate to have graduate students or technicians from a neighboring lab, or even visiting scientists, utilize these materials without prior written consent from the material provider.

Materials generated in an ISU laboratory

Material generated in an ISU laboratory have similar considerations as above. If the material is to be transferred to a third party, it should be accompanied by an MTA. For transfers among ISU laboratories, MTAs are not required. However, it is important to notify the ISU laboratories receiving the materials that the materials should not be further transferred without your knowledge/permission. For certain materials, an MTA can be used between ISU faculty/staff members.

Similar to materials received from third parties, the source of the funding matters. For example, if materials are generated in an ISU laboratory utilizing funding from a company, it is not appropriate to use these materials in a project funded by another company, or with personnel visiting your laboratory from outside of ISU.

Why it matters

The funding source for the research and the source of the materials are important because they impact ownership and intellectual property. For example, by co-mingling materials from Company X with funding from Company Y, the terms of the sponsored research agreement signed with Company Y usually conflict with the terms of the MTA signed with Company X. The conflicting terms usually include intellectual property clauses and can be very difficult to resolve.

Material received inappropriately (without a signed MTA) or utilized in another sponsored project could jeopardize your ability to publish, protect your intellectual property, and/or to continue utilizing the data in future research. You should not utilize materials in your research program which you did not purchase or obtain directly via an MTA. In addition to the effects on your research program, this jeopardizes the relationship between the material provider and ISU.

Appropriate Signatures

It is important to remember that ISU faculty/staff are not authorized signatories of ISU. The faculty/staff member receiving the materials should sign the agreement to indicate he or she understands the terms and conditions and agree to abide by them. OSPA is the official signatory which can legally agree to the terms and conditions of the agreement. In addition, all MTA negotiations are handled by OSPA.

If you have any questions about this tip sheet please contact: Lisa Lorenzen, 2810 Beardshear, Phone:(515)294-0926, Email: llorenze@iastate.edu

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