



**New U-M Guidance
for Animals Administered Human-Derived Substances
Frequently Asked Questions**

Additional questions or concerns not answered here should be directed to hds-questions@umich.edu.

GENERAL FAQs

What materials are covered by the new requirement?

For the purposes of the new requirement, human-derived substances cover all materials that are of human origin. These include, but are not limited to: cells and cell lines, tissues, blood and blood products, and stool.

Do I have to move to ABSL-2 housing right away?

No, we are currently in the process of gathering data to determine anticipated researcher needs for ABSL-2 housing over the next year and a half. In order to best accommodate researcher needs, we are asking anyone who is currently using, or who anticipates using, substances requiring ABSL-2 housing to complete the [ABSL-2 Facilities Planning Questionnaire](#) by December 15, 2016.

The information collected from this questionnaire will be used to better understand the capacity and scope that the Unit for Laboratory Animal Medicine will need in order to accommodate all ABSL-2 housing requests. This data will be taken to the Institutional Animal Care & Use Committee in January 2017 to help formulate a phased plan to transition study teams into ABSL-2 housing early next year. Our goal is to have the transition completed by May 1, 2017.

Every effort will be made to accommodate all researcher needs, and to minimize impact on study teams and affected animals. The best way to ensure that we can accommodate your needs is to complete the [ABSL-2 Facilities Planning Questionnaire](#) as soon as possible so that we can plan accordingly.



Why do I have to complete the ABSL-2 Facilities Planning Questionnaire?

A select number of ABSL-2 containment housing facilities will be created across campus. Housing in these specialized areas is granted on a first-come, first-served basis. In order to accommodate anticipated researcher needs for ABSL-2 housing over the next year and a half, we strongly encourage all investigators who currently use, or anticipate using, ABSL-2 housing to complete the [ABSL-2 Facilities Planning Questionnaire](#) so that we can make every effort to plan for, and accommodate, your requests.

Can I conduct my own human-derived substances testing?

Due to concerns over managing quality controls, we cannot allow individual study teams to conduct their own testing. However, ULAM has worked with both Charles River Laboratories and IDEXX-RADIL to enable an appropriate panel to be tested at a discounted price.

Additional details are available at <http://research.med.umich.edu/ibc-absl2>.

What are the practical implications for moving to ABSL-2 housing?

Additional training will be required prior to housing animals under ABSL-2 conditions. Animals housed in ABSL-2 containment areas will also be subject to biocontainment per-diem rates.

Why was this decision made?

This institutional guidance was established to ensure the health and safety of our program personnel while continuing to improve upon the humane and responsible care and use of animals. The decision was made after careful consideration and input from the Animal Care & Use Program, the U-M Institutional Biosafety Committee (IBC), the department of Occupational Safety & Environmental Health (OEH), and the Unit for Laboratory Animal Medicine (ULAM). Benchmarking with other peer institutions was also conducted to better understand best practices for this category of animal research, and to more closely align U-M with similar institutions.

How do I upload my testing documentation to eRAM?

Step-by-step instructions on how to upload your testing documentation are available [here](#). If you have any questions or concerns during this process, please contact your Research Compliance Associate in the Animal Care & Use Office.



I have multiple cell lines. Do I have to have them all tested?

Yes. It is strongly recommended that each human-derived substance be tested to ensure safe practices, especially if you intend to file for an exemption to the new U-M guidance that requires all animals administered a human-derived substance be housed in ABSL-2 facilities unless that substance has been demonstrated to be free from blood-borne pathogens and other viruses of concern.

Do I need to perform the testing if my cell lines have been passaged over time?

Yes, if you want to file for an exemption to the new guidance. Per federal rules and regulations, all primary human cell explants and subsequent in-vitro passages of human tissue explant cultures must be regarded as containing blood-borne pathogens.

I know another researcher who administers the exact same human-derived substances to animals that my lab does. Do I still need to have my substances tested, or can I submit the same test results that the other researcher used to file an exemption from the new guidance?

You do not need to conduct your own testing provided that the material (e.g., cell line) is exactly the same as the one tested by the other researcher. However, please submit a copy of the same test results so that the documentation can be associated with your specific animal use protocol.

Will additional training be required for a move to ABSL-2 housing?

Yes, a move to ABSL-2 housing will require additional hazards training for all personnel listed on the IACUC-approved protocol BEFORE facility access can be granted. Once the determination has been made to move the project to ABSL-2 housing, the protocol will be amended to reflect these changes. Training will then be assigned based on an individual's animal handling details as outlined in the amended protocol.

Specific questions about hazards training should be directed to the ULAM Training Core at ulam-trainingcore@umich.edu.



SAMPLE SUBMISSION FAQs

If I am using human cell lines either from a commercial or non-commercial source do I need an IBC approval?

Yes, research and teaching activities involving the use of human-derived materials (i.e. human cell or cell lines, tissues, or fluids) require IBC approval. All human-derived materials require BSL-2 practices while working with them in the laboratory. The IBC application is available through www.eresearch.umich.edu.

How does ATCC assign biosafety levels for cell lines?

ATCC assigns biosafety level (BSL) designations for the purposes of safe shipment and not the laboratory or animal housing containment requirements. Since cell lines cannot be tested for all viruses, ATCC recommends handling all human and primate cultures under BSL 2 conditions, just to be safe.

How do I obtain screening results from ATCC or other commercial vendors?

ATCC screens human cell lines for certain pathogenic viruses. Each Lot number provided by ATCC is tested and the results are provided on the Certificate of Analysis. You will need to have the Lot number for the cell line you wish to obtain the screening results for.

Can I submit the ATCC Product Sheet as verification of the screening results?

The ATCC Product Sheet does not provide the screening results and will not be acceptable documentation for the risk assessment. The screening results are provided on the Certificate of Analysis. Please contact other commercial vendors directly to obtain the screening results.

How do I submit cell lines to the vendors for screening?

IDEXX-RADIL

Please request the UMich h-IMPACT panel on the submittal form and refer to the following link for additional details on proper sample collection and submittal:

<http://www.idexxbioresearch.com/impact-sop>

Charles River

Individuals should sign up for an LTM user account (data management system which enables individuals to create their orders/submission forms online).



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Follow this link to sign up; <https://lrm.criver.com/LTMPublic/RequestAccount.aspx>

- For existing customer accounts, please indicate the LTM™ account number.
- New accounts, please also [complete the LTM™ Customer form](#).
- Please request the UMich Custom Human Clear Panel

Collection/Submission Instructions:

- Send two (2) undiluted 200µL samples
- Cell number is not critical; however, please note if there are more than 5 x 10⁷ cells/mL
- If possible submissions for PCR Panels that include Mycoplasma testing should be passaged without antibiotics prior to shipping

Storage/Shipping Conditions:

- Store frozen, at -20 degrees Celsius
- Ship overnight frozen on dry ice

Online sample collection/shipping supplies are available by request form via this link: www.criver.com/radsshipping. *These supplies are offered free of charge.*

Who can I contact for assistance with shipping cell lines to the vendors for screening?

M-Ship is a comprehensive packaging and shipping service for dangerous goods/hazardous materials and dry ice packages. Any questions can be directed to shipping.umich.edu or by calling (734) 763-8786.

Additionally, personnel who prepare biological materials for shipment, or who will transport or receive biological material shipments, must be trained and certified. The **course number BLS209w**, which covers shipping exempt human/animal specimens, infectious substances, and dry ice, is available for sign up on the EHS website: www.ehs.umich.edu.

Who should I contact with questions?

For questions or concerns regarding this new guidance, please send an email to hds-questions@umich.edu.