

OUTGOING HUMAN SAMPLE(S) WITHOUT INTELLECTUAL PROPERTY

A material transfer agreement (MTA) from University of Florida (UF) is not required for sending out de-identified human sample(s) for research that:

- Are not part of an invention disclosure to the Office of Technology Licensing (OTL),
- Are not protected under an issued or pending patent application, or
- Are not part of a contract (e.g.: consortium agreement) with distribution restrictions.

For the purpose of this guidance, “Human Sample(s)” or “Sample(s)” refer to human specimen(s), sample(s), tissue, or cell line(s) without intellectual property (IP) or contractual restrictions.

If you have Human Sample(s) of any kind that you wish to provide to another researcher outside of UF for research or other purposes that are not part of the Institutional Review Board (IRB) protocol under which those Sample(s) were collected, **you will need to confirm the following requirements are met before sending the Human**

Sample(s) outside of UF:

Needs	Action Item	Contact Unit
<i>Division of Environmental Health & Safety (EH&S) Requirements</i>	<ul style="list-style-type: none">• You have a valid training certificate to ship biological materials. A certificate can be obtained by successfully completing the “Shipping and Transport of Biological Materials” course and certification is valid for two years. To enroll, email your name and UF ID to bsa@ehs.ufl.edu and request enrollment in the shipping course.• If you handle human tissue you must have completed Bloodborne Pathogen/Biomedical Waste training within the past year. Training is available online through myTraining (http://mytraining.hr.ufl.edu) and can be found by searching for course number (“EHS850G”). To check your last training date, log in to myTraining and click the “Training Transcript” link located under “Manage Training” on the left hand side of the screen.• If the Sample(s) contains recombinant DNA or is <i>known</i> to be infectious, you must have an approved Biological Agent or Recombinant DNA registration on file with the Biosafety Office.	Environmental Health and Safety (EH&S), Biological Safety Office Sharon Judge sjudge@ehs.ufl.edu 352-392-1591 http://www.ehs.ufl.edu/programs/bio/

<p><i>Institutional Review Board (IRB) Requirements</i></p>	<ul style="list-style-type: none"> • You have or had UF IRB approval to obtain the Sample(s). • Informed consent was obtained from subjects for the collection and use of the Sample(s). • Informed consent includes information that de-identified Sample(s) may be released from UF. • No Protected Health Information (PHI) is released outside UF unless the purpose you are releasing it is specifically covered in the informed consent the subjects have signed. • The recipient of the Sample(s) has received their local IRB's approval for the receipt/use of the Samples. • You keep a log of any Samples you release to another institution. • If you have Human Sample(s) that are coded yet de-identified when sent off-campus, you will need a Confidentiality Agreement signed by the UF Principal Investigator (PI) sending the samples, and the non-UF PI receiving the samples (see IRB website at http://irb.ufl.edu/irb01/forms/forms1.html and select the Confidentiality Agreement for Data and/or Specimens form). 	<p>Institutional Review Board (IRB) Peter Iafrate or Sherri Mizrahy Ufirb-l@lists.ufl.edu 352-273-9600 http://irb.ufl.edu/</p>
<p><i>Division of Research Compliance Requirements</i></p> <p>Only needed if sending Samples outside of the U.S.</p>	<ul style="list-style-type: none"> • <u>Shipments to Cuba, Iran, North Korea, Sudan, Syria, or the Crimea Region of Ukraine</u> – Exports from the U.S. to these six embargoed areas require prior U.S. Government approval. Do not ship any materials to, or share any data with, these six embargoed destinations without prior approval from the Division of Research Compliance (compliance@research.ufl.edu) and a valid license from the relevant U.S. Government agency. • <u>International Shipments (other than to Cuba, Iran, Sudan, Syria, or the Crimea Region of Ukraine)</u> – The U.S. export laws prohibit certain U.S. transactions with restricted parties (i.e., entities or individuals identified on various U.S. Government restricted lists). To ensure that the recipient of your shipment is not a restricted party, you may request a Restricted Party Screening from UF's Division of Research Compliance (compliance@research.ufl.edu). 	<p>Division of Research Compliance Matthew Battiston compliance@research.ufl.edu 352-392-9174 http://research.ufl.edu/faculty-and-staff/research-compliance/export-controls.html</p>

<p><i>Only applies to departing PIs</i></p>	<ul style="list-style-type: none"> • Notify your Research Dean, Department Chair or Departmental Contact to complete a “Notification of Departing PI” form: http://research.ufl.edu/faculty-and-staff/forms/notification-of-departing-pi.html • You have a consent from your college representatives (e.g.: Research Dean or Department Chair) to move the Sample(s). 	<p>Respective college or department representative</p>
--	--	--

For PIs who want an agreement to send out Sample(s), the letter agreement listed below can be used.

- [Letter Agreement](#)