This following provides an example of an informed consent document for use where an individual research result or incidental finding is “deemed” returnable, but the initial informed consent obtained at the time the subject donated the specimen, did not offer a choice to receive or refuse results or findings. This result-specific informed consent addresses potential risks, benefits, and ramifications of receiving the result or finding, so that the subject may make a contemporaneous, informed decision.

This particular example follows the standard research consent format as if the return procedure were a part of an IRB approved research repository protocol. However, the level of detail and format required may differ depending on whether or not the return procedure was determined to be a part of human subject research. Language should also be customized to describe the unique situation that exists based on the individual subject and the result or finding. Choose from optional wording (in italics), and delete language that is not applicable as well as instructions from the final document.

Purpose:

You are being contacted by (the X bank, your primary/clinical care provider, a medical specialist, a genetic counselor) to inform you about a result or incidental finding discovered, based on your (previous) participation in a (research study or research specimen bank). An incidental finding is an unforeseen finding discovered during the course of the research, but does not have anything to do with the goals of the research.

Generally, tests done for research purposes are not meant to provide clinical information. Researchers that receive your de-identified (specimen/information) from a specimen bank typically do not know who donated the (specimen/information). However, in the event that a researcher discovers a finding they believe may be important for the health of a donor or the donor’s family, he/she contacts the bank.

The bank has a special committee who meets to assess the finding to determine if it is in your best interest to contact you. The committee bases their determination on a number of criteria including how accurate the test is that identified the result/finding, if a valid test exists to confirm the result/finding and if there are actions that may be taken based on the result/finding.

If the committee decides that you should be contacted, the authorized bank staff that has access to the code that links specimens to their donor re-identifies the specimen so that you may be contacted and offered the opportunity to receive the result/finding.

It is important to remember that (scans, procedures, tests) done for research are not meant or designed to diagnose or provide clinical information. Therefore (we have had the test repeated in a clinical laboratory, OR if you choose to receive the result/finding, additional clinically valid tests, interpreted by qualified clinical professionals, may be required to confirm the result/finding).

What are the benefits, risks, and implications of receiving the result/finding?

There is no guarantee that you will get any benefit from receiving the result/finding. However, receiving the result could allow you to (seek clinical care, adopt preventive practices, and/or make informed healthcare decisions).

There is a risk of distress from learning the result. There is a risk that (therapy, treatments, counseling) used to treat the result/finding will not work for you. There is always a risk that the result or finding is
determined to be false. Any of these outcomes could cause you or your family emotional or psychological distress, financial hardship, ….. There may be risks from receiving the result/finding that at this time are unknown.

Genetic result risks (if applicable):

The results of genetic research apply to both you and your family members. In some cases, it could be used to make it harder for you to get or keep a job or insurance, or impact reproduction plans, family relationships, immigration status, paternity suits, (if applicable). Genetic information could be used in ways that could cause you or your family distress.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it prohibit discrimination on the basis of already known genetic disease.

If you choose not to receive the result/finding, are there other choices?

Whether or not you choose to receive the result/finding is voluntary. You will not lose any benefits or rights you would normally have if you choose not to receive the result/finding.

If you do not want to be in the receiving the result/finding, (there are no other choices except not to receiving the result/finding OR you may contact ____ in the future should you change your mind and wish to re-consent to receiving the result/finding). Your decision will not affect your care.

If you choose to receive the result/finding, you will be provided with ___(testing to confirm, treatment, genetic counseling). _______ will be provided at no cost to you and/or you will be responsible

Who will see information about the result/finding?

Access to information about you as part of the research has been limited to protect your confidentiality. To date, the only individuals who have seen your identifiable protected health information are those authorized by the bank consent and research authorization you signed when you donated your specimen. The research repository personnel have not, nor will they place the result/finding in your medical record.

If you choose to receive the result/finding, (medical providers such as physicians, counselors, healthcare staff, and medical specialist)may see or have access to your identifiable protected health information as part of your clinical care.. Your clinical caregivers may include the result/finding in your medical record as part of your clinical care.

If you choose not to receive the result/finding, (indicate disposition of result/finding i.e., will be destroyed, will remain as part of the bank/repository record unless you choose to withdraw the result/finding).

We will make every effort to protect your health information: however, we are not responsible if you or your family choose to disclose your health or medical information.
Single-Subject Consent to Receive or Refuse Result or Incidental Finding
SAMPLE CONSENT

What will it cost to receive the result/finding?

You will not be charged to receive the result/finding. In addition you will be provided with _____(i.e., X test to confirm the result, referral to appropriate practitioner, one consultation visit with a genetic counselor).

If you choose to receive the result/finding, you will decide whether to proceed with further examinations, tests, and/or treatments you and your primary care or specialist determines are medically reasonable and necessary. You and your insurer (Medicare or Medicaid) will bear the costs of such further exams, tests, or treatments.

What else do you need to know?

You are encouraged to discuss the option of receiving the result/finding with your family and primary doctor or medical provider that you trust. Ask any questions that come to mind now. In the future if, you have questions contact________________. If you have questions about your rights as a volunteer in the X specimen bank, contact the staff in the Office of Research Integrity at the University of Kentucky between 8:00 am and 5:00 pm, Mon-Fri at 85-257-9428 or 1-866-400-9428.

You are the participant or are authorized to act on behalf of the participant. You have read this information, and you will receive a copy of this form after it is signed.

Decision to receive or refuse receipt of research result or incidental finding:

☐ I chose to receive the result or finding after reading or having this form read to me and having my questions answered.

or

☐ I chose NOT to receive the result or finding after reading or having this form read to me and having my questions answered.

When developing the consent/authorization form, please format to ensure the signature lines fall on a page containing text.

_________________________________                        ____________________________
Signature of research subject or *research subject’s legal representative Date

<table>
<thead>
<tr>
<th>Printed name of research subject or *research subject’s legal representative</th>
<th>Representative’s relationship to research subject</th>
</tr>
</thead>
</table>

*(If, applicable) Please explain Representative’s relationship to subject and include a description of Representative’s authority to act on behalf of subject:

____________________________________________________________________________
____________________________________________________________________________

Name of [authorized] person obtaining informed consent/HIPAA authorization Date

______________________________________________
Signature of Principal Investigator or Sub/Co-Investigator

2/20/14