CONSENT FORM FOR TISSUE BANKING
ADDENDUM FOR THERAPEUTIC STUDIES

TITLE OF RESEARCH STUDY

You are invited to participate in this research study because you have agreed to take part in another study ([Group study number, and title of study]). The information in this consent form is provided to help you make an informed decision whether or not to participate. If you have any questions, please do not hesitate to ask.

You will be undergoing surgery to diagnose and/or remove a tumor, or to remove a piece or all of a diseased organ. This surgical procedure is performed as part of your treatment. At the time of your surgery, this tumor or organ will be sent to the Pathology laboratory for diagnosis or routine examination. When these tests are completed, the rest of the tumor or organ is usually discarded.

We would like to take any left-over tumor or organ to use for research tests. This will be stored in a central facility (called a “tissue bank”) which is not located at UNMC. Your sample will be stored there permanently and will not be available for use in making health care decisions for you.

Some of these research tests are already planned. However, at some time in the future pieces of this stored tissue may be used by other researchers for other tests which are not known at this time. Before any research is performed on your stored tissue, the research must be reviewed and approved by a special committee called the Institutional Review Board (IRB), which has been formed to protect the rights of human subjects of research. In most cases, you will not be told what your tumor sample is being used for.

The tissue sample will be marked with a code which can be used, if necessary, to identify you. Sometimes, researchers need additional information to study the tissue effectively, like simple facts about your medical history (for example, your age, or sex, or whether you have any specific conditions or illnesses such as diabetes or high blood pressure). Other times the researchers may need more personal information. The IRB will review these studies and decide if giving this information to the researchers has any possibility of causing you harm. The IRB may require that the researchers get your written consent before getting more information. Any information obtained will be kept in the strictest confidence.

In most cases the results of these research studies will not be of any use to you or your doctor, and you will not be told the results. In some cases, the researchers or the IRB may decide that the results may be useful to you or your doctor, in which case, they may notify you or your doctor.
There will be no cost to you or your insurance company for storing the tissue, or for any research tests performed on the tissue.

Allowing your tumor or organ to be stored in the tissue bank is entirely voluntary, and you may decide not to participate in this study. Your decision about participating will not influence your treatment or your participation in the other study ([Group study number]). or affect your relationship with your doctor at UNMC.

By signing this document, you are saying that the information on this consent form has been explained to you, that you have read and understood this consent form, that your questions have been answered, and that you have decided to participate. If you think of any additional questions, please ask one of the investigators listed at the end of this form. You will be given a copy of this consent form to keep.

_________________________________ _____________________
Signature of Subject Date

_________________________________ _____________________
Signature of Witness Date

_________________________________ _____________________
Signature of Investigator Date