 **Instructions for Completing the**

**Lincoln Memorial University IRB Authorization Form Template**

IMPORTANT - Please review the following as you prepare the authorization form:

* Use the template below to create your HIPAA authorization form. Required language is in ordinary font and the instructions that you need to replace with study-specific language are *italicized in red*. Make sure that you replace these sections with study-specific language in ordinary font.
* **NOTE:** The Lincoln Memorial University IRB WILL NOT review or approve your authorization form unless it appears in the Lincoln Memorial University authorization template.

If you have questions concerning use of the template or need assistance preparing the consent form, please contact the Lincoln Memorial University IRB at 423-869-6834, melissa.miracle02@lmunet.edu or 423-869-6323, kay.paris@lmunet.edu.

**Authorization to Use and Release Protected Health Information for Research**

1. **What is the purpose of this form?**

Federal privacy laws protect the use and release of your identifiable health information, which is called protected health information. Under these laws, your protected health information cannot be used or disclosed to the research team for this research study unless you give your permission. You don’t have to sign this form. However, if you decide to participate in this research study, you must sign this form as well as the consent form. This form will describe the ways that the researchers, the research staff and the research sponsor will use your protected health information for the research study.

1. **What protected health information will be used and released?**

If you give your permission and sign this form, you are allowing *[Provide the name of the institution where the research will be conducted or where information will be gathered, e.g. Lincoln Memorial University.]* to use and release of certain kinds of health information about you for the purposes of this research study: *[title of research study]*.

The information that will be used and released for this research study includes all information about you that will be collected during the research study for research purposes and the health information about you in medical records that is related to the research study. For this study, this information is: [List the kinds of identifiable health information that will be collected for the study such as demographic information, test results, medical history, and diagnostic and medical procedures.].

1. **Who will use my protected health information and to whom will it be released?**

Your protected health information may be released to the following:

1. The research team so they can conduct the research described in the consent form
2. Other people who are required by law to review the quality and safety of the research study if applicable including:
3. The Lincoln Memorial University Institutional Review Board
4. The Food and Drug Administration (FDA)
5. The Office for Human Research Protections (OHRP)
6. The research sponsor and or its representatives
7. Government agencies in other countries
8. *[Fill in with other receivers or delete this line.]*

Once your protected health information is released outside of Lincoln Memorial University, the information may not be protected by federal privacy laws.

1. **Does my permission expire**

This permission does not have an expiration date.

1. **Can I cancel my permission?**

You can cancel your permission at any time. If you want to cancel your permission, please write to:

*Principal Investigator’s Name*

*Principal Investigator’s Address*

If you cancel your permission, you may no longer be in the research study. If you cancel your permission, information that was collected and released before your cancellation may continue to be used and released as needed to maintain the reliability of the research.

1. **Signature**

If you agree to the use and release of your protected health information, please sign below. You will be given a signed copy of this form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Research Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name of Research Participant

For Personal Representative of the Research Participant (if applicable)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   \_\_\_\_\_\_\_\_\_\_\_\_\_\_
Signature of Personal Representative Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name of Personal Representative

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Personal Representative Relationship or Authority