

**THE OHIO STATE UNIVERSITY
HIPAA RESEARCH AUTHORIZATION FORM**

Beginning April 14, 2003, the new HIPAA Privacy Rule requires that Ohio State University Principal Investigators (PIs) provide research subjects with greater detail than what is currently included in the IRB-approved consent form concerning how a subject's past, present and future health-related information (collectively, Protected Health Information or PHI) will be used, shared and protected during the research. Specifically, the Privacy Rule now requires that PIs inform subjects of the following: 1) what specific kinds of information will be used or disclosed to others during the course of the research; 2) the specific identities of collaborating investigators, sponsor companies or sponsor agencies that will potentially receive copies of subjects' PHI during the research; 3) that subjects have a right to review their research-related PHI; and 4) that subjects have the express right to revoke their authorizations for the release of PHI at any time.

To meet these new requirements, PIs using PHI obtained from medical or research records from the Ohio State University Hospitals, The Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, OSU & Harding Behavioral Health Care & Medicine, the Ohio State University Hospitals East and the Primary Care Network (the University Health System), or other University operated health centers or clinics, must now complete and receive a signed copy of the University's "Authorization to Use Personal Health Information in Research" form (the Authorization) below from subjects enrolling in research studies on or after April 14th (or be granted a waiver by a HIPAA Privacy Board) in addition to obtaining a signed IRB-approved consent form. The form will need to be carefully prepared by PIs to ensure that the Authorization covers ALL of the necessary uses and disclosures of personal health information used in clinical research. Failure to do so may violate the Privacy Rule and result in penalties against the University as well as individual civil and criminal penalties against the Principal Investigator.

INSTRUCTIONS TO RESEARCHERS
FOR PREPARING THE RESEARCH AUTHORIZATION FORM

1. Complete the first section of the Authorization form with title of the study, the OSU IRB protocol number, and PI name. Add subject name at the time of authorization. Do not include these instructions as part of the completed Authorization form.
2. "Uses and Disclosures Covered by this Authorization" – List every known non-OSU person, class of persons, or organizations (including the sponsor agency or company, known subsidiaries of the sponsor, cooperative data groups, etc.) that may create, disclose, receive, and/or use the information in connection with the study. Fill in the blanks on the form (and delete the instructions in italics as well as inapplicable bulleted sections) as appropriate. If information will not be disclosed outside of The Ohio State University, delete all bullets and insert "None". Note: if a person(s) or organization is not listed on the form, they may not create, disclose, receive or use PHI in connection with the study.
- 3a. "HIPAA Privacy Contact" – If the research involves the use of medical records from the University Health System, where applicable, insert the contact and address: HIPAA Privacy Manager, the Ohio State University Medical Center, 140 Doan Hall, 410 W. Tenth Avenue, Columbus, Ohio 43210.

- 3b. If the research solely involves the use of personal health records at non-University Health System clinics or health care facilities (for example, the Dental School, Optometry School, Nisonger Center, Younkin Center, Psychological Services Center, Anxiety and Stress Disorder Clinic, Marriage & Family Therapy Clinic, Camera Center or faculty practice group such as OSU-P) insert the name and address of the appropriate Privacy Contact for the center, school, clinic or practice group. If unknown, contact the director of the health center, school, clinic or practice group or the Office of Legal Affairs at (614) 292-0611 for the contact and address of the applicable Privacy Contact.
4. The Authorization must be presented to all newly enrolled or “re-consented” subjects in IRB-approved research beginning April 14, 2003 at the time the IRB-approved consent form is signed. The subject or his/her legally authorized representative must be provided with a copy of this form after it has been signed. The original, signed copy must be retained in the research file for a period of six years from the date the Authorization was signed (or longer, according to sponsor requirements). Prior IRB approval of the Authorization is not required; however, the Privacy Contact and/or HIPAA Privacy Board may conduct audits of the Authorization to ensure completeness.
- 5a. “Notice of Privacy Practices” – Each subject who receives health care services at the University on or after April 14, 2003 should receive a copy of a Notice of Privacy Practices (NPP) and sign an acknowledgement (NPP Acknowledgement form) that (s)he obtained the NPP.
- 5b. If the research involves the use of health and/or medical records from the University Health System and the subject has not received a copy of the University Health System’s NPP, provide the subject with a copy of the NPP. The subject should sign a copy of the University Health System’s NPP Acknowledgement form. The original, signed copy of the NPP Acknowledgement form must be retained in the research file for a period of six years from the date the NPP Acknowledgement was signed (or longer, according to sponsor requirements). The University Health System’s NPP and NPP Acknowledgement form are available in electronic format on the Office of Responsible Research Practices (ORRP) website at <http://www.orrp.ohio-state.edu/> as well as the Medical Center’s website at <http://www.osumedcenter.edu>.
- 5c. If the research involves the use of health records at other non-University Health System clinics or facilities (including the sites listed above in item 3b.) and the subject has not received a copy of the facility or clinic’s individual NPP, provide the subject with a copy of the NPP. Contact the director of the applicable health center, school, clinic or practice group to obtain a copy of the NPP and the NPP Acknowledgement form. The original, signed copy of the NPP Acknowledgement form must be retained in the research file for a period of six years from the date the NPP Acknowledgement was signed (or longer, according to sponsor requirements).

**THE OHIO STATE UNIVERSITY
AUTHORIZATION TO USE
PERSONAL HEALTH INFORMATION IN RESEARCH**

Title of the Study: The OSU Comprehensive Cancer Center Leukemia Tissue Bank

OSU Protocol Number: 1997C0194

Principal Investigator: Michael A. Caligiuri M.D.

Subject Name _____

Before researchers use or share any health information about you as part of this study, The Ohio State University is required to obtain your authorization. This helps explain to you how this information will be used or shared with others involved in the study.

- The Ohio State University and its hospitals, clinics, health-care providers and researchers are required to protect the privacy of your health information.
- You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.
- If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.
- Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at the Ohio State University. For example, this may include your medical records, x-ray or laboratory results. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

Please read the information carefully before signing this form. Please ask if you have any questions about this authorization, the University's Notice of Privacy Practices or the study before signing this form.

Initials/Date: _____

Those Who May Use, Share And Receive Your Information As Part Of This Study

- Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study. Other Ohio State University staff not involved in the study but who may become involved in your care for study-related treatment will have access to your information.
- Those who oversee the study will have access to your information, including:
 - Members and staff of the Ohio State University's Institutional Review Boards, including the Western Institutional Review Board
 - The Office for Responsible Research Practices
 - University data safety monitoring committees
 - The Ohio State University Research Foundation
- Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include:
 - The Food and Drug Administration
 - The Office for Human Research Protections
 - The National Institutes of Health
 - The Ohio Department of Human Services

These researchers, companies and/or organization(s) outside of The Ohio State University may also use, share and receive your health information in connection with this study:

The information that is shared with those listed above may no longer be protected by federal privacy rules.

Initials/Date_____

Authorization Period

This authorization will not expire unless you change your mind and revoke it in writing. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Signing the Authorization

- You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.-
- You will not be able to take part in this study and will not receive any study treatments if you do not sign this form.
- If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your authorization must be revoked in writing. To revoke your authorization, please write to:
- Michael A. Caligiuri M.D. Tzagournis Medical Research Facility, 420 W. 12th Ave., 326A, Columbus, OH 43210.
- Signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

Contacts for Questions

- If you have any questions relating to your privacy rights, please contact [Kathleen Ojala RN JD MHA, HIPAA Privacy Contact, the Ohio State University Medical Center, 140 Doan Hall, 410 W. Tenth Avenue, Columbus, Ohio 43210, 614-293-4477.](#)
- If you have any questions relating to the research, please contact please contact Dr. Michael Caligiuri, e-mail: michael.caligiuri@osumc.edu, Phone: 614-293-7521
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Signature

I have read (or someone has read to me) this form and have been able to ask questions. All of my questions about this form have been answered to my satisfaction. By signing below, I permit Michael A. Caligiuri M.D. and the others listed on this form to use and share my personal health information for this study. I will be given a copy of this signed form.

Signature _____
(Subject or Legally Authorized Representative)

Name _____
(Print name above)
(If legal representative, also print relationship to subject.)

Date _____ Time _____ AM / PM