INVESTIGATORS INSTRUCTIONS FOR PREPARING THE RESEARCH AUTHORIZATION FORM

When Is This Form Required? In addition to an approved Informed Consent, this form is required to be signed by study participants in all research involving the use of Protected Health Information (PHI), unless the IRB specifically approves a Full Waiver of this Authorization or unless another exception applies.[*] **Please Note:** This authorization may NOT be used for the access, use or release of Mental Health information in the District of Columbia. If such information is needed a separate form is required.

Which Study Participants Need To Sign This Authorization? Study participants enrolled prior to April 14, 2003 who have already signed an Informed Consent **DO NOT** need to sign this Authorization also, unless changes in the protocol would require the participant to sign an amended Informed Consent. All study participants enrolled after April 14, 2003 must sign this Authorization in conjunction with the approved Informed Consent.

What Happens If Authorization (or Waiver of Authorization) Is Not Obtained? MedStar Researchers may not be able to use PHI in their study and a Covered Entity's Privacy Officer (or their designee) may deny the use and disclosure of PHI unless this form is properly completed by the Principal Investigator.

What do I do if a research participant revokes this Authorization? Research participants have the right to revoke this Authorization at any time. However, an individual may not revoke an Authorization to the extent the researcher has acted in reliance on the Authorization. For example, this would permit the continued use and disclosure of PHI to account for a subject's withdrawal, from the research study, as necessary to incorporate the information as part of a marketing application submitted to the Food and Drug Administration, to conduct investigations of scientific misconduct, or to report adverse events. After the subject has revoked the Authorization, no additional PHI may be collected or used for the study protocol. In the event a subject revokes this Authorization the investigator must notify the custodian of records which maintains the records received pursuant to this Authorization.

Can I or a research sponsor make any revisions to this form? Yes, all dark blue fields require user revision. All other proposed revisions require review by MedStar's Research Privacy Lead and IRB approval of the Alteration of Authorization.

Where to Direct Questions About this Form? Any questions about the Research Authorization form should be directed to the Research Privacy Lead or to MedStar's Privacy Office. They will assess the Principal Investigator's request for permission to use or disclose PHI for research.

Specific Form Completion Instructions

General Instructions:

1. This instruction page SHOULD NOT be submitted to the IRB.
2. Only the **blue text** on the HIPAA authorization can be altered. If the sponsor requests changes in the non-blue text, these requests must be submitted with justification to the MHRI Research Privacy Lead/Research Compliance Director.
3. The HIPAA authorization should be submitted as a PDF rather than a Word Document if possible to prevent checkboxes from changing to another symbol.

Headers and Footers

1. Study Name: Insert Name of Research Protocol
   a. Include study title, IRB number and Sponsor study number where appropriate.
2. Footer
   a. The footer should contain "General Research Authorization" and version of the form
   b. For **Oncology** protocols being reviewed by Georgetown's IRB remove the logos and the IRB stamp box.

Who may have and use my health information? – This section identifies who is permitted to receive and use PHI for research activities.

1. Identify the Principal Investigator, class of other persons (i.e. Co-Investigators); it is possible to include all PIs here.
2. Insert sponsor's name
3. Other
   a. Identify any other persons, classes of persons, or entities which may be permitted to obtain and use PHI in connection with the research. Sponsors can add others here if needed.
   b. Do not leave this section blank. If nothing is to be included under Other, put N/A

Who may give (release or disclose) my health information? **–** This section identifies who is permitted to disclose/release PHI to the researchers for research purposes. The section is broadly written to include any health care providers or others who generate or use health information. When known, please identify the specific hospital/trial site which will be releasing PHI for the research activity.

[*] *Note: Reviews preparatory to research and research on decedents which require the use of PHI may be performed without this Authorization form provided the Principal Investigator provides the Covered Entity with appropriate certifications of use. A Limited Data Set/Data Use Agreement may also be used in lieu of this Authorization upon approval from the MedStar Privacy Office. A Full or Partial Waiver of Authorization may also be granted by the IRB if the required conditions are met.*

1. Insert name of Hospital/clinical trial site
2. If multiple sites, insert MedStar Health here. You do not need to list individual hospitals or sites.

What health information may be used for this research study? This section identifies what health information may be used or disclosed in connection with the research (both conditional and optional). Researchers are required to obtain and use only the PHI minimally necessary to conduct the research. For instance, if the PHI required for the research is a subset of all medical records, please indicate the records requested in the space provided. Acceptable descriptions might be "laboratory results from July 2002 to present," "all laboratory results," or "results of MHRI performed in July 2002." Check all appropriate box(es) describing the PHI in a way that allows both the prospective research participant, and any person or organization that must use or disclose information pursuant to this Authorization, to understand what information may be used or disclosed. This section also contains optional authorization for future research that may be requested by the sponsor. Researchers are required to obtain the authorization from the participants for these optional sections if PHI, biospecimens, data, tissue is to be used for future research that is not part of the current research study. Participants must initial next to the appropriate checked box.

1. Box 1 should be checked for all studies
2. If there is future research stemming from the medical records or other health care related records, as indicated by language in the ICF, please specify the disease(s) and/or types of research that the PHI may be used to study. If there is no future research, replace the **blue text** with N/A and add N/A to the initials block.
3. If there is an optional portion to the study, as indicated in the language of the ICF, describe any optional parts of the study that the participant can agree to. If there is no optional portion(s), replace the **blue text** with N/A and add N/A to the initials block.
4. Box 2 is usually checked for all studies as well. Follow directions in 2 and 3 above for this section as well.
5. Box 3 is usually not checked.

What could happen if I agree to this use or disclosure of my health information? – This section contains ***required*** language which describes potential consequences for agreeing to the authorization. Any alterations require IRB approval of a Waiver or Alteration of Authorization.

What rights do I have? – This section describes certain rights of research participants and limitations on those rights.

1. Insert Name and contact information.
    a. Insert PIs name and mailing address
    b. It is possible to include all PIs here.
2. Optional statement for blinded studies only, if the IRB approves the restriction of access to a patient's medical record during the course of the study, you may include a statement informing the individual that he or she will not be permitted to inspect or copy the PHI described in the Research Authorization while the research study is in progress. To monitor this requirement, you may need to obtain an agreement with the health care facility that maintains the patient's PHI. *This optional statement should be removed if the individual will be permitted to access his or her information during the study.*