

Authorization Template Instructions

First, complete the Authorization Cover Form. It will help you to develop the Authorization Form. The language in this template authorization cannot be revised. However, there are several places within the Authorization where you will need to add information or delete information. Please follow along with the cover form you just completed and the highlighted template attached.

Since this form must be specific to each study, the information on page 1 of the form, identifies the study to which the authorization applies. Please complete the header information on the form where highlighted. A complete address (not interoffice address) is necessary here in case a subject wants to revoke their authorization. Also complete the blank line at the bottom of each page to indicate what the CHRMS or CHRBS number is. Just click on CHRMS/CHRBS, select the appropriate committee and delete the other and type in the number. If this is a cooperative group study, you must also indicate the specific group study number. Then close the Header/Footer window.

Covered Entities (page 1, 3rd paragraph)

“This Authorization applies to each Covered Entity who maintains personal health information about you that is relevant to this research study. Fletcher Allen Health Care, Inc. (“FAHC”) is one such covered entity. As of the date that you sign this Authorization, others include:

_____.

[This blank must be filled in by the researcher before you sign this authorization.]

We have intentionally left this line blank, as there may be different Covered Entities who maintain personal health information that is pertinent to the study. You must complete this line in one of two ways when you **execute** this Authorization. If FAHC is the only Covered Entity who maintains subject health information that is relevant to the study, write “None” in the blank at the time the subject is signing it. If there are other Covered Entities list them.

We understand that in some cases you may be aware of other covered entities that are not patient specific but will always be part of the project. (i.e. collaborators at other hospitals) If that is the case, you should list these at the time of initial submission. As a double-check, they should match those that are listed on your cover sheet under “Covered Entities”.

1. Protected Health Information

2nd bullet

- **Pre-existing health information pertaining to you that the researchers will need to use in connection with the performance of the study, such as, inpatient medical records, outpatient medical records, primary care physician’s notes (such as internists, family practitioners, obstetrician-gynecologists), specialist’s notes (such as surgeons, oncologists, cardiologists, and others as needed). We will review your records as few years back as necessary to gather the pertinent information to perform this study. [Include the following when appropriate: We will not access mental health records or _____ (identify other types of sensitive information), as it is not relevant to this study.]**

If you are accessing mental health records or other sensitive information you must state so here. Your cover sheet should reflect this as well under #1.

example: Although the information may be available to us, we will not be reviewing your files for sensitive information such as mental health, HIV status or genetic information.
or example: It will be necessary for us to review your records including any mental health information given the research purpose. However we will not be reviewing your files for any other sensitive information such as HIV status or genetic information.

3rd bullet

- All of the health information resulting from the tests, procedures, medications and other treatments you will receive in the course of this research study. These tests, procedures, medications and treatments are set forth in the consent form that you signed, and can be found under the **[specify the section of the consent form where the patient could review this information]** section of the consent form. More specifically, the types of tests, procedures, medications and other treatments include: **[Identify the types of information by specifically cutting and pasting the relevant information from the consent form, if it is practical to do so (e.g., if it is only a couple of paragraphs long), or, identify the information in summary format, if it would be impractical to cut and paste information from the consent form].**

You could list either the section or sections or the page numbers. Revise language accordingly.

If the procedures are few please list otherwise we would suggest that you include a summary for this section i.e., laboratory tests, x-rays, other diagnostic tests, etc.

2. PHI Sharing within the Covered Entity or Entities.

6th bullet

- **[Identify the other units or departments of a Covered Entity, and the persons or classes of persons within them, who may use or disclose PHI for this research study. In addition, identify a description of each purpose of the use or disclosure.]**

We believe that we have covered all of the possible scenarios in this section however wanted to leave an option to identify additional. Please determine if you need to add to the list. Otherwise this bullet can be deleted from your form. Refer back to your cover form first page.

3. PHI Sharing outside the Covered Entity or Entities.

4th bullet

- Authorized representatives of the sponsor of this research study, **[specify name of sponsor and/or contract research organization]**, for the purposes of monitoring the accuracy and completeness of the research data, monitoring and reporting on patient safety matters, and performing required scientific analyses of the research data;

Please fill in appropriately with the sponsor's name (should match your consent) and/or the clinical research organization's name. If there is no sponsor you should remove this section completely.

6th bullet

- **[Include if applicable - "Authorized representatives of the study sponsor may also be present during your participation in certain research procedures, for the purpose of monitoring such procedures"];**

Remove if not applicable.

7th bullet

- **Authorized representatives of regulatory agencies, for the purpose of monitoring the research [And, specifically list the U.S. Food and Drug Administration if research study involves a regulated evaluation of any article (e.g., drug, device, electronic product, food additive)];**

There could be multiple regulatory agencies however the only one we require be listed by name here is the FDA.

example: The U.S. Food and Drug Administration will have access to your protected health information for the purpose mentioned above.

8th bullet

- **[Include if applicable – “Authorized representatives of the Vermont Cancer Center and/or the General Clinical Research Center, for the purpose of exercising their oversight responsibility for this research study”];**

If your study required initial review by either the Protocol Review Committee of the Vermont Cancer Center or the Scientific Advisory Committee of the General Clinical Research Center, include if applicable. If neither applies please remove this section.

10th bullet

- **[Identify the name or other specific identification of other persons or classes of persons to whom the information may be disclosed, i.e., statistical center, data coordination center, etc. In addition, identify a description of each purpose of the requested use or disclosure.]**

example: The UVM Biometry Department will have access to your health information to conduct the required statistical analysis for this study.

If not applicable delete this section.

10. Contacts for Questions

If you have any questions or concerns about your privacy rights, you should contact the Principal Investigator at - _____ or the Privacy Officer at the appropriate Covered Entity. For FAHC, the Privacy Officer is Michael Hawkins and he can be reached at (802) 847-3532.

Fill in the contact number.

Signature Section

The person obtaining authorization should be listed as key personnel on your study.

This form must be signed by all parties prior to the commencement of any research activity.

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DRAFT 3/5/03

AUTHORIZATION FORM

AUTHORIZATION TO PERMIT THE USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION FOR RESEARCH PURPOSES

TITLE OF STUDY:

**PRINCIPAL INVESTIGATOR NAME:
ADDRESS:**

CHRMS/CHRBS NUMBER:
[delete one]

Purpose and Scope of Authorization

You have agreed to participate in the study identified above, and have signed a separate consent form that explains the study procedures and provides representations regarding the confidentiality of your personal health information.

This Authorization is required by privacy regulations that are a part of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and other applicable laws. Any health care provider who is subject to the HIPAA Privacy Regulations is referred to in those regulations as a "Covered Entity" (meaning, it is governed by those regulations).

This Authorization applies to each Covered Entity who maintains personal health information about you that is relevant to this research study. Fletcher Allen Health Care, Inc. ("FAHC") is one such covered entity. **As of the date that you sign this Authorization, others include:**

[This blank must be filled in by the researcher before you sign this authorization.]

This Authorization legally permits FAHC and other Covered Entities, even if they are not identified by name in this document, to use and disclose your personal health information for this research study, but only in accordance with the restrictions set forth below. A Covered Entity might not be identified by name above because at the time you signed this Authorization, we may not have known that the Covered Entity maintained personal health information about you that was relevant to the research study.

The HIPAA Privacy Regulations use a special term to identify your personal health information – they call it "protected health information", or "PHI", for short. We refer to "PHI" below to mean your personal health information.

This Authorization gives you detailed information about how your PHI will be used, disclosed and protected in the context of this study, and answers the following questions:

- What PHI about you will be used or disclosed by a Covered Entity?
- Who within each Covered Entity may use or disclose your PHI?
- To whom may a Covered Entity disclose your PHI?
- How long will a Covered Entity be able to use or disclose your PHI?
- Will you be able to access your PHI associated with this study?
- What happens if you decide not to sign this Authorization?
- Can you change your mind and revoke this Authorization?

CHRMS or CHRBS #
[delete one]

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- What happens once your PHI has been disclosed by a Covered Entity?
- Will the results of the study be presented in publications?
- Who should you contact with any questions or concerns regarding your privacy rights?

1. What PHI about you will be used or disclosed by a Covered Entity?

The following PHI may be used by a Covered Entity, or disclosed to authorized persons by a Covered Entity, in connection with your involvement with this research study.

- Basic personal demographic information, including name, address, social security number, date of birth, occupation, marital and family status, and similar information.
- Pre-existing health information pertaining to you that the researchers will need to use in connection with the performance of the study, such as, inpatient medical records, outpatient medical records, primary care physician's notes (such as internists, family practitioners, obstetrician-gynecologists), specialist's notes (such as surgeons, oncologists, cardiologists, and others as needed). We will review your records as few years back as necessary to gather the pertinent information to perform this study. *[Include the following when appropriate: We will not access mental health records or _____ (identify other types of sensitive information), as it is not relevant to this study.]*
- All of the health information resulting from the tests, procedures, medications and other treatments you will receive in the course of this research study. These tests, procedures, medications and treatments are set forth in the consent form that you signed, and can be found under the *[specify the section of the consent form where the patient could review this information]* section of the consent form. More specifically, the types of tests, procedures, medications and other treatments include: *[Identify the types of information by specifically cutting and pasting the relevant information from the consent form, if it is practical to do so (e.g., if it is only a couple of paragraphs long), or, identify the information in summary format, if it would be impractical to cut and paste information from the consent form].*

2. Who within each Covered Entity may use or disclose your PHI?

The following persons or classes of persons within each Covered Entity are authorized to use or disclose your PHI for this research study:

- The Principal Investigator (the individual with primary responsibility for the research project) and the Principal Investigator's study team, to the extent such persons are employees of a Covered Entity, for the purpose of conducting the study;
- Employees of a Covered Entity's Health Information Management Department (or other holder of health records), for the purpose of managing the proper release of your PHI for this research study;
- Health care providers employed by a Covered Entity, for the purpose of (1) fulfilling orders made by the investigators for health care services (e.g., laboratory tests and diagnostic procedures) associated with the research study; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal operations (e.g., quality assurance);
- Other employees of a Covered Entity who may reasonably need to access your PHI, for the purpose of performing their jobs (e.g., to ensure the integrity of the research, to ensure proper billing for treatment associated with the research, to ensure appropriate grant accounting, for billing and auditing, to maintain records resulting from the research, and for other similar and related matters);
- Other employees of a Covered Entity who may need to access your PHI, for the purpose of treatment, payment and health care operations, as such terms are explained in a Notice of Privacy Practices previously provided by each Covered Entity to you;

CHRMS or CHRBS # _____
[delete one]

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- *[Identify the other units or departments of a Covered Entity, and the persons or classes of persons within them, who may use or disclose PHI for this research study. In addition, identify a description of each purpose of the use or disclosure.]*

3. To whom may a Covered Entity disclose your PHI?

As part of this study, a Covered Entity may disclose your PHI (including the results of study tests and procedures), to the following persons or classes of persons:

- The Principal Investigator and the Investigator's study team, to the extent such persons are not employees of a Covered Entity, for the purpose of conducting the study;
- The University of Vermont ("UVM") Institutional Review Boards (or other institutional review boards), for the purpose of overseeing the protection of human subjects;
- Health care providers who are not employed by a Covered Entity, for the purpose of (1) fulfilling orders made by the investigators for health care services (e.g., laboratory tests and diagnostic procedures) associated with the research study; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal operations (e.g., quality assurance);
- Authorized representatives of the sponsor of this research study, *[specify name of sponsor and/or clinical research organization]*, for the purposes of monitoring the accuracy and completeness of the research data, monitoring and reporting on patient safety matters, and performing required scientific analyses of the research data;
- Authorized representatives of other medical centers or institutions participating in the research study, including members of any data safety monitoring board established for this study, for the purpose of enabling their full and active involvement in the research study;
- *[Include if applicable - "Authorized representatives of the study sponsor may also be present during your participation in certain research procedures, for the purpose of monitoring such procedures"];*
- Authorized representatives of regulatory agencies, for the purpose of monitoring the research *[And, specifically list the U.S. Food and Drug Administration if research study involves a regulated evaluation of any article (e.g., drug, device, electronic product, food additive)];*
- *[Include if applicable – "Authorized representatives of the Vermont Cancer Center and/or the General Clinical Research Center, for the purpose of exercising their oversight responsibility for this research study"];*
- UVM employees who may reasonably need to access your PHI, for the purpose of performing their jobs (e.g., to ensure the integrity of the research, to ensure proper billing for treatment associated with the research, to ensure appropriate grant accounting, for billing and auditing, to maintain records resulting from the research, and for other similar and related matters);
- *[Identify the name or other specific identification of other persons or classes of persons to whom the information may be disclosed, i.e., statistical center, data coordination center, etc. In addition, identify a description of each purpose of the requested use or disclosure.]*

4. How long will a Covered Entity be able to use or disclose your PHI?

This Authorization for this specific study does not expire. Your PHI may be maintained in a research repository (i.e., a database) by a Covered Entity for this specific study. However, a Covered Entity may not re-use or re-disclose your PHI collected in this study for another purpose other than the research described in this document unless you have given written permission for the Covered Entity to do so or the Covered Entity has obtained permission to do so from an Institutional Review Board in accordance with applicable laws. An Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects.

CHRMS or CHRBS # _____
[delete one]

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5. Will you be able to access your PHI associated with this study?

You will be able to have access to your PHI that is created or obtained by a Covered Entity in the course of this research study, to the extent such access is otherwise permitted by applicable laws, but only after this study has concluded. You will not be able to access the PHI during your participation in the study, to prevent the knowledge of study results from affecting the reliability of the study. Nevertheless, your PHI will be available to your treating doctors should an emergency arise that would require those doctors to know this information to best treat you.

6. What happens if you decide not to sign this Authorization?

You are not obligated to sign this Authorization. However, if you decide not to sign the Authorization, you will not be allowed to participate or continue to participate in the research study, which means you will not be entitled to receive any treatment related to the research. A decision to not sign this Authorization will otherwise have no effect on your current or future medical care from a Covered Entity or payment for that medical care, nor will it cause any penalty or loss of benefits to which you are otherwise entitled.

7. Can you change your mind and revoke this Authorization?

You may withdraw your permission for the use and disclosure of any of your PHI for this research study, but you must do so in writing to the Principal Investigator at the address set forth above. Even if you withdraw your permission, the Principal Investigator for the research study may still use and disclose your PHI that was collected before your written request, to the extent necessary to preserve the integrity of the study. If you so withdraw, you may no longer participate in the research study.

8. What happens once your PHI has been disclosed by a Covered Entity?

We believe that most institutions involved with research understand the importance of preserving the confidentiality of participant health information. However, once a Covered Entity discloses your PHI, in a manner permitted by this Authorization, a re-disclosure of your PHI by the recipient will not be covered by this Authorization, and may not be subject to the HIPAA Privacy Regulations or other privacy laws. Of course, each Covered Entity and UVM agree to protect your PHI by using and disclosing it only as permitted in this Authorization and as directed by state and federal law.

9. Will the results of the study be presented in publications?

The results of the research study may be presented in publications, however names and other personally identifying information about you and other research participants will not be revealed in such publications.

10. Who should you contact with any questions or concerns regarding your privacy rights?

If you have any questions or concerns about your privacy rights, you should contact the Principal Investigator at - _____ or the Privacy Officer at the appropriate Covered Entity. For FAHC, the Privacy Officer is Michael Hawkins and he can be reached at (802) 847-3532.

All of the above has been explained to me and all of my current questions have been answered. I understand that, throughout my participation in the research study, I am encouraged to ask any additional questions I may have about the research use and disclosure of my PHI. Such future questions may be answered by the Principal Investigator or the Investigator's study team.

CHRMS or CHRBS # _____
[delete one]

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I have read this Authorization, and acknowledge that I am the research subject or authorized to act on behalf of the research subject. By signing this Authorization, I agree to allow the use and disclosure of my PHI for the purposes described above, and I agree to the other terms identified above. A copy of this Authorization (as signed below) will be given to me.

Subject's Name [print]

[Signature]

Date

Person obtaining authorization [print]

[Signature]

Date

For subjects unable to give authorization, the authorization is given by the following legally authorized subject representative:

Subject Representative [print]

[Signature]

Date

* If a representative signs the authorization, a description of such representative's authority to act for the subject must be provided below:
