

INDIANA UNIVERSITY
AUTHORIZATION FOR THE RELEASE OF HEALTH INFORMATION FOR RESEARCH

Introduction: You have the right to decide who may review or use your Protected Health Information ("PHI"). The type of information that may be used is described below. When you consider taking part in a research study, you must give permission for your PHI to be released from your doctors, clinics, and hospitals to the research team, for the specific purpose of this research study.

What does this authorization relate to? This authorization relates to the following study:

Gail H Vance, MD

1011003012/9309-46

PRINCIPAL INVESTIGATOR (in charge of Research Team) *IRB PROTOCOL #*

SPONSOR #

NAME OF RESEARCH PARTICIPANT

BIRTHDATE

STREET ADDRESS

CITY, STATE & ZIP CODE

What information will be used for research purposes? The PHI that will be used for research purposes may include some or all of your health records. This includes, but is not limited to: information provided by you directly to the Research Team, hospital records and reports; admission histories, and physicals; X-ray films and reports; operative reports; laboratory reports; treatment and test results; immunizations; allergy reports; prescriptions; consultations; clinic notes; and any other medical or dental records needed by the Research Team.

Specific Authorizations: I understand that this release also pertains to records concerning hospitalization or treatment that may include the categories listed below. I have the right to specifically request that records NOT be released from my health care providers to the Research Team. However, I understand that if I limit access to any of the records listed below, I may not be able to be in this research study. Check limitations, if any, below:

- Mental health records
- Psychotherapy Notes
- HIV (AIDS)

- Sexually transmitted diseases
- Alcohol / Substance abuse
- Other: _____

Who will be allowed to release this information?

I authorize the following persons, groups or organizations to disclose the information described in this Release of Information/Authorization for the above referenced research study:

- Treating providers**
- Hospitals, clinics or other places where I have received treatment**
- Other:** _____
- The Principal Investigator and the Research Staff**

Who can access your PHI for the study? The people and entities listed above may share my PHI (or the PHI of the individual(s) whom I have the authority to represent), with the following persons or groups for the research study: the Research Team, IU Institutional Review Board and its designees, Research Sponsor and its representatives, Research Organizations, the Department of Health & Human Services or other US or foreign government agencies as required by law, and to the Food and Drug Administration (FDA) or a person subject to the jurisdiction of the FDA in order to audit or monitor the quality, safety or effectiveness of the product or activity.

The **Research Team** includes the Principal Investigator, his/her staff, research coordinators, research technicians and other staff members who provide assistance to the Research Team. If there is a **Research Sponsor(s)**, this shall include: _____N/A_____ and any **Research Organizations** who provided assistance to the **Research Sponsor(s)** including, but not limited to: __N/A__.

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Expiration date of this Authorization: This authorization is valid until the following date or event:

- Specify Date ___/___/___ End of the Study
 Other: _____ None; authorization is valid indefinitely

Efforts will be made to ensure that your PHI will not be shared with other people outside of the research study. However, your PHI may be disclosed to others as required by law and/or to individuals or organizations that oversee the conduct of research studies, and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals. Thus, the Research Team cannot guarantee absolute confidentiality and privacy.

I have the right:

1. To refuse to sign this form. Not signing the form will not affect my regular health care including treatment, payment, or enrollment in a health plan or eligibility for health care benefits. However, not signing the form will prevent me from participating in the research study above.
2. To review and obtain a copy of my personal health information collected during the study. However, it may be important to the success and integrity of the study that persons who participate in the study not be given access until the study is complete. The Principal Investigator has discretion to refuse to grant access to this information if it will affect the integrity of the study data during the course of the study. Therefore, my request for information may be delayed until the study is complete.
3. To cancel this release of information/authorization at any time. If I choose to cancel this release of information/authorization, I must notify the Principal Investigator for this study **in writing** at: Indiana University School of Medicine, Department of Medical and Molecular Genetics, 975 W. Walnut St., #130, Indianapolis, IN 46202. However, even if I cancel this release of information/authorization, the Research Team, Research Sponsor(s) and/or the Research Organizations may still use information about me that was collected as part of the research project between the date I signed the current form and the date I cancel the authorization. This is to protect the quality of the research results. I understand that canceling this authorization may end my participation in this study.
4. To receive a copy of this form.

I have had the opportunity to review and ask questions regarding this release of information/authorization form. By signing this release of information/authorization, I am confirming that it reflects my wishes.

Printed name of Individual/Legal Representative

Signature of Individual/Legal Representative

Date

**If signed by a legal representative; state the relationship and identify below the authority to act on behalf of the individual's behalf.*

***Individual is:** a Minor Incompetent Disabled Deceased

***Legal Authority:**

- Custodial Parent Legal Guardian Executor of Estate of the Deceased
 Power of Attorney Healthcare Authorized Legal Representative
 Other: _____

For IU Human Subjects Office Use ONLY

IRB REVIEWED