# Authorization for Use and Release of Health Information for Research Purposes

**Study Title:** _____

**IRB Number:** _____

**Principal Investigator:** _____

**Address:** _____

**Phone Number:** _____

The Study Doctor and/or study staff at the study site(s) have rules to protect information about you. Federal and state laws, including the Health Insurance Portability and Accountability Act (HIPAA), also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- CHI Health
- Name of Sponsor
- Creighton University

We cannot do this study without your permission to see, use and give out your information. You do not have to give us permission. If you do not, then you will not join this study.

This authorization to use and disclose your information will not expire You can cancel your permission to use and disclose your information at any time by writing to the Study Doctor at the name and address listed on page 1 of this consent form. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others. After this information is shared with others it may not be protected by this law.

**What information may be used and given to others?**

The study staff will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

**Who might get this information?**

The sponsor of this research including any persons or companies that are:

- Working for or with the sponsor

- Owned by the sponsor
- Working for or with CHI (or Creighton University)

**Your information may be given to the following (as applicable):**

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Federal and state agencies such as the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS)
- Governmental agencies in other countries
- Governmental agencies who require mandated reporting for things such as communicable diseases (Hepatitis, HIV etc.)
- Other Catholic Health Initiatives personnel
- Creighton University Institutional Review Board (IRB) and other internal departments that provide support and oversight at Creighton University

**Why will this information be used and/or given to others?**

- To do the research
- To study the results
- To see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

**May I review or copy my information?**
Yes, but only after the research is over.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

**I am authorizing the release of the following records from my health care providers: (*check as applicable*)**

☐ This project will not require any records from your health care providers

☐ The following portions of my health records **not including** alcohol and substance abuse testing or treatment, AIDS-related information including HIV status, or information regarding pregnancy or sexually transmitted disease testing or treatment) pertaining to services received by me during: Dates of treatment: from _____ to _____

☐ My entire health record (**not including** alcohol and substance abuse testing or treatment, AIDS-related information including HIV status, or information regarding pregnancy or sexually transmitted disease testing or treatment)

☐ My entire health record, (**including** alcohol and substance abuse testing/treatment, and/or AIDS related information including HIV status, or information regarding pregnancy or sexually transmitted disease testing or treatment). These records are protected by federal confidentiality rules. It is my understanding the researcher cannot make any further disclosures of this information without my expressed future written consent.

Additional instructions:

_____

_____

**I HAVE READ AND UNDERSTAND THIS FORM. I AM SIGNING IT VOLUNTARILY. I AUTHORIZE THE USE AND DISCLOSURE OF MY HEALTH INFORMATION FOR RESEARCH PURPOSES AS DESCRIBED IN THIS FORM.**

***A copy of this form has been given to me.*** _____

Subject's / Representative's Initials

**I request and authorize the use and disclosure of my health records to the Principal Investigator for the above research study.**

_____ _____

**Subject's Name (Print)** **Subject's Date of Birth**

_____ _____

**Subject's / Representative's Signature** **Date of Signature**

_____

**Representative's Printed Name and Relationship of Representative to Subject (If Applicable)**