

AUTHORIZATION FOR USE AND DISCLOSURE OF INFORMATION

Use of your personal health information is critical to the success of this research study. However, efforts will be made to protect the confidentiality of your personal health information consistent with federal privacy laws.

All or part of your medical records, along with the records of all other subjects participating in this study from this and other institutions, will be sent to Alliance to be reviewed and analyzed by physicians and other study personnel.

Unless otherwise specified in the consent document, test results, (for example, lab and x-ray) will be included in your general medical record and may be accessed by physicians and other health care professionals providing care to you outside the study and will be disclosed as part of the medical record as permitted by law and this authorization.

For purposes of quality assurance, data analysis and research oversight, your personal information may also be disclosed to qualified representatives of Alliance; Nebraska Methodist Hospital; Nebraska Methodist Hospital Institutional Review Board; the Food and Drug Administration (FDA); officials of the Department of Health and Human Services (DHHS); research oversight bodies; and other entities who are directly participating in, monitoring, or supporting this research. These entities may see information that specifically identifies you. All of these entities, however, are committed to protecting the confidentiality of your information.

The exact information that will be used and disclosed will vary depending upon your treatment, but may include your name, age, sex, diagnosis, medical history, lab tests, x-ray reports, type of treatment, your response to treatment and any other information about you or your medical care that is contained in your hospital records, doctors' office records, laboratory, operating room and other records.

By signing below, you authorize the study doctors to use your information described above in the course of this study and to disclose your information to the entities listed above at any time. Once disclosed, your information may be subject to redisclosure and no longer protected by federal privacy laws.

You may choose not to sign this authorization for use and disclosure of your information. However, if you choose not to sign this authorization, you will not be eligible to participate in the research study. The reason for this is because the success of the research study depends upon use of the information we collect in the course of the study. A decision not to sign this authorization and not participate in the research study will not affect your ability to continue regular treatment with your doctor.

If you sign this authorization, your authorization is valid indefinitely and has no termination date. However, you may revoke this authorization at any time, without penalty, by voluntarily withdrawing from the research study. After you withdraw from the study the researchers will no longer use or disclose your personal information for this research.

You have a right to inspect and copy your personal information that is being used and disclosed by the research study doctors to the extent permitted by federal privacy laws. However, if you are enrolled in a study which includes treatment, and if your access to any study information is prohibited by the study protocol, your right of access to some or all of the information may be suspended without further notice to you, while the research is in progress; your right of access would then be reinstated upon conclusion of the research.

SIGNATURE

I authorize the research investigators to use and disclose my information as explained above. I certify that I have received a copy of this authorization.

_____	_____	_____
Date	Time	Subject's Signature/Signature of Subject's Personal Representative

_____	_____
Authority of Personal Representative if signing on behalf of the Subject	Printed Name of Subject/Subject's Personal Representative

_____	_____	_____
Date	Time	Signature of Person Conducting Informed Consent Discussion

Printed Name of Person Conducting Informed Consent Discussion