

The Heart of a Healthy Community

Institutional Review Board

Authorization for Use or Disclosure of Protected Health Information (PHI) for Research

Arrowhead Regional Medical Center, Office of Research and Grants 400 N Pepper Ave, Colton, CA 92324

Phone: 909-580-6263 / Email: ARMC-IRB@armc.sbcounty.gov

TITLE OF STUDY:	[Enter Title]
PRINCIPAL INVESTIGATOR:	[Enter PI Name]
Others who will use, collect, or	[Enter other names and groups]
share PHI:	

What is the Purpose of this Form?

Federal and state privacy laws give you the right to control the use of your protected health information. Under these laws, Arrowhead Regional Medical Center ("ARMC") cannot use or release your protected health information for research purposes unless you give your permission. By signing this form, you are giving permission to ARMC to use or share your protected health information as described below for research purposes for the study named above (the "Study").

Why am I being asked to share my Protected Health Information?

The main reason for sharing this information is to be able to conduct the Study. The Study cannot be reasonably performed without the protected health information.

What Protected Health Information will be Used or Shared?

The protected health information about you related to the Study, that may be used or shared, in connection with the Study, include, but are not limited to the following:

[List the protected health information that will be collected in the study. The information here should be the same as the information identified in the protocol.]

Will any Sensitive Protected Health Information be Used or Shared?

If any of the check boxes are marked below, the research team will also be collecting the sensitive information on the corresponding box. That information will only be used and shared for the Study if you give your permission by putting your <u>initials</u> on the corresponding line(s).



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I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment (initials)
I agree to the release of HIV/AIDS testing information (initials)
I agree to the release of genetic testing information (initials)
I agree to the release of information pertaining to mental health diagnosis or treatment (initials)

Who May Use, Receive, or Share my Protected health information?

By signing this form, you are giving permission for the following parties to use, share, and receive your protected health information in connection with the Study:

- ARMC;
- The research team for the Study at ARMC and any other research sites who are involved in the Study;
- Individuals and institutions who provide services to you in connection with the Study;
- Individuals and institutions with authority to oversee or consult on the Study, including, but not limited to the ARMC Institutional Review Board and Office of Research and Grants; and
- Individuals and institutions who are required by law to review the quality and safety of the Study, including, but not limited to U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, and the sponsor of the research (if any).

All reasonable efforts will be used to protect the confidentiality of your protected health information, which may be shared with others to support the Study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those persons who receive your protected health information may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete.

Does my Permission Expire?

Yes, your permission, as set forth in this form, expires when the Study is complete.



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Am I Required to Sign this Form?

No, you may refuse to sign this form. However, if you do not sign this form, you will not be able to participate in the Study. Refusing to sign will not affect the present or future care you receive at ARMC and will not cause any penalty or loss of benefits to which you are entitled.

If I sign this form, can I withdraw my permission later?

Authorization

Yes, you may withdraw your permission regarding the use and disclosure of your protected health information at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new protected health information will be used for the Study. However, study personnel may continue to use the protected health information that was provided before you withdrew your permission to the extent permitted by law. Also, if the law requires it, the researchers, sponsor, and government agencies may continue to look at your records to review the quality or safety of the Study.

If you wish to withdraw your permission to use or disclose your protected health information

in the Study, you can do so by: (1) informing the Principal Investigator (identified on the first page) in writing, or (2) asking a member of the research team to provide you with a form to fill out to revoke your permission and providing the team member with the completed form.

By signing this form, I agree that my protected health information may be used and shared for research purposes for the Study as described in this form. I understand I have the right to receive a copy of this authorization.

Signature of Patient

Or Patient's Legal Representative

Printed Name of Legal Representative

Representative's Authority

(if any)

Representative's Authority

to Act for Patient

Signature of Investigator Obtaining

Date