

AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION

Authorization to Use and Disclose Protected Health Information for Clinical Research

On occasion, Dr. Richard N. Marple and/or Dr. Rajesh Bhandari are involved in medical research and they may think that you are a candidate for one of these medical research studies. With your permission, your medical records (Personal Health Information) may be reviewed to determine if you qualify for involvement in these medical research studies.

During screening for a research study, and during a research study if you consent to participate, Drs. Marple and Bhandari, hereinafter referred to as study doctors, and research study staff will collect or create personal health information about you (for example, medical histories and any results of any tests, examinations or procedures you undergo while in the study) and record it on study forms. The study doctor will keep this personal health information in your study- related medical records (that we refer to as "your records"). In addition, the study doctor may obtain, and include in your records, information regarding your past, present and/or future physical or mental health and/or condition, such as medical records from your primary care physician. Your records may include other personal information (such as social security number, medical record numbers, date of birth, etc...) which could be used to identify you. Health information that could identify you is called "Protected Health Information" referred to as PHI.

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization." Therefore, you may not participate in any study unless you give your permission to use and disclose your PHI by signing this authorization. By signing, you are agreeing to allow the study doctor, or "Investigator" and staff to use your PHI to conduct this study, to monitor your health status; possibly, to develop new tests, procedures and commercial products.

By signing this authorization, you also are agreeing to allow the study doctor to disclose PHI as described below:

- Your PHI may be disclosed to the sponsor of the study any agents, representatives or consultants working on behalf of the sponsor to conduct the study (referred to as "the sponsor"). The sponsor will analyze and evaluate the PHI and may disclose it to the United States Food and Drug Administration (FDA) or similar regulatory agencies in the United States and/or foreign countries. The study staff will assign a code number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the sponsor; however, the sponsor may look at your complete records, which would identify you. In addition, the sponsor may visit the study site to oversee the

way the study is being conducted and may review your PHI during these visits to make sure the information is correct.

- The Institutional Review Board (IRB) has access to your PHI in relation to its responsibilities as an institutional review board.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Your identity will remain confidential and, except for the disclosures described as above, will not be shared with others unless such disclosure is required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have the right to see and make copies of your PHI. You are agreeing, however, by signing this form, not to see or copy your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This authorization will never expire unless and until you revoke (cancel or withdraw) it. You have a right to revoke at any time. If you revoke the authorization, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this information. If you revoke this authorization, you will not be allowed to continue participation in research studies.

In order to be screened for eligibility in a clinical research trial:

____ **I AGREE TO ALLOW RELEASE OF MY RECORD FOR
CLINICAL TRIAL SCREENING**

____ **I DO NOT ALLOW RELEASE OF MY RECORDS FOR
CLINICAL TRIAL SCREENING**

Signature

Printed Name

Date and Time