
HIPAA Authorization for Research

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to study personnel Gary Berke and Jeremy Fishel of Berke Prosthetics and SynTouch, INC to use or disclose (release) your health information that identifies you for the research study described here:

Title: Validation of Reflex Enabled Myoelectric Hand for Improved Fragile Grasping

IRB Number: 170921-168b

Purpose: The objective of the study is to observe, record, and compare how upper limb amputees use each of three different myoelectric prosthetic hands. This is evaluated using timed fragile grasping tasks, recorded use patterns during at-home wear, ACMC evaluated performance during a task of daily living, and surveys. The purpose of this is to determine and quantify the comparative benefit of a prosthetic hand that is equipped with contact detecting sensors and a biologically inspired reflex for fragile grasping tasks.

The health information that we may use or disclose (release) for this research:

- Prosthetic hand information including handedness, hand type, size, and cosmesis color
- Study related hand use performance records obtained during this study
- All patient records that were released to the provider for use during this study or collected during the study and in the possession of the provider
- Questionnaire responses collected during this study

The health information listed above may be used by and/or disclosed (released) to:

The United States Department of Defense (funding agency)
Heartland Institutional Review Board

Berke Prosthetics and SynTouch, INC are required by law to protect your health information. By signing this document, you authorize Berke Prosthetics and SynTouch, INC to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, Berke Prosthetics and SynTouch, INC may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to:

Berke Prosthetics & Orthotics

2001 Winward Way, Suite 100

San Mateo, CA 94404

Phone: (650) 5705861 | Email: gberke@berkeprosthetics.com

This Authorization will expire at the end of the research study.

Signature of participant or participant's
personal representative

Date

Printed name of participant or participant's
personal representative

If applicable, a description of the personal
representative's authority to sign for the participant