HIPAA AUTHORIZATION TO USE OR DISCLOSE (RELEASE) YOUR HEALTH INFORMATION FOR A RESEARCH STUDY

Instructions for Filling Out the HIPAA Authorization Form

(Please remove this page before presenting authorization to research subjects.)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that requires the protection of identifiable sensitive patient health information from being disclosed without the patient's consent or knowledge. HIPAA applies to individual's protected health information (PHI) by covered entities subject to the rule. A covered entity can include healthcare providers, health plans, healthcare clearinghouses, and business associates. Please contact your HIPAA privacy officer at hipaaprivacy@wichita.edu or 316-978-4HIP for more information.

You will present this form to be filled out by your research subject(s) anytime you are collecting data from a HIPAA covered entity that is not de-identified or part of a limited data set. (Please reference the Vizio document entitled *Flowchart for Use of HIPAA Authorization for Research* for more information). Not all medical or healthcare facilities, plans, or clearinghouses are covered under HIPAA, so you will need to clarify with these entities if they are a HIPAA covered or not.

When filling out who the information will be disclosed to, WSU IRB and ORHP must *always* be selected.

The authorization form must be written using lay language, at an 8th grade reading level (similar to the level used in popular magazines and newspapers) that is appropriate for the participant population. DO NOT use language copied from the protocol or a grant proposal; avoid technical jargon. The form should be written as if the investigator and participant are engaged in conversation.

The use of language in the first-person tense is not permitted (e.g., "I understand that ...") because it can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Therefore, please use second-person language in the document (e.g., "You understand that…").

All pages must be numbered and should follow the following format "page X of X." When appropriate, write the full name of all acronyms that are mentioned within the document. Unless otherwise noted all sections of the HIPAA Authorization Form (formatted as shown with proper headings and WSU logo) are required. The format of the template should be appropriate for all research studies.

If you have questions concerning use of the template or need assistance preparing the HIPAA Authorization Form, please contact the HIPAA Privacy Officer at hipaaprivacy@wichita.edu or 316-978-4HIP.

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Participant's Full Name:

Principal Investigator(s):

Research Study Title:

If you sign this document, you give permission to all health care providers at to use or disclose (release) your protected health information that identifies you for the research study described below:

The health information that may bed used or disclosed (released) for this research includes (information checked below):

Protected Health Information (PHI) Under HIPAA Law

- ☐ Name
- ☐ Home Address
- ☐ All elements of dates (except year) for dates directly related to an individual, including birth, admission, discharge, and date of death
- ☐ Telephone and/or Fax numbers
- ☐ Electronic mail addresses
- ☐ Social security numbers
- ☐ Certificate/license numbers
- ☐ Medical record, account, and health plan beneficiary numbers
- ☐ Labs, pathology reports, evaluations, treatment notes, and other notes stored in medical record system
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Device identifiers and serial numbers
- ☐ Biometric identifiers, including fingerprints and voiceprints
- ☐ Web universal resource locators (URLs)
- ☐ Internet protocol (IP) address numbers
- ☐ Full-face photographic images and any comparable images
- ☐ Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification Other (please specify):

Special Categories Requiring Participant Initials

- ☐ Drug, alcohol, or substance abuse records
- ☐ Psychotherapy notes and evaluations
- ☐ Mental health records
- ☐ Genetic information
- ☐ HIV/AIDs test results

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

☒ Wichita State University - Institutional Review Board for oversight purposes (*must be selected*)
☐ Study Sponsor: LC Industries/Envision Research Institute
☒ Office of Human Research Protections (OHRP) in the US Department of Health and Human Services (DHHS) for safety, efficacy, and compliance reports (*must be selected*)
☐ Food and Drug Administration
☐ National Institutes of Health
☐ Other federal or state agencies that have authority over the research project or other governmental offices as required by law
☐ A data safety monitoring board, if applicable
☐ A statistician for data analysis
☐ Outside lab for specimen processing
☐ Other (please specify):

The is required by law to protect your health information. By signing this document, you authorize 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 the following items:

- You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment.
- The may not withhold or refuse treating you based upon whether you sign this Authorization when the treatment does not include research-related treatment by the covered entity, or the covered entity is not providing health care solely for the purpose of creating PHI to disclose to a researcher.
- You may change your mind and revoke (take back) this Authorization at any time, except to the extent that the or has already acted based on this Authorization. To revoke this Authorization, you must write to:

This Authorization will expire on:

HIPAA AUTHORIZATION TO USE OR DISCLOSE (RELEASE) YOUR HEALTH INFORMATION FOR A RESEARCH STUDY

Signature of Individual (if 18 years of age or older): _____

Signature of Parent or Legal Representative (if applicable): _____

Relationship to Individual, if not signed by Individual: _____

Date _____