HIPAA[1] authorization to use and disclose individual health information for research purposes

a. Purpose: As a research participant, you authorize the Principal Investigator and the researcher's staff to use and disclose your individual health information for the purpose of research directly related to **[***insert appropriate disease***]**, for conducting the research study entitled:

[*insert study title***]**

b. Individual Health Information to be Used or Disclosed: Your individual health information that may be used or disclosed to conduct this research includes: demographic information (e.g., age, date of birth, sex, weight), medical history (e.g., diagnosis, complications with prior treatment), physical examination findings, and laboratory test. (e.g., blood tests, biopsy results).

c. Parties Who May Disclose your Individual Health Information: The researcher and the researcher's staff may obtain your individual health information from:

[*insert hospital(s) or individuals who may obtain their information here)***] where you have received treatment**.

d. Parties Who May Receive or Use Your Individual Health Information: The individual health information disclosed by parties listed in item c and information disclosed by you during the course of the research may be received and used by the following parties:

- **[***insert your facility or organization***]**
- **U.S. government agencies that are responsible for overseeing research such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)**
- **Study Sponsor: [***insert sponsor name if applicable***] and its study monitors, representatives, collaborators, affiliates and licensees**
- **HCA-HealthONE Institutional Review Board as a group**

e. Right to Refuse to Sign this Authorization: You do not have to sign this Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in this study or receive any research-related treatment that is provided through the study. However, your decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

f. Right to Revoke: You can change your mind and withdraw this authorization at any time by sending a written notice to the Principal Investigator to inform the researcher of your decision. If you withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. In addition, your records may continue to be collected and reviewed if you experienced an adverse event (a bad side effect) and to complete monitoring of study-related visits that have already occurred. No further health information about you will be collected by or disclosed to the researcher for this study. If you revoke your authorization, you will no longer be able to participate in this study.

g. Potential for Re-disclosure: You individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected. Examples include potential disclosures for law enforcement purposes, mandated reporting or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

h. This authorization does not have an expiration date.

i. You have the right to see and copy your records. However, if you sign this form, you will not be able to find out what treatment (arm) you were on until after all participants finish the study.

You may revoke your authorization at any time by sending a written request to your study doctor at the *[physician address or organization address]*. If you revoke your authorization, your participation in the study will end and the

---

1 HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information

study personnel will stop collecting medical information from you. In addition, study personnel will stop using your information and will stop disclosing your information, except to the extent study personnel have relied on information that has already been collected from you. For example, the study personnel may need to use or disclose information obtained before you revoked your authorization in order to preserve the scientific integrity of the study.