Covenant Medical Center
Institutional Review Board

HIPAA authorization requirement for consent

1. List the information you intend to use
    - Use must list in the authorization all the health information you plan to use or disclose. This includes standard PHI, as well as subject's history, physical findings and lab test results.

2. The people/organizations who may use or disclose the information
    - This will be the principal investigator and the research team

3. The people or organizations who will receive the information
    - The study sponsor and any others who will be receiving PHI directly from the site such as clinical research organization, central labs, as well as oversight agencies such as the institutional review board or the FDA or the Office of Human Rights Protection.

4. The purpose of the disclosure
    - The description of the study (including the study title and explanation).

5. Expiration date or event
    - The date which you will cease using their information. "End of study" or "never", or statements such as "15 years after the end of the study are acceptable.

6. Right to refuse to sign the authorization

7. Right to revoke the authorization
    - Under HIPAA, subjects can still withdraw from a study verbally. However, you must tell subjects that they must withdraw in writing to revoke your subsequent use or disclosure of their PHI. After a subject has revoked authorization, you can still use enough of it to inform the sponsor of the revocation. If you have already submitted the data to the sponsor, you do not have to retrieve it.