CONFIDENTIALITY:

1. Provide a statement explaining how individual identifiers will be used in maintaining the research records. (E.g., “Your research record will be labeled with your name.” or “Your research record will be labeled with a code number. A master key that links your name and the code number will be maintained in a separate and secure location.”)

2. If the study involves the use of a federal Certificate of Confidentiality, provide the information about the certificate and how it protects subject information from re-disclosure.

3. If information about the subject’s participation in the study or the results of procedures performed in the study will be placed in the participant’s clinic record (as contrasted with the research record), then this should be explained. Indicate that information placed in the medical record may be available to the participant’s insurer (or, if they are making a workman’s compensation claim, even to their employer).

4. State that individual participants will not be identified in any presentations or publications based on the results of the research study.

5. Insert the HIPAA authorization portion of the confidentiality section. [template below]