

**REVIEWER'S CHECKLIST
HIPAA PRIVACY AUTHORIZATION REQUIREMENTS**

SP Code: _____

Please verify that the following HIPAA-required authorization elements and requirements are included in your draft consent/authorization form by checking off each and signing below.

- A specific and meaningful description of identifiable information to be used or disclosed.**
- The person(s) or class of persons authorized to ask the individual for permission to use or disclosure their identifiable data** (e.g., investigators and staff at Marshfield Clinic and St. Joseph's Hospital).
- The person(s) or class of persons, both internal and external, with whom identifiable information will be shared.**
- A description of each purpose for which you will use or share (both internally and externally) identifiable information.**
- An expiration date or event on which you will no longer use or disclose identifiable data.** End of research study or a statement indicating there is no expiration date is sufficient for research activities.
- Line for signature of the individual and date, and if to be signed by an authorized representative, a mechanism to record a description of such representative's authority to act for the individual.** If you use the standard MMREF IRB consent form signature line format, this information will be included.
- If a treatment trial, a statement that the institution has the ability to condition research-related treatment upon receipt of a signed research consent/authorization, and the consequences (e.g., inability to provide treatment under the research protocol) to the individual should they refuse to allow the researcher to use or share identifiable information as described in the consent/authorization. If not a treatment study, a statement that the institution cannot condition treatment, payment, enrollment or eligibility for benefits upon receipt of a signed research consent/authorization.**
- The potential for information that is shared with others outside the institution to be further shared by the recipient and no longer protected by the HIPAA Privacy Rule.**
- A statement informing the individual of the right to revoke the authorization including any exceptions to this right, informing them that revocations must be in writing, and describing how the individual may revoke the authorization.**
- Any exception to the individual's right to access health information during the study** (important for blinded studies).
- Written in plain language**
- Plan to provide a copy of the authorization to the individual**
- If a separate or stand alone authorization, authorization includes name of PI, SP code, study title, and version date.**

Signature of Reviewer

Date

Comments/explanations of inadequacies are noted on the back of this form.