# Informed Consent Self-Assessment Tool

Purpose: This form is for investigators to conduct a self-assessment of their IRB approved study to ensure that the regulatory and institutional requirements for obtaining and documenting informed consent are met. Please complete one self-assessment for each enrolled participant. Keep completed self-assessments with your study related records as documentation of ongoing oversight of the research.

1. STUDY INFORMATION

IRBNet #:

Study Title:

PI Name:

Date Self-Assessment Completed:

Person Completing Self-Assessment:

2. INFORMED CONSENT PROCESS

Informed consent was obtained before the participant began any research activities.

 [ ]  Yes

 [ ]  No

The person obtaining consent was a member of the research team, and listed on the most recently approved Cover Sheet.

 [ ]  Yes

 [ ]  No

The consent process took place in a private area (or as specified in the approved protocol).

 [ ]  Yes

 [ ]  No

The potential participant was allowed sufficient time to consider participation.

 [ ]  Yes

 [ ]  No

All of the participant’s questions were answered.

 [ ]  Yes

 [ ]  No

 [ ]  N/A

3. INFORMED CONSENT DOCUMENTATION

The consent form used was the currently approved version.

 [ ]  Yes

 [ ]  No

The consent form contained the IRB approval stamp.

 [ ]  Yes

 [ ]  No

The consent form listed the participant’s printed name.

 [ ]  Yes

 [ ]  No

The consent form was signed and dated by the participant (or their parent/guardian).

 [ ]  Yes

 [ ]  No

The consent form was signed and dated by the person obtaining consent.

 [ ]  Yes

 [ ]  No

The participant received a copy of the consent form.

 [ ]  Yes

 [ ]  No

4. CONSENT FORM STORAGE

The executed consent form was stored securely in accordance with the approved protocol.

[ ]  Yes

 [ ]  No

5. OBSERVATIONS OR COMMENTS