# 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