Summary of Use of iMed Informed Consent Process Audit

An audit was conducted of a randomized sample of patients enrolled during the third quarter (April – June) of FY 2023 to review the use of iMed consenting process. A total of 50 consents were reviewed (23 non-English speaking patients, 27 English speaking patients). Of the 23 non-English speaking patients consented, 12 used the short form process. Protocols that are being reviewed by ASRC were not reviewed since those informed consents are reviewed on a monthly basis.

Issues found with iMed consenting process:

- Four teams used the incorrect short form version during the short form process – see below reminder for more information. Per communication with the IRBO, this is considered a minor protocol deviation to be reported at time of continuing review. Teams that used the incorrect version have been notified.
- One embedded question was not answered in the consent document.
- In two cases, the investigator signed iMed consent prior to patient.
- In one case, the incorrect selection was made in NIH Administrative Section: Spanish long form was used for consent, but the following was selected:

> ____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

Issues found with the Documentation of Research Consent notes:

- In two cases, Documentation of Research Consent notes were not located. The teams were contacted and late notes were entered.
- In three cases when the short form consent process was used, the note did not contain any information about use of the short form and/or use of interpreter.
- In two cases, there was incorrect information in the note.

Reminders:

- When using the short form, select the version based on when the protocol was INITALLY approved. For example, protocol 01C0129 the below version **is incorrect** since the protocol was INITALLY approved PRIOR TO January 21, 2019

MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY CHINESE (SIMPLIFIED) – REVISED COMMON RULE FOR STUDIES INITIALLY APPROVED AFTER 1/21/2019

机构/中心： NCI

首席研究员： [redacted]

研究项目编号：01-C-0129

研究项目名称： Eligibility Screening for the NIH Intramural Research Program Clinical Protocols

- Review completed consent document in iMed prior to saving to ensure that all embedded questions and signatures are captured correctly and in the proper order (patient must always sign first).
- When using a fully translated long form, a witness is not required; therefore, the section option in the NIH Administrative Section should be selected:

> ____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is:_____.

- Document the consent process in CRIS within 1 business day per CCR SOP PM-2.
- When documenting the informed consent process, select ALL types of consent process used. If you are using the short form process, you must also select "Use of Interpreter" for the note.