eCRO-05-120 INFORMED CONSENT PROCESS

1 PURPOSE

To describe the process followed by clinical Investigators for obtaining consent from individuals prior to their participation in a research study in order to ensure a consistent approach and adherence to the Human Research Protection Program (HRPP).

2 SCOPE

This procedure applies to all research studies managed by ethica CRO Inc.

3 ADDITIONAL DEFINITIONS

None

4 RESPONSIBILITY

4.1 It is the responsibility of the clinical Investigator to ensure that informed consent is obtained from each prospective research participant before he/she participates in the research study.

4.2 The Investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.

5 POLICY

5.1 Obtaining informed consent is a fundamental ethical requirement in connection with research involving humans; it reflects the basic principle of respect for persons. Respect for persons requires that research participants, to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them.

5.2 Informed consent assures that prospective research participants will be informed of the nature of the study and can knowledgeably and voluntarily decide whether or not to participate.

5.3 Informed consent must be obtained voluntarily, without coercion, especially when vulnerable populations are involved.

5.4 Special consideration to obtaining free and informed consent must be given when a research study involves vulnerable populations such as minors (assent) or incapable adults. These individuals may be more susceptible to coercion or undue influence.

5.5 Informed consent must be obtained prior to performing any study specific procedures, including screening

procedures for the purpose of determining eligibility for the study.

6 PROCEDURE

6.1 INFORMED CONSENT PROCESS

6.1.1 Informed consent should be thought of as an educational process that takes place between the Investigator and the prospective research participant rather than simply a form that must be signed. Informed consent must be viewed as a continuous dynamic process rather than an isolated event during the clinical study. Therefore, consent should be reassessed at each study visit.

6.1.2 In the process of obtaining informed consent, each element of consent should be carefully, patiently, simply, and entirely explained to the prospective research participant in terms that he/she can understand, including the potential risks pertaining to research. The Informed Consent Form (ICF) review may be done on-site or remotely by using telecommunication technology (e.g., videoconference, telephone). In order to achieve this objective, the informed consent process should be conducted in a private setting and the Investigator or sub-Investigator should be available to answer questions that the prospective research participant may have.

6.1.3 Informed consent language and its documentation must be written in "lay language" (i.e. understandable to those being asked to participate). Use of scientific jargon and legalese is not appropriate. Simple declarative sentences are most appropriate for explaining the study's purpose, duration, experimental procedures, alternative treatments (if applicable), risks, and benefits.

6.1.4 The ICF should be available in the language of the research participant.

6.1.5 The ICF is a teaching tool as well as a legal instrument. To ensure that the research participant will be able to make an informed decision about whether to participate (particularly in instances where a study involves significant risk, or prospective research participants are likely to have difficulty understanding the procedures that will involve them), Investigators should use audiovisual aids, enlist the help of lay people in explaining informed consent, or periodically assess the prospective research participant's understanding of informed consent by asking questions.

6.1.6 Consent must be obtained in a private setting by a member of the research staff knowledgeable with all aspects of the study and sensitive to the concept of undue influence and therapeutic misconception.

6.1.7 Prospective research participants should be given an adequate place and the necessary time to read and review the ICF. For instance, prospective research participants should be given the opportunity to take the ICF home for review prior to signing the document, as appropriate. If the consent process is done remotely, the site should send the paper or electronic version of the ICF to the prospective research participants who will take the necessary time to review the ICF prior to signing the document.

6.1.8 If there exists some type of dependence, ascendancy, or subordination of the research participant to the Investigator that prevents him or her from freely conferring his or her consent, consent should be obtained by another member of the study team who is completely independent of the Investigator-research

participant relationship.

6.1.9 The process of consent must be conducted in a private, confidential, and safe setting to facilitate a constructive dialogue between the prospective research participant and the person(s) involved in obtaining consent. The Investigator's office or an examination room would likely be an appropriate location whereas a patient waiting room or a pre-op area would be examples of locations which may not be conducive to the obtainment of a legally effective informed consent.

6.1.10 The informed consent process is normally formalized through the signature of the ICF by the research participant and the Investigator. Therefore, each person signs the IRB-approved ICF on the same visit, as appropriate. If the consent process is done remotely, the personnel conducting the consent process must verify that the research participant physically signed the ICF by viewing the signature page via videoconference or obtaining a photo or scanned copy of the signature page. In order to obtain the signatures from each person on the same visit, the research site should either sign a separate copy of the ICF or ask the research participant to send a copy of the ICF electronically or by fax. The research site should file all signed components as one combined document. Finally, research participants should receive a signed and dated copy of the electronic or paper version of the ICF as a reference and a reminder of the information reviewed during the consent process.

6.2 TRAINING AND MONITORING

6.2.1 Informed consent process described in Section 6.1 will be reviewed by the ethica CRO Inc. CRA during the Site Initiation Visit (SOP eCRO-05-221, attachment eCRO-05-221-A Sample Monitoring Plan).

6.2.2 As part of the monitoring activities described in SOP eCRO-05-221, the CRA will:

- Verify that written informed consent was obtained prior to commencing study procedures
- Verify that the most recent approved version of the ICF and HIPAA was signed.
- Complete the Informed Consent Verification Form (attachment eCRO-05-221-C.2) to ensure that each participant signed each version of the ICF and HIPAA.

6.2.3 Informed consent process described in Section 6.1 will also be reviewed by the CRA throughout the duration of the study to ensure that research participant consent is continuous.

6.3 AMENDED INFORMED CONSENT

6.3.1 An amended informed consent form must first be approved by the IRB/REB (see SOP eCRO-05-109 IRB Submissions). The informed consent process described in Section 6.1 must be repeated when amendments are made to the informed consent form.

6.3.2 When amendments are made to the informed consent form, the informed consent process described in Section 6.1 will be reviewed by the ethica CRO Inc. CRA during the monitoring visit to ensure that all research participants have been re-consented with the IRB-approved amended ICF.

6.4 ALTERATION OR WAIVER OF THE INFORMED CONSENT

6.4.1 A study may deviate from or obtain a waiver to follow the general requirements for consent if the Study Protocol demonstrates to the satisfaction of the IRB that:

6.4.1.1 the research involves no more than minimal risk to participants;

6.4.1.2 the alteration to consent requirements is unlikely to adversely affect the welfare of participants;

6.4.1.3 given the research design, it is impossible or impracticable (see Glossary) to carry out the research and to address the research question properly if the prior consent of participants is required;

6.4.1.4 in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and

6.4.1.5 the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent, and/or withdrawing data and/or human biological materials, shall be in accordance with ICH-GCP Guidelines and the country's regulations.

7 ATTACHMENTS

None

8 OTHER APPLICABLE SOPs AND REFERENCES

eCRO-05-109 IRB Submissions

eCRO-05-221 Monitoring Plans

9 HISTORY

eCRO-05-120 Version 1 dated 04-Nov-2021 administrative changes, effective date remains the same.

05-026 Version 2 dated 15-Mar-2021 was converted to eCRO-05-120 Version 1 in electronic format. The electronic version of the SOP was reviewed and approved as per SOP eCRO-00-001.

05-026 Version 1 dated 19-Apr-2019 sections 6.1.2, 6.1.7, 6.1.10, were revised for an ICF process conducted remotely.

10 EFFECTIVE DATE

eCRO-05-120 Version 1 & 2, 04-Nov-2021