eCRO-05-112 INFORMED CONSENT FORM DEVELOPMENT & REVIEW

1 PURPOSE

To describe the process followed by ethica CRO Inc. in developing or reviewing an Informed Consent Form (ICF) and ancillary documentation to ensure a consistent approach and adherence to the Human Research Protection Program (HRPP).

2 SCOPE

Applies to all ICFs developed or reviewed by ethica CRO Inc.

3 ADDITIONAL DEFINITIONS

Assent: An individual's affirmative agreement to participate in a study obtained in conjunction with the consent from the individual's parents, guardian or legally authorized representative. Mere failure to object or absence of affirmative agreement should not be construed as assent.

4 RESPONSIBILITY

It is the responsibility of Clinical Project Manager (CPM) to develop ICFs and ensure compliance with guidelines and local country regulations and requirements, as applicable.

It is understood that the roles and responsibilities outlined in this SOP, whether or not explicitly indicated, are to be carried out by the incumbent of the position mentioned herein or a trained delegate.

5 POLICY

5.1 ICFs that are developed by ethica CRO Inc. must be developed according to the appropriate template (i.e., ethica CRO Inc. template or Sponsor template). All ICFs developed by ethica CRO Inc. must be reviewed against the appropriate ICF checklist (see attachment eCRO-05-112-B ICF Checklist - Canada, eCRO-05-112-C ICF Checklist -General Req., and/or eCRO-05-112-D ICF Checklist -USA) to ensure that the ICF contains all applicable elements and clauses.

5.2 ICFs that are developed by the Sponsor and used in studies managed by ethica CRO Inc. must be reviewed against the appropriate ICF checklist (see attachment eCRO-05-112-B ICF Checklist - Canada, eCRO-05-112-C ICF Checklist -General Req., and/or eCRO-05-112-D ICF Checklist -USA) to ensure that the ICF contains all applicable elements and clauses.

5.3 ICFs shall clearly indicate the process in place to address research participant inquiries and concerns.

5.4 The ICF must be approved by an IRB prior to consenting research participants.

5.5 The ICF can be revised at any time throughout a study whenever important new information becomes available that may be relevant to the participant's consent. Revised ICFs must be resubmitted to the IRB for approval prior to implementation.

5.6 The ICF will be translated as needed into the language of the study participant.

6 PROCEDURE

6.1 FORMAT

- Unless the Sponsor requests a specific ICF template and/or ancillary documentation, ICFs are to be developed according to the ICF Template (see attachment eCRO-05-112-A-EN or eCRO-05-112-A-FR).
- ICFs are to be written in the second person (i.e. you, your, etc.) using a level of language known and understood by the research participant (i.e. use of appropriate lay terms (5th to 8th grade level) (see http://www.firstclinical.com/icfglossary).
- ICFs must be tested against the Flesch Reading Ease, and the Flesch-Kincaid Grade level tests.
- The ICF footer should include sequential page numbering (page X of Y), version and date of the document.
- Use of Arial font (size 11 for body text, size 12 for section headings) is preferred.
- All sections should follow the specific order listed in the ICF Template.
- ICFs must be reviewed against the appropriate checklist(s) to ensure that the ICF meets all applicable regulatory requirements (see attachment eCRO-05-112-B ICF Checklist - Canada, eCRO-05-112-C ICF Checklist -General Req., and/or eCRO-05-112-D ICF Checklist -USA).
    - The checklist(s) used to review the ICF must be completed, signed and filed along with the respective ICF in the Trial Master File (TMF).

6.2 CANADIAN STUDIES

If the study is to take place in Canada, the ICF will be created according to:

- TCPS – Chapter 3, and
- ICH-GCP Guidelines – Part 4

The ICF will take into consideration the legislation and guidelines of the provinces where the study is being conducted.

6.3 U.S.A STUDIES

6.3.1 If the study is to take place in the USA, the ICF will be created according to:

- FDA regulations – 21 CFR Part 50, and/or
- HHS regulations – 45 CFR 46

- ICH-GCP Guidelines – Part 4

The ICF will also take into consideration the legislation and guidelines of the states where the study is being conducted (e.g. California Bill of Rights).

6.3.2 If the study is conducted by entities covered under the Health Insurance Portability and Accountability Act (HIPAA) (i.e., health plans, health care clearinghouses, heath care providers), the CPMs shall:

- Integrate the language of the HIPAA Authorization Form Template (see attachment eCRO-05-112-F) into the ICF Template (attachment eCRO-05-112-A-EN).

6.4 ASSENT

6.4.1 Although the involvement of an individual not legally competent to give consent in a study (e.g., children/minors, incapable adults) requires the permission of their parents or legally authorized representatives, the Investigator shall determine, by way of assent, the wishes of the individual whenever the individual understands the nature and consequences of the study.

6.4.2 Unless the Sponsor requests the use of a specific template, the Assent Form Template (attachment eCRO-05-112-E) shall be used for development of an Assent Form.

- Assent Forms are to be written in the second person (ie, you, your, etc) using a level of language that takes into consideration for the age, maturity, and psychological state of the legally incompetent individual.
- The Assent Form footer should include sequential page numbering (page X of Y), version and date of the document.
- Use of Arial font (size 11 for body text, size 12 for section headings) is preferred.
- All sections should follow the specific order listed in the Assent Form Template.

6.5 TRANSLATION

6.5.1 A qualified, certified translation service will be used to ensure all ethical and cultural standards are met, and to address any regional linguistic differences that may exist. Translators must first be qualified as per SOP eCRO-03-004. Once the translator is on the Qualified Vendor List, a Certificate of Translation Accuracy should be provided to the CPM by the translation service provider and filed in the TMF to verify that a certified translation process was employed for the translation of each ICF.

6.6 ICF VERSIONS

6.6.1 The document creator shall ensure that the created date, or revised date, and version numbers are identified on page one and incorporated in the document header or footer.

6.6.2 The first draft of the ICF will be identified as Version 0.1. The following drafts will have an increase of “0.1” in the version number (e.g.: 0.2, 0.3, 0.4, 0.5, and so forth)

6.6.3 Once the ICF is finalized, the first final version will be identified as Version 1.0 and will include the date when the document was finalized. This final version will be submitted to the IRB and/or the Regulatory Agency of the country (e.g.: Health Canada and FDA).

6.6.4 Final documents undergoing revision will be noted as Version X.1 for the first drafts. While the document is undergoing review, subsequent drafts versions will increase by "0.1" (e.g.: 1.1, 1.2, 1.3, and so forth).Once the revised ICF is finalized, the version will increase by "1.0" over the version being revised. For example, the draft 1.3 will become a final 2.0.

6.6.5 A track-change version of the draft or final ICF must be kept in order to identify the changes from one version to the next . The track-change version should also be submitted to the IRB with the final ICF.

6.6.6 Subsequent final ICFs version numbers will increase by "1.0" (e.g.: 1.0, 2.0, 3.0, and so forth).

7 ATTACHMENTS

eCRO-05-112-A-EN ICF English Template

eCRO-05-112-A-FR ICF French Template

eCRO-05-112-B ICF Checklist - Canada

eCRO-05-112-C ICF Checklist – General Req.

eCRO-05-112-D ICF Checklist – USA

eCRO-05-112-E Assent Form Template

eCRO-05-112-F HIPAA Authorization Form Template

8 OTHER APPLICABLE SOPs AND REFERENCES

eCRO-03-004 Auditing of Vendors & Subcontractors

9 HISTORY

eCRO-05-112 Version 1 section 5.3 was added.

05-012 Version 4 dated 15-Mar-2021 was converted to eCRO-05-112 Version 1 in electronic format. The electronic version of the SOP was reviewed and approved as per SOP eCRO-00-001.

05-012 Version 3 dated 19-Apr-2019 section 4 was revised to include a general statement about roles and

responsibilities of incumbent or trained delegate; section 6.1 third bullet point was added; section 6.5.1 was revised to specify that the translation service must first be qualified as per SOP 03-004; section 6.6 was added; section 7 attachment identification numbers were revised; the following attachments were revised:

- attachment 05-012-A-EN and 05-012-A-FR Procedures section were revised to include instructions if the study involves the use of Telehealth.
- attachment 05-012-A-EN Risks and 05-012-A-FR Risques sections were revised to include possible risks related to telecommunication technologies if the study involves Telehealth.
- attachment 05-012-A-EN Benefits and 05-012-A-FR Bénéfices sections were revised to include potential benefits related to the use of telecommunication technologies if the study involves Telehealth.
- attachment 05-012-A-EN Confidentiality and 05-012-A-FR Confidentialité sections were revised to include a statement related to privacy and confidentiality if the study involves Telehealth.

05-012 was previously described in:

- 05-026 ICF Development and Review, Version 2, dated September 2, 2015
- 05-026 ICF Development and Review, Version 2, dated October 31, 2013

10 EFFECTIVE DATE

eCRO-05-112 Version 2, 13-Jul-2022

eCRO-05-112 Version 1, 04-Nov-2021