eCRO-05-114 STUDY ADVERTISEMENT & RESEARCH PARTICIPANT RECRUITMENT

1 PURPOSE

To describe the process followed by ethica CRO Inc. for the development of study advertisement and recruitment materials employed to recruit research participants for a 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 Associate Director of Clinical Research to oversee and confirm that all elements of this procedure are properly implemented and followed.

4.2 It is the responsibility of Clinical Project Managers (CPMs) and Clinical Research Associates (CRAs) to adhere to the elements of this procedure.

4.3 It is understood that 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 This procedure shall be applied in order to ensure that the selection of research participants is equitable.

5.2 See SOP on Regulatory Compliance (eCRO-05-003).

6 PROCEDURE

6.1 EQUITABLE RECRUITMENT OF RESEARCH PARTICIPANTS

6.1.1 The Associate Director of Clinical Research shall ensure that the burdens or discomforts affecting research participants enrolled in a study are not disproportionately higher in comparison to the benefits they receive through their participation;

6.1.2 The Associate Director of Clinical Research shall ensure that the overall burdens and benefits of a study are distributed equitably, in light of particularly disadvantaged individuals or groups;

6.1.3 The Associate Director of Clinical Research shall ensure that a study does not exclude research participants on the basis of race, ethnicity, culture, religion, mental or physical ability, sex, sexual orientation, reproductive capacity or age, unless there is a valid justification for such exclusion.

6.2 DEVELOPMENT OF STUDY ADVERTISEMENT AND RECRUITMENT MATERIALS

6.2.1 Study advertisements must be developed in a way that are not deceptive or coercive, do not involve undue inducement, and do not state or imply a certainty of favourable outcome or other benefits beyond what is outlined in the study protocol and informed consent form.

6.2.2 Study advertisements must contain the following:

- the words 'research' or 'clinical' qualifying the term 'study';
- the name of the Investigator, or at least the name of the facility in which the study is being conducted.

6.2.3 Study advertisements must not contain the following, either explicitly or implicitly:

- claims that the test article is safe or effective for the purpose under investigation;
- claims that the test article is known to be equivalent or superior to any other drug or device;
- claims that the test article is a 'new treatment', 'new medication', or 'new drug' without explaining that the test article is investigational. The latter will be indicated by such phrases as 'under investigation', 'experimental' or 'not yet approved for medical use';
- a promise of 'free medical treatment'. The fact that research participants will incur no costs (e.g., for study visits, study-related medication or study-related care) through their participation in the study can be stated;
- a certainty of favourable outcome or other benefits beyond what was outlined in the consent document and the protocol;
- exculpatory language.

6.2.4 Inclusion of the following information in study advertisements is acceptable:

- name and address of the Investigator and/or research facility;
- condition under study and/or the purpose of the study;
- inclusion criteria that will be used to determine eligibility for the study;
- a brief list of participation benefits, if any (e.g., no cost health examination);
- time or other commitment required of research participants;
- that research participants will be paid, but should not emphasize the payment or the amount to be paid through typographical or other means, such as bold type or repetition;
- location of the study and the person or office to contact for further information.

6.3 RECRUITMENT INCENTIVES

6.3.1 No Investigator shall receive finder's fees or other rewards in consideration for their identification or successful recruitment of research participants into a study.

6.3.2 No Investigator shall receive completion fees or other rewards in consideration for the number of research participants successfully completing a study.

7 ATTACHMENTS

None

8 OTHER APPLICABLE SOPs AND REFERENCES

None

9 HISTORY

05-014 Version 1 dated 19-Apr-2019 was converted to eCRO-05-114 Version 1 in electronic format. The electronic version of the SOP was reviewed and approved as per SOP eCRO-00-001.

10 EFFECTIVE DATE

eCRO-05-114 Version 1, 04-Nov-2021