# **ADVERTISING GUIDELINES FOR CLINICAL RESEARCH**

## **NZ HEALTH AND DISABILITY ETHICS COMMITTEES**

#### **HDEC MUST REVIEW THE METHODS AND MATERIAL THAT INVESTIGATORS PROPOSE TO USE TO RECRUIT PARTICIPANTS**

Direct advertising for research participants is not in and of itself an objectionable practice.

HDEC considers advertising clinical research studies to potential participants to be part of the informed consent process. All participant-facing recruitment material for HDEC-approved studies must be approved by HDEC prior to use.

The guidelines have been developed to help prevent potential participants from being confused, misled or unduly influenced by advertising material.

#### **RECRUITMENT MATERIAL THAT SHOULD BE SUBMITTED FOR REVIEW**

Recruitment materials that should be submitted to HDEC include:

* Ad copy for digital platforms, including but not exclusive to Facebook, Twitter, paid search platforms, and banners.
* Website text for landing pages
* Scripts for phone recruitment
* Video advertisements
* Print advertisements, including text and images to be used. Note that the order of the text submitted should not be altered in any final advertisement.
* Text for radio advertisements
* News articles or advertorials designed to drive recruitment.

Where personal / health data is collected during the pre-screening process for a specific study or suite of studies, the following should be submitted:

* The pre-screening questionnaire
* Information about the management of questionnaires (access, storage, potential use including retention for other clinical trials, maximal retention time frame). This should specifically address data collected from potential participants who do not complete the questionnaire for any reason, or who fail the pre-screening questionnaire.
* Where a third-party clinical trial recruitment company is utilised, the company’s privacy policy should be included with the submission and made clearly available to potential participants.

#### **GUIDELINES FOR RECRUITMENT MATERIAL**

HDEC will review content, as well as the font size and type, and other visual effects, in determining whether materials meet the following guidelines.

1. No explicit or implicit claims should be made that the investigational treatment is safe or effective, unless this has been proven in the population and indication under study. Potential therapeutic benefit should not be overstated.

*Example: “Want to improve your diabetes? Enrol in our trial.” would not be approved by HDEC.*

1. No explicit or implicit claims should be made that the investigational treatment is equivalent or superior to existing treatments, unless this has been proven in the population and indication under study.
2. Recruitment materials should not use language such as "new treatment," "new medication," "new drug" or “new device” to describe investigational treatments, without explaining that the treatment is investigational. Such phrases may lead potential participants to believe that they will be receiving a treatment that has already been approved by Medsafe.

*Examples: "investigational medication" or “potential new medication” would be approved, but "new medication" or “new treatment” would not be approved.*

If the study involves an approved product this may be indicated, and the investigational component of the research outlined.

1. For therapeutic studies where participants will receive investigational treatment or placebo, this should be stated. Potential participants may otherwise assume they will all receive active treatment.
2. Phrases such as “Hurry”, “Call now”, “Don’t miss out”, “Places filling fast”, “Enrolment limited” should not be used.
3. Recruitment materials should not promote "free medical treatment" or “free specialist care” to refer to study-related care participants will receive.
4. Potential study benefits should not be over-emphasised. The relative size of type used and other visual effects (placement of information, bolding, change in colour, animation, exclamation marks etc) should not unduly promote compensation or benefits.
5. If the trial is paid, specific compensation may be mentioned, but not emphasized e.g. through prominent placement, larger or bolder type, or other devices (flashing font, exclamation marks, etc). Specific compensation should in general not be mentioned in recruitment material aimed at paediatric populations.
6. Language, language devices or images that may be perceived as misleading, deceptive, ambiguous, or which play on fear should not be used.

*Example: “Asthma can be dangerous in kids” would not be approved by HDEC.*

1. For commercially sponsored or funded trials, the study funder should be stated.
2. Where a third-party recruitment company is recruiting on behalf of a Sponsor and/or research site, the name and address of the research site and/or Sponsor should be included.
3. A statement that the study has been approved by HDEC, together with HDEC study reference number, should be included.
4. If stock photos of persons are used in recruitment material, efforts should be made to ensure that these are representative of the New Zealand population.
5. Though not required, advertising material may include the following information to help potential participants make the decision to take part in a study:

* the condition under study
* the purpose of the research
* a summary of eligibility criteria in lay language
* a general description of the time commitment for the study
* who to contact for more information.

#### **FORMAT FOR SUBMISSION**

Where possible, advertising portfolios should be compiled into a single attachment, rather than be uploaded as multiple single files.

#### **REFERENCES**

NEAC National Ethical Standards, December 2019.

https://www.asa.co.nz/codes/codes/therapeutic-and-health-advertising-code/

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects> accessed 16/05/2022.