Recruitment of study participants by means of advertising

Definition of direct advertising

1. Advertising includes newspaper advertisements, radio and television commercials, online advertising, social media, advertising on notice boards, posters and leaflets and personally addressed letters.

Review of advertising by ethics committees

2. The ethics committee (EC) must review and approve the advertising materials as part of the documentation submitted for the initial review. If advertising measures are only used after the study has started, the advertising materials should be submitted to the EC after the rest of the documentation.
3. The whole recruitment concept, including the associated texts and recordings for radio or television recruitment in the form in which they will be publicly used, must be submitted to the EC (Art. 24 para. 1 ClinO, Art. 14 para. 1 HRO).
4. The sponsor must give contract agencies that specialise in recruiting trial subjects precise instructions and documents on how study participants should be recruited. These should also be submitted to the EC.
5. The review of the advertising materials by the EC should ensure that they do not exert any form of pressure or promise a positive result or other benefit beyond what is set out in the protocol and Patient Information

Unacceptable formulations

6. Advertising may not explicitly or implicitly claim that the medicinal product, medical device or intervention is safe or effective in the application under investigation, or that it is known to be equivalent or superior to any other medicinal product, medical device or intervention.
7. Neither brand names of products nor the name of the sponsor or manufacturer may be mentioned.
8. Advertising for recruitment to studies with non-authorised medicinal products or non-marketable medical devices may not be labelled as "new treatment", "new medicine" or "new drug", without explaining that the product or device is under clinical investigation.
9. Advertising may not promise "free medical treatment" simply because participants will not be charged for taking part in the study.
10. No remuneration must be promised for taking part in a study that is expected to produce a direct benefit (Art. 14 HRA).
11. Any references to remuneration should be presented in a low key manner (e.g. not in a heading or first line).
12. The sponsor may not be named as a direct contact address, unless he/she is also an investigator.
13. Box numbers are not permitted in advertisements.

Compulsory content of advertising materials

14. Advertising must be limited to the information that potential study participants require to decide whether they are interested in and also suitable for the study. Where appropriate, advertising should include the following points:
    a. a statement to the effect that the advertisement is for a study (research project);

b. the name and address of the clinical investigator and/or the research establishment;
c. the condition that is being investigated, and/or the purpose of the study;
d. a summary of the criteria for determining suitability (e.g. age group, indication);
e. a short and objective listing of the benefits – if any – of taking part;
f. information on the aim and nature of the study (incl. authorisation status, placebo arm).
g. the time requirement (number of visits) and other commitments that participants have to enter into;
h. a statement to the effect that all information will be treated confidentially;
i. a statement to the effect that there will be no direct benefit (if applicable).
j. the location at which the study will take place and the person or agency to be contacted if further information is required;
k. the fact that anyone who responds to the advertising will be registered for this purpose;
l. the procedure for contacting interested individuals;
m. if an e-mail address is given for contact purpose, information on whose e-mail address this is;
n. the intended reimbursement; and
o. a statement to the effect that making contact only signifies an interest in receiving further information

Additional requirements when people interested in the study make contact by phone

a. data protection laws must be observed;
b. callers must be guaranteed anonymity if they so request;
c. only the minimum possible personal data should be obtained from callers;
d. explanations provided over the phone are not a substitute for a study briefing (Art. 16 para. 2 HRA); and
e. a procedure for dealing with callers who request further information must be defined and described.

Additional requirements for recruitment via a call centre

a. advertisements that invite potential participants to phone a call centre must state that the number given is that of a call centre and not the trial centre or the sponsor;
b. call centre employees must introduce themselves at the start of the call and explain their role in the recruitment process. The discussion guide must be submitted to the ethics committee; and
c. callers' / call recipients' details should be destroyed after they have been sent to the sponsor and must not be used for any other purpose. If this is not done, callers must give their explicit written consent to the recording, processing and use of their data.

Dealing with reactions attributable to advertising measures

15. The EC's review also includes the precautionary measures in place for people who respond to the advertising.
    The procedure for dealing with reactions to the advertising must be documented and submitted to the ethics committee.

16. This documentation should include the qualifications of the person responsible for the initial contact (e.g. qualified nurse). This is particularly important if patients are being addressed.
    The measures in place for informing and managing patients who are not suitable for participation in the planned study must also be described.
    Unsuitability may be established as early as the initial contact or only after a screening

examination. There must be a description of how these patients will be advised or helped to contact a suitable institution or clinic.

17. If there are plans to examine potential participants to establish their suitability, a preliminary information document should be provided. This document must be separate from the actual Patient Information and must be submitted to the EC.
    This should contain information on the nature of and reasons for the screening examination and provide a brief description of the study. Furthermore, the consequences of certain results of the examination should be explained (e.g. in the event of an exceptional finding).
18. Potential participants must be informed that the personal data they are asked to give will be protected in accordance with the Data Protection Act and that it will be deleted when the assignment has been completed. Non-participants should also be informed that their data will be deleted.
19. The procedure for paying compensation and remuneration to the participants must be explained, as must the sums involved.

The following documents were used to prepare these guidelines:

- Swissethics guideline on the recruitment of test subjects with advertisements/flyers, 2011
- FDA - Information Sheet "Guidance for Institutional Review Boards and Clinical Investigators**"**, 2010 Update
- EU - "Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use", February 2006
- Advertising guidelines of the Forum of Austrian Ethics Committees; November 2006
- Recommendations for recruitment measures, Working Group of Medical Ethics Committees in the Federal Republic of Germany, November 2011