

TMG Coordinator's Corner

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**Success consists of doing the common things
of life uncommonly well.**

-Author unknown-

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Topic of the Month: Recruitment Part I – Mass Media as a Tool for Patient Recruitment.

Common reasons for failure to recruit patients for clinical trials are:

- Delayed start-up
- Inadequate planning
- Insufficient effort and staff
- Over-optimistic expectations

Recruitment and retention are the result of planning, organization, staff, and resources. One of the useful tools to give potential subjects a chance to participate in the study is advertising.

Advertising includes, but is not necessarily limited to: newspaper, radio, TV, bulletin boards, posters, and flyers that are intended for prospective subjects. **Not included** are:

1. Communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects);
2. News stories; and
3. Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

Health Canada considers direct advertising for study subjects to be the start of the informed consent and subject selection process. Advertisements should be reviewed and approved by the IRB as part of the package for initial review.

When advertising is to be used, the IRB should review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting subjects is not coercive and does not state or imply a certainty of favourable outcome or other benefits beyond what is outlined in the consent document and the protocol. The IRB should review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, the IRB should review the final audio/video tape. The IRB may wish to caution the clinical investigators to obtain IRB approval of message text prior to taping, in order to avoid re-taping because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be accomplished through expedited procedures.

Advertising for recruitment into investigational drug studies should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatments" leads study subjects to believe they will be receiving newly improved products of proven worth.

Advertisements should not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type.

Generally, Health Canada believes that any advertisement to recruit subjects should be limited to the information the prospective

subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements. It should be noted, however, that Health Canada does not require inclusion of all of the listed items:

1. The name and address of the clinical investigator and/or research facility;
2. The condition under study and/or the purpose of the research;
3. In summary form, the criteria that will be used to determine eligibility for the study;
4. A brief list of participation benefits, if any;
5. The time or other commitment required of the subjects;
6. The location of the research and the person or office to contact for further information.

The success of mass media for patient recruitment can be attributed to three key factors:

1. Mass media permeates many aspects of everyone's lives; we rely on it for news, information and entertainment.
2. Mass media reaches a huge population. Because of the growing need for study subjects and increasingly difficult study design, massive numbers of potential subjects must be reached in order to reach recruitment goals.
3. Mass media provides an advertiser the ability to generate an immediate or "direct" response. This is a "call to action" where the advertisement generates a phone or web-based response to the message.

TMG SOP of the Month:

SOP 1-02: Use of Standard Operating Procedures

PROCEDURE DESCRIBED: THE USE OF TMG SOPs.

Key takeaways:

- ❖ SOPs are the formal documents that describe the standardized procedures that will be followed in the conduct of clinical research.
- ❖ One or more SOPs are required to describe each of the following areas:
 - Administration
 - Ethics
 - Study Preparation
 - Study Conduct
 - Safety
 - Quality
 - Site SOPs
- ❖ Each TMG SOP must have a title, a number, a date of issue, an effective date.
- ❖ Every time when TMG site receives new or updated SOP 'Receipt of SOPs' form will be filled in.
- ❖ One master copy of all versions of all SOPs is stored in the TMG archive; if a site is scheduled to undergo an audit on a study spanning two or more SOP versions, contact TMG to request a copy of the archived version(s) to be available for the audit/inspection, in case they are required.

Site Management: Thinking Like an Auditor

Can you answer these questions about your site?

- Is there a subject diagnosis?
- Was the investigational product properly disposed of?
- Was blinding maintained?
- Is drug administration documented?
- Did IRB approve significant stages or amendments?
- Were all screened subjects entered, and if no what was the reason?

Remember even if you know answers to these questions these information should be documented. What is not documented doesn't exist!

Get inside the Inspector's Head:

- Verify handwriting

- Copy site signature log and verify who wrote what
- Check that number of Informed Consent forms matches the number of subject enrolled to the study.
- Look for inconsistencies among data from different sources
- Pick one subject and complete "100% source document review" for him/her.

Signs to an Inspector of Impending Problems:

- Little or no PI involvement
- Infrequent CRA-PI meetings
- Turnover of study coordinators
- High number of missed procedures
- Unsigned/undated entries in source documents
- Different answers from site staff to the same question(s)

Coordinator's Corner Challenge:

- 1) Which guidelines or reports have focused on research subject protection?
 - A. Dayton
 - B. Oslo
 - C. Helsinki
 - D. Munich
- 2) A serious adverse event (SAE) contains which of the following conditions:
 - A. Death
 - B. Life-threatening
 - C. Hospitalization
 - D. A and B
 - E. B and C
 - F. A and C
 - G. A, B and C
- 3) IRB stands for _____.
 - A. Institution Review Board
 - B. Institutional Review Branch
 - C. Institutional Review Board
 - D. Institutional Research Board
- 4) Which TMG SOP will you follow if you are expecting an audit:
 - A. 4-01
 - B. 2-02

- C. 3-02
- D. 6-02
- E. 3-04

5) Informed Consent is _____.

- A. the process by which a fully informed patient can participate in choices about her health care
- B. a form that is filled by PI when recruiting a subject
- C. a process that is completed by PI after subject's participation in the study
- D. not so important because subject doesn't have to know what the a key facts are about the study

Answers will appear in next issue.

Need help?

Don't hesitate to contact TMG with any questions. Email your request to: george@tmginvestigators.com

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