

Recruitment Guidelines

Contents

1.	Purpose	1
2.	Background	2
3.	Undue Influence	2
4.	The Use of Incentives in Research	2
ı	Jse of Lotteries	3
5.	Recruitment Materials	3
6.	Language Requirements	4
7.	Social Media/Online Recruitment	4
8.	Use of Email for Recruitment	5
9.	Student Recruitment	6
9	Students as Research Participants	6
(Other Considerations	6
(Cooperative Activities Program (CAP)	7
10.	Screening and Recruitment in Health Research	7
	Privacy Principles Related to Approach/Screening Activities in AHS Operational Areas (also applicab to other clinical settings)	le 7
		7
	Approaching Patients for Study-specific Consent to Participate	
١	Pre-Screening of Patients for Eligibility to Develop a Pool of Potentially Eligible Candidates	8
11.	Be The Cure	8

1. <u>Purpose</u>

The purpose of these guidelines is to inform researchers regarding the requirements related to the recruitment of human research participants as well as the provision of guidelines and templates for recruitment materials.



2. Background

The decision to participate in research should be voluntary and the approach to recruitment is an important element in assuring voluntariness. In particular, how, when, why and where participants are approached and who recruits them are important elements in assuring voluntariness. Participant recruitment is intrinsically tied to informed consent and indeed, is the first step in this process. Because of this, all recruitment and advertising methods must be reviewed and approved by the Research Ethics Board (REB) prior to their implementation.

The ARISE application should fully describe the recruitment procedures and all applicable materials should be appended in the documents section. Once ethics approval has been obtained, additional approvals may still be required. Many organizations require operational approval prior to undertaking any recruitment activities with their staff, clients or in their facilities.

Participant recruitment cannot begin until REB approval has been granted.

3. Undue Influence

Article 3.1 of the Tri-Council Policy Statement 2 (TCPS2) states that undue influence and manipulation arise when prospective participants are recruited by individuals in a position of authority. This imbalance in power can be real or perceived. It is often seen in the workplace (employer vs employee), the health field (physician vs patient), or academics (instructor vs student), to name a few. The REB examines the existence and acknowledgement of this relationship and what steps are in place to ensure that it has the least impact on the individual's decision to participate. The REB also considers elements of trust and dependency in relationships, such as those between caregiver and dependent. The risk of undue influence is greater in situations of ongoing or significant dependency. Pre-existing entitlements to care, education and other services should not be prejudiced by the decision of whether or not to participate in, or withdraw from, a research project.

Coercion is a more extreme form of undue influence that involves a threat of harm or punishment that would immediately negate the voluntariness of participation or otherwise.

4. The Use of Incentives in Research

Incentives, or "compensation," include anything offered to participants, monetary or otherwise, to encourage participation in research. This is distinct from reimbursing participants for expenses they incur by participating in the research (for instance transportation costs or parking) which is not problematic from an ethics perspective. It should not be assumed that people must be compensated in order to participate in research studies; however, compensation can improve participation rates.

The TCPS 2 specifies that the "onus is on the researcher to justify to the REB the use of a particular model and the level of incentives." Research Ethics Boards are instructed to weigh the benefits and risks of a procedure, which means that marginal ethical considerations can be outweighed by larger benefits.



When offered, incentives should be appropriate in type and amount. That is, the incentive must not be so attractive as to be seen as an inducement to participate. The element of voluntariness must always be considered; incentives should not be so large or attractive as to encourage reckless disregard of the risks associated with participation. Researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and capacity of participants, the customs and practices of the community, and the magnitude and probability of harms.

Incentives should be provided fairly to all participants, with equal compensation for equal participation being the norm; however, unequal compensation can arise in at least the following ways:

- by design
 - A study design may require a greater time commitment or more effort from some participants than others who may therefore be compensated accordingly.
 - Custom may dictate a differing level of compensation First Nations expect compensation for Elders that differs in kind or extent from that for other participants.
- by tying compensation to performance
 - e.g. compensation may be tied to performance as a means of motivating active and energetic performance.
- by chance
 - Participants may perform slightly different tasks (by chance, or random assignment into different experimental conditions). Although every participant has an equal expected compensation before the study begins, they do not once they are assigned to an experimental group, and sizable differences in compensation among subjects arise which are not under their control. This chance element should be explained to participants as part of the informed consent process.

Use of Lotteries

- Some researchers may wish to compensate participants using a draw or lottery instead of or in addition to giving every participant a smaller prize. As there are legal issues pertaining to lotteries which must be taken into account, it is recommended that researchers refer to the Guidelines on Compensation of Human Research Participants for further details.
- A lottery must not require participants to pay money or other valuable consideration in order to
 participate. The probability of winning the prize should be given when recruiting participants as
 part of informed consent. In addition, winning the lottery must be based on skill as well as
 chance. Thus, many lotteries require the participants to answer a skill-testing question in order
 to qualify for a chance to win the prize.
- Investigators must provide the odds of winning in both the information letter and within their ethics application (section 4.6 in the ARISE system).

5. Recruitment Materials

All recruitment materials should contain the following:



- Institutional logo(s) of the PI (i.e., UofA, AHS or Covenant Health)
- The UofA Ethics ID (Pro000XXXXX) should be in the footer, with a version date
- The full study title should be present
- The name of the principal investigator
- A clear statement that one is being invited to participate in a research study
- A contact name (such as study coordinator) with phone number and email address. This contact number should be a UofA phone number. Personal phone numbers should not be included, especially student phone numbers.
- A brief description of the eligibility criteria. Any specific exclusion criteria should also be mentioned (as applicable)
- It is acceptable to state that an incentive will be offered but there should be no emphasis on the amount
- Provide an estimation of the time required to take part in the research
- Images may be used but should not detract from the information about the study and should not be overly emphasized. E.g., images should not include reference to money if an incentive is offered.

<u>Use of Sponsor Logos - Clinical Trials:</u>

Sponsor branding and logos should not be included on participant facing materials. It is felt that the branding is advertising, which may be potentially misleading and/or coercive to participants. If logos and document headers are used they should be those of the local research team (e.g. University of Alberta, AHS).

6. <u>Language Requirements</u>

- Use simple/lay language
- Avoid jargon
- Do not use acronyms, abbreviations or mnemonics
- Avoid terms such as "new treatment", "new medication" or "new drug" without explaining that the test article is investigational
- For clinical research, avoid the use of acronyms that imply a favorable outcome, e.g., CURE, PROTECT, HEAL, etc.
- Use "research" or "research study" instead of "trial"
- Use "participant" in place of "patient", "volunteer" or "subject"
- Use "healthy participant" in place of "healthy volunteer" or "healthy control"
- Use "investigational" instead of "experimental"
- Use "at no cost" instead of "free"
- Avoid the use of language that is overly incentivizing, e.g., "Do you want to make \$50?!!"

7. Social Media/Online Recruitment

Recruitment in private online spaces such as a group page, chat room or discussion board requires specific permissions from the group or page moderators. The ARISE application should explicitly outline the website or social media network that will be used to post online recruitment notices. Where social



media is used, it is recommended that you do not log in with personal accounts or profiles to post the recruitment notices. Where possible (e.g., Twitter), a temporary account that is research-specific only should be used.

Researchers should seek out and be familiar with the data and privacy policies that any given social media platform has in place and in particular, know where data are stored and rules surrounding their use, etc.

When using Twitter or similar applications, the following should be provided:

- Information about the Twitter account from which the recruitment notices will originate;
- The 280-character tweet; and
- Information about the landing page individuals will be taken to if they click on the URL link in the tweet.

Where Facebook or a similar application is used, the following should be provided:

- The recruitment notice/ad;
- Information about the pages/groups where the notice will be posted;
- Information about whether the pages/groups are open or closed; and
- Information about the account from which the ad is posted.

When recruiting on social media it is important to think carefully about the implications of the confidentiality of the recruitment process. For example, individuals may comment on a recruitment posting on Facebook, or tag a friend they think might be interested in participation. This makes it visible to others. These postings should include explicit instructions that questions regarding participation should be via direct or private messaging instead of publicly online. Additionally, comments should be disabled for the post.

If you are using an online classified site such as Kijiji or Craigslist, care should be taken not to post in employment sections but rather in volunteer or research sections, if available.

8. Use of Email for Recruitment

Health Research: Where health information may be conveyed, the REB understands that use of email for recruitment purposes does not meet the privacy and security standards outlined in the AHS email policy (provide link?). As such, the REB is unlikely to approve of any email-based methods of recruitment where personal health information is directly linked to the email. Other scenarios will be considered on a case-by-case basis, ensuring compliance with AHS and University of Alberta policies. Where email recruitment can be used, it is imperative that no reference to the individual's health diagnosis be included in the subject line of the email. The subject line should be generic, i.e., "Invitation to participate in a research project" instead of "Invitation to participate in a research project for those living with Diabetes". Additionally, the use of email should be in accordance with the REB's "Use of Email to Communicate with Study Participants Guidance" and best practices. The researcher must submit the subject line along with the email content for approval by the REB.



Non-Health Research: The use of email for recruitment can be a useful tool, particularly for online survey invitations. Care must also be taken to project the privacy of the recipient of the email. As with health research, an individual's privacy can be compromised depending on the subject of the research. Therefore, the subject line should be as generic as possible. The REB must approve both the content of the email as well as the subject line. Additionally, the use of email should be in accordance with the REB's "Use of Email to Communicate with Study Participants Guidance" and best practices.

Third Party Email Recruitment: Where a third party, i.e., data custodian or other entity, sends out the recruitment email on behalf of the research team, a copy of that email should be submitted to the REB for approval. The email should include a clear statement that the email is being sent on behalf of the study team and that any questions or indications of participation should be addressed to the study team and not by reply to the sender, in order to protect their confidentiality.

9. Student Recruitment

Students as Research Participants

Many University researchers recruit students for their studies. Participating in research can have educational value in, for example, exposing students to the methods used in a discipline or engaging them in the analysis of their own data. However, students in classrooms represent a captive audience if they are recruited to participate in their instructor's research project. Thus, in-class research raises a number of ethical issues:

- Undue Influence, or pressure to participate, is a major concern if an instructor plans to use his or
 her own students as participants, particularly during class time. Students may feel that their
 grades will be affected by their participation. Experimentation in a classroom setting may raise
 the issue of confidentiality, as students may be able to read or hear one another's responses;
- In-class research raises concerns about the anonymity of participants because it is relatively easy to tell if someone is participating or not. E.g., they fill out a questionnaire, or do something else or leave the room;
- For research to take up any teaching time, it should have educational value.

In these cases, when the instructor applies for REB approval for research involving his/her students or classes, s/he will need to address mechanisms of free and informed consent and the risks associated with issues of confidentiality and anonymity.

Other Considerations

If any materials (e.g. papers, tests, etc.) produced by the students are to be prospectively collected and analyzed, consent from the students is needed. Fully informed consent on how the materials will be used, with guarantees of confidentiality are essential. The consent form should explicitly state that no penalties will result by not agreeing to participate. If possible, instructors should wait until the final date to contest one's marks has passed so that a real or appearance of potential for evaluative effect on student/participants no longer exists.



If the instructor intends to involve some students as participants, and not others, a third party should be involved in recruitment and selection to provide some distance between teacher/researcher and student/participant. The teacher/researcher should not know who has agreed to participate while the teacher-student relationship still exists. It is normally advisable that identifiable data be analyzed only after grades have been submitted so that a real, or appearance of potential, evaluative effect on student/participants no longer exists.

Cooperative Activities Program (CAP)

The Cooperative Activities Program (CAP) manages research activities involving the following Edmontonarea school districts:

- Edmonton Public Schools
- Edmonton Catholic Schools
- Elk Island Public Schools
- St. Albert Public Schools
- Greater St. Albert Catholic Schools

All proposed research projects involving the participation of human participants initiated by, or in collaboration with, University of Alberta personnel seeking the involvement with a CAP district must submit a CAP Application after obtaining ethics approval from the appropriate Research Ethics Board (REB).

CAP is administered by the Associate Dean, Research in the Faculty of Education. Further details, including the CAP application form (including the guidelines and procedures) can be found on their website.

10. Screening and Recruitment in Health Research

Privacy Principles Related to Approach/Screening Activities in AHS Operational Areas (also applicable to other clinical settings)

When recruiting patients to a Research Ethics Board (REB) approved clinical health study:

- AHS will work to provide restricted access to the least amount of identifiable health information under REB approved conditions to enable research related activities where a waiver of patient consent was granted for the study.
- Contingent upon the operational approval conditions, members of the research team (whether an AHS employee or not) may approach a potential participant directly if no health information has been accessed prior to the initial contact. A poster or brochure in these areas may be used to provide awareness to patients who may be approached.
- Members of the research team (as an AHS employee or not, who is not acting in the role of primary caregiver or member of the assigned care team) may not initiate contact with a potential participant when they have previously accessed health information of that patient (i.e., as part of the pre-screening process). For the comfort of the potential participants in AHS



operational areas, an AHS employee or care provider should be the first point of contact with that patient to obtain permission for researchers to approach.

Approaching Patients for Study-specific Consent to Participate

- At admission, an AHS staff member who is not part of the research team could be the first point
 of contact with the potential participant to promote the comfort and trust between the
 patients, caregiver and researchers. They may provide a brochure, direct attention to a poster
 or state something similar to the following upon check-in, "This is a research hospital and you
 may be approached about research. You don't have to agree and it won't impact your care".
- A member of the research team may approach the potential participant to solicit their interest in participating in the study and perform the enrollment process of gathering of consent.

Pre-Screening of Patients for Eligibility to Develop a Pool of Potentially Eligible Candidates

If the REB has NOT waived the consent requirement:

- a) A member of the research team (i.e., clinical research coordinator, research assistant) may follow the recruitment process and ask the patient if they would sign a study specific consent form (i.e., Consent to Screen Form) prior to accessing the patient's medical record. This consent form must clearly identify the study to which they are being pre-screened and provide explicit consent for the researcher to access the patient's health record;
- b) A research team member with appropriate access and training can then access the relevant electronic medical records (EMRs) and paper charts (as approved per the study) for prescreening activities to confirm potential eligibility;
- c) A research team member may approach the potential participant to solicit their interest in participating in the study and perform the consenting process for enrollment.

If the REB has waived the consent requirement:

- A member of the research team may review the relevant EMRs and paper charts (as approved per study) for the purposes of pre-screening patients to determine eligibility for the study;
- b) A member of the patient's care team must then approach the agreeable potential participant to request their permission for researchers to approach the patient;
- c) A research team member may then approach the agreeable potential participant to solicit their interest in participating in the study.

11. Be The Cure

Be The Cure (bethecure.ca) is a website to allow Albertans to learn about health research studies that are actively recruiting human participants. The website allows the general public to browse and search currently recruiting studies through a user-friendly interface.

In order to post a study on Be The Cure:

Applications must be approved by the HREB (Health Panel or Biomedical Panel) REB 3 & 4; and



• The online ARISE application form must have the Be The Cure specific pages completed.

If your study already has REB approval, you can submit an amendment to have your study listed on the Be The Cure website.