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Recruiting & Advertising for Research Participants

Recruitment of research participants is a challenging aspect of research involving human participants. Federal regulations require the IRB to review the methods and material that investigators propose to use to recruit participants to ensure that subject selection is equitable and include racial, ethnic, educational, socioeconomic, and gender diversity appropriate to the condition studied. All recruitment efforts must also respect personal rights to privacy and confidentiality, be compliant with the Health Insurance Portability & Accountability Act (HIPAA), and avoid coercion or undue influence of potential participants. The CCH IRB requires all recruitment and advertising methods and materials be reviewed and approved by the IRB prior to recruiting any participants.

I. Contacting Prospective Participants Identified from Medical Records

- You must have permission to go through medical records to identify prospective participants or when designing a research study. This is accomplished through a HIPAA authorization waiver or partial waiver and the preparatory to research provision respectively. Please see “HIPAA Guidance for Clinical Research” available in Corporate Compliance Policies on the intranet.
- Cold calls or direct mailings from an investigator without clinical access and unknown to the potential participant are not allowed. Contact must be initiated through a CCH provider who has clinical access or a treatment relationship. Persons with clinical access include the care provider of the patient or a member of the same clinical care team. The clinician may approach the potential participant about participation in their own study or on behalf of another investigator.
- If participants are to be enrolled from among the clinician’s own patients, consent procedures must be put in place to ensure that participants do not feel obligated to participate because the investigator is their treating physician. There is always concern about the possibility of undue influence and patients feeling obligated to participate, because it is their provider who is asking. While CCH does not absolutely prohibit providers obtaining consent from their own patients, researchers are asked to think about this issue and address it. There are many possible ways to do this. One can contact the patient in writing initially, and allow him/her to pursue it further, if interested. One can ask a colleague or other study staff to present the study to a patient. One can have a nurse or colleague re-contact the patient after the investigator has had the consent discussion and offer them an opportunity to ask additional questions, raise concerns, or opt out, with someone who is not their clinician.
- A clinician may provide information about research to patients with whom he/she has a clinical relationship on behalf of an investigator from another institution if he/she believes the patient would benefit from participation in the research without that study being approved by the CCH IRB. In this case only descriptive information is given to the patient without any stated or implied endorsement of the research (i.e., a summary of the research, and the name and phone number of the researcher conducting the trial). The IRB considers this interaction to be a clinical referral, not organized recruitment, and not subject to IRB review. Example: My colleague is interested in recruiting subjects for a weight loss research intervention. If you are interested in learning more about this you may contact Dr. Somebody or his/her research staff at 312-000-0000.

- If approaching a patient on behalf of an investigator from another institution, the patient's consent is required before identifying information is given to the study investigator. Recruitment for an outside institution must be reviewed and approved by the CCH IRB. Releasing the names and addresses of patients to someone not employed by CCH, who does not have any clinical reason to know this information, is a violation of the patient's rights to privacy and confidentiality. Only employees with a clinical reason to know about patients' conditions should contact them about possibly participating in research.
- In order to be able to recruit CCH patients for another institution's research study by providing their contact information to the other institution, there must be a CCH Responsible Investigator (RI). The CCH Responsible Investigator must submit a **recruitment only** request in IRBManager by submitting an exemption request and selecting "other" and "recruitment only" in the form. This application must include a description of the research study and consent to contact (see Appendix 1). The recruitment may not commence until all approvals are complete. These studies will receive an IRB number and be designated as recruitment only with a "R."
- If a CCH employee is to be an author on a study from another institution, or is otherwise substantively involved, whether or not compensated for participation, the CCH employee is a collaborator and the protocol must be reviewed by the IRB (i.e. full or expedited review, not "recruitment only").
- If a CCH employee is participating in the study as an employee of another institution, at which the research is done and *if that research involves CCH patients*, it is a collaboration and may not be reviewed as "recruitment only". If a researcher at another institution also has privileges at CCH, that person may be the responsible investigator, however, the protocol would then be a CCH protocol and would not be eligible for "recruitment only" review.
- A clinician involved in the care of a patient may contact potential participants by mail and enclose a card to be returned indicating the desire to be contacted to participate in a study or a number for the potential participant to call. Potential participants may be sent up to three letters, but if the person does not respond, the investigator must remove that person from the contact list. Failure to respond does not imply consent to contact. Letters must be approved by the IRB prior to sending.
- Prospective participants who have declined to participate in a research study may not be approached again for that study. It is an infringement of a person's autonomy not to accept that person's decision, and any further approaches could be seen as coercive.

II. Recruitment Materials

- Direct advertising for study participants is the start of the informed consent process. All advertising and recruitment materials must be reviewed and approved by the IRB to ensure they are not misleading, imply a favorable outcome beyond what is outlined in the consent form/protocol, or include any exculpatory language. This is especially critical when a study may involve participants who are likely to be vulnerable to undue influence and coercion. The IRB reviews all recruitment materials, including flyers/ads, posters, invitation letters/emails, "Dear. Dr." letters requesting referrals, videos, radio scripts, sponsor's national advertising materials, and ads placed on print or social media.
- When direct advertising is to be used, the IRB reviews the information contained in the advertisement and the mode of its communication. The IRB must approve the final copy of printed or electronically posted ads. The IRB will evaluate not only the verbal content, but the relative size of type used and other visual effects. When ads are produced for broadcast, the IRB should review the final audio or video tape. When posting advertising flyers in community settings, obtain approval from that facility in addition to IRB approval.

- Generally, any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in ads:
 - ✓ The name and institution of the clinical investigator and/or research facility;
 - ✓ The condition under study and/or the purpose of the research;
 - ✓ Summary of the criteria that will be used to determine the eligibility for the study;
 - ✓ A brief list of participation benefits, if any (e.g., no-cost health examination);
 - ✓ The time or other commitment required of the subjects; and
 - ✓ The location of the research and the person or office to contact for further information.
- When constructing advertising materials, keep in mind to AVOID any of the following:
 - ✓ Payment information emphasized by larger or bold type;
 - ✓ Promises "free medical treatment" when the intent is only to say participants will not be charged for taking part in the study;
 - ✓ Statements or implications of a certain favorable outcome or other benefits beyond what is outlined in the informed consent and protocol;
 - ✓ Exculpatory language; and
 - ✓ Proprietary information or product name, unless approved by sponsor.
- For FDA regulated studies, advertising materials are NOT to include any of the following:
 - ✓ Claims, either explicit or implicit, about the drug, device, or biologic that are inconsistent with FDA labeling;
 - ✓ Statements that compensation for participation will include a discount on the purchase price or the product after FDA approval;
 - ✓ Claims, either explicit or implicit, that the drug, biologic or device is safe or effective for the purposes under investigation;
 - ✓ Claims that the test article is known to be equivalent or superior to any other drug, biologic or device.
 - ✓ Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as "new treatment", "new medication" or "new drug" without explaining that the test article is investigational.

III. Recruitment Using Social Media

- Social media can provide an effective tool for researching potential subject populations. However, using social media and online techniques for recruitment must be approached with caution. IRB review and approval prior to implementation is required.
- The specific media intended for use should be described and a copy or screen shot of the ad or post including text, images, tags, etc. should be provided for IRB review. Any hashtags that will be associated with the post should be included as well as where the ad will be posted. Posting ads directly on personal pages is discouraged as it may be considered an invasion of privacy.
- Postings that allow public comment could result in unintended disclosures of private information or misrepresentations regarding the investigational product's effectiveness. If applicable, describe for the IRB your process for handling user-generated content including who will monitor comments or public postings. Disabling the user comment option may be useful for pages that have potential to elicit comments that could bias study results.
- If making or responding to comments, identify views as your own. If you identify yourself as a CCH employee online, it should be clear that the views expressed are not necessarily those of the institution.

- If posting in online classified ads or job posting websites, limit posting to one appropriate category such as miscellaneous or health/medical. Posting in multiple categories may be perceived as nuisance or harassment.
- Make sure you are complying with the terms of use of the platform you are using, including privacy policies, prohibited content, posting location, and frequency.
- Seek permission to access or interact with closed groups. As a rule, do not engage in a manner that would be improper in an equivalent live setting. For example, it would be inappropriate to show up unannounced to a private support group meeting to recruit research participants. Obtain approval and request an introduction from the administrator or moderator before engaging in a similar activity online.
- Once enrollment is closed, be sure to remove, replace, or disable study-specific advertising.

IV. Payments to Participants

- The proposed method and timing of disbursement should not be coercive or present undue influence. The IRB considers whether listing payment amounts could be considered undue influence.
- In some cases, it is more ethical to state that participants will be compensated, but not list the dollar amount. Generally, ads for Phase I-III clinical trials and other significant risk research should not state the amount to be paid to potential participants. For other studies, the IRB considers request to list payment amount on a case-by-case basis.
- Payment should not be contingent upon completion of the entire study and should generally be paid at each study visit. Any credit for payment should accrue as the study progresses. Payment of a small portion as an incentive may be allowed upon completion of a study when such incentive is not coercive. Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.
- Payment to participants who withdraw from the study should be made at the time they would have normally received payment had they not withdrawn, unless it creates inconvenience or a coercive practice.
- All information concerning payment, including the amount and schedule of payments should be set forth in the informed consent. Payment to research participants for participation in studies should not be included as a benefit in the analysis of risks and benefits.
- Compensation for participation in a trial offered by the sponsor should not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
- Ads may state that participants will be paid, but should not emphasize the payment or the amount to be paid. In general, the IRB recognizes that the legitimate costs to patients who participate in research --car fare, lost wages, child care, and food -- may be appropriately reimbursed without creating a coercive situation. In general \$10-\$20 per hour including time used in transportation, plus child care and food costs are acceptable. If a study runs through mealtime, meals may be provided or paid. In some cases, additional payments may be considered, but this determination will be made for projects on a case-by-case basis. Acceptable forms of payment include cash, gift cards, pre-loaded debit cards, money orders or electronic deposits.

- Of important note is that total payments equal or greater than \$600 in a calendar year period are tax reportable income to IRS. Participants should be advised to report their income to the IRB if the payments are equal or greater than \$600 in a calendar year. This includes all studies the participant has received payment for in that calendar year. Participants should also be advised that additional income may increase their household income and possibly cause them to become ineligible for certain benefits, including Medicaid.

V. Recruitment Bonuses & Finders' Fees

- Based on legal and ethical concerns including conflicts that might arise, the CCH IRB does not allow finder's fees and/or incentive payments to physicians, researchers, study team members, or other professionals for referring or identifying potential participants, meeting targeted enrollment numbers, or even timely completion of the study.
- Such payments may increase the likelihood that the person referring patients may be influenced by the promise of compensation and not act in the best interest of their patient. For example, a significant bonus may result in the promotion of unfounded benefits of study participation or the recruitment of individuals who may not meet study inclusion criteria. Failure to recruit and enroll participants properly may result in study participants being exposed to unnecessary risks and may diminish the public trust in research.
- Recruitment incentives are not limited to a financial payment but may be extended to authorship, future paid consulting work, or even opportunities for future research support.
- Current research participants may receive payments for identifying or referring potential study participants. This payment should not be contingent on if the potential participant enrolls in or finishes the study. The discussion should be limited to telling the person about the study and seeing if they would be interested in obtaining additional information. There must be no undue influence, and if the person is not interested, the discussion should be terminated.

VI. Passive Consent

- An investigator may not recruit potential study participants by sending a letter that requires the participant to send back a postcard (or to telephone) only if they do NOT wish to participate. Participants may become unwitting participants if they never receive the letter, do not speak/read English, or are confused by the instructions. The IRB only approves a "passive" consent procedure if the federal criteria for waiving informed consent are met.

VII. Pre-Screening

- Pre-screening typically includes a brief overview script or description of the research followed by collecting basic information related to eligibility and suitability from potential participants.
- If using a pre-screening process (phone, in-person, email, online) to assess potential eligibility, describe the process and provide the script and sample questionnaire for IRB review. All of the above rules apply regarding contacting potential research participants.
- All regulations regarding the protection of PHI apply to data collected for pre-screening. All PHI should be securely stored and destroyed as soon as possible to protect PHI.



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Date

****Detailed Sample Recruitment Explanation/Permission Form: Must be on CCH Letterhead****

Name of Study
Name of CCH Responsible Investigator

(Facility name) is cooperating with (other institution name) to recruit persons who may want to become participants/subjects in a research study that (other institution) is undertaking.

The study involves (brief description).

You are being invited to the study because you have characteristics (eligibility criteria).

This study will not take place at (CCH facility). However, with your permission, your name and contact information will be given to (other institution) so that they may contact you with more information about the study. If you sign this agreement, you are giving permission for (CCH facility) to release the information that you (eligibility criteria) as well as the contact information you provide.

You are not automatically agreeing to participate in the study, just by signing this form. You are only agreeing to be contacted to learn more about the study and to consider whether or not to participate. You may agree to participate or withdraw, once you are given additional information by (other institution). You may also withdraw from a research study at any time, even after you have agreed to participate without any penalty. Your care at (CCH facility) will not be affected by your participation in this study or your decision to not participate.

I agree to have the following contact information released to (Investigator name)
_____ at (Institution name)
_____, and for them to contact me about their study.
Allowing this will mean that they know I am a patient at (CCH facility name)
_____ and that I meet the eligibility requirements because I _____.

Preferred Contact information (Phone/email/text/postal mail)

Printed name: _____ Date: _____

Signature: _____