Emory IRB

Advertising and Recruiting for Human Subjects Research

Before starting any recruitment activities, including posting passive fliers, you **must** first have IRB approval for your research project, including your recruitment plan.

[Recruitment via Review of Medical Records or Prior Research Data](#Recruit) **(including EHC front-door authorization to be contacted for research studies)**

[Posting Advertisements (](#PostingAds)***[fliers, radio ads, emails, etc.](#PostingAds)***[)](#PostingAds)

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**Recruitment via Review of Medical Records or Prior Research Data**

1. **To review medical records to find potentially eligible subjects, you normally must first have IRB approval for your study.** The medical records department at EHC requires IRB approval and a “partial HIPAA waiver” to review medical records for recruitment purposes. HIPAA does allow researchers within a covered entity to review medical records to do some “preparatory to research” activities such as seeing if there are enough eligible patients to carry out a study, but before searching for patients to contact, you should have IRB approval.
2. **Generally, Emory does not allow ‘cold calling’ (or cold-writing) patients based on information contained in their medical records**, due to sensitivity around privacy.Providers that have a treatment relationship with the patient are, however, able to approach their patients about their research studies.
3. **If you do not have a treatment relationship with the patient/are not part of a treatment group that cares for the patient, you have the following options:**
	1. Ask the patient’s treatment provider to inform the patient about the study and to provide the patient with your contact information. If the provider is not otherwise collaborating with you on the research and is not expected to have an in-depth discussion with the patient about the study, then the provider is not considered part of the research team and does not have to be listed as study personnel.
	2. Ask the patient’s treatment provider to get permission from the patient for you to contact him or her about the study. This permission should be recorded in the patient’s medical record by the treatment provider. Again, the provider would not be considered study personnel unless their study involvement went beyond this step.
	3. Contact eligible patients from the Emory medical record/Clinical Data Warehouse IF AND ONLY IF they have signed the **front-door authorization to be contacted for research studies** (see the relevant flag in the patient’s medical record). Remember: you must have IRB approval for the research study – including this recruitment method – before identifying these patients and contacting them. *Status updates on this initiative will be provided through Emory University and Emory Healthcare channels*.
	4. If none of the above are adequate, you may obtain written permission from the relevant treatment providers at Emory to contact their patients about your study. The letter sent to the patients must indicate that the treating physician has agreed that they are informed about the research opportunity.
		1. *Sample language for letter*: “Your physician, Dr. [Name], has recommended that we notify you of this research opportunity. We would like to call you to tell you about the study and see if you would like to participate.”

**Phone Calls with “Opt-Out” Option**

For **recruitment only (not enrollment)**, it is sometimes acceptable to send an initial message/letter about a study that says you will follow up with a call after a while. (The preceding guidelines must still be followed re: who can reach out, and how.)

The initial message should contain contact information so that the participant can request not be to further contacted about the study.

* 1. *Sample language for letter*: “In the next few weeks, one of our team members at Emory will call you about the study. Your participation is strictly voluntary. If you have any questions about this project or do NOT wish to be contacted, please call [Name] at [number]. We hope that you will agree to speak to us.”

**Posting Advertisements (*fliers, radio ads, emails, etc*)**

You must get IRB approval of any advertisements, notices, posters, radio spots, brochures, etc. which are intended to advertise the study and/or aid in recruitment. Likewise with recruitment-related letters.

*Important*: Compensation must not be highlighted/accentuated beyond the other information about the study.

Submit materials in their **final formatting** (font, color, etc).

Video or Audio (e.g. a radio or tv ad): it is best to submit the wording to the IRB initially before you record the ad, then once IRB has requested any revisions, record the ad and submit the final copy/video to the IRB. Please contact the IRB with questions about how to submit large files or unique file formats.

*Guidelines for study ads*

Must include:

* The name and address of the researcher and/or research facility;
* The condition under study (if applicable) and/or the purpose of the research;
* In summary form, the criteria that will be used to determine eligibility for the study;
* A brief list of participation benefits, if any (e.g., a no-cost health examination, participation in a nutrition program, etc…);
* 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.
* *Important:* compensation must not be highlighted/accentuated beyond the other information about the study.

For drug or device studies:

* No claims should be made, either explicitly or implicitly that the drug, biologic, or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic, or device. Such representation would not only be misleading to subjects but would also be a violation of the FDA’s regulations concerning the promotion of investigational drugs and investigational devices.
* 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. A phrase such as "receive new treatment" implies that all study subjects will be receiving newly marketed 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.

For additional information, see the [FDA Information Sheets.](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects)

**Using ResearchMatch**

Emory, Children’s Healthcare of Atlanta, Morehouse, and Georgia Institute of Technology have access to a great tool for recruitment: ResearchMatch.org, a registry of individuals who have expressed interest in joining research studies. Please see our ResearchMatch instructions at <http://irb.emory.edu/forms/new.html> (section entitled “ResearchMatch”) for more information.

**Postings on Clinical Trials Websites or Other Listings (e.g. ClinicalTrials.gov)**

When information posted on a clinical trial website is limited to directory listings with basic descriptive information, no IRB review is required. Any information beyond this would make the posting a recruitment tool that requires IRB review. Basic descriptive information includes:

* study title
* purpose of the study
* protocol summary
* basic eligibility criteria
* study site location(s), and
* how to contact the study site for further information.

Information exceeding such basic listing information includes descriptions of clinical trial risks and potential benefits or solicitation of identifiable information.

**Press Releases and News Stories**

University press releases and news stories that mention human volunteers for research studies may not require IRB review if they are not intended to recruit for specific studies, but instead to publicize important research taking place at the University. Press releases and news articles would be definition be produced by an Emory communications office or Emory publication, not by the study team (though the study team can of course contribute information for the story).

News stories should abide by the following guidelines, however, and writers are encouraged to consult the IRB Director or senior staff member to make sure the line between the news story and study advertisement is not crossed, and especially that FDA guidelines for the promotion of drugs and devices are adhered to.

* Stories should avoid creating a “therapeutic misconception” that there is any certain benefit to the participant.
* Any time an investigational drug or device is mentioned, it must be referenced as “investigational” or “unapproved.” In general, clinical trials should not be referred to simply as therapy or treatment.
* Press release writers should point out when study participation is strictly altruistic versus providing actual benefit.
* Generally, it would not be appropriate for a news story or press release to mention compensation for participation.

**\*\* Important information about screening for eligibility \*\***

Please see our [Consent Toolkit](http://irb.emory.edu/forms/consent_toolkit/index.html) on our website for guidance.

**NOTE:** If you plan to recruit subjects from the **Atlanta VA Medical Center**, you must also submit your request to the VA R&D committee, even if the actual study will not be conducted there.