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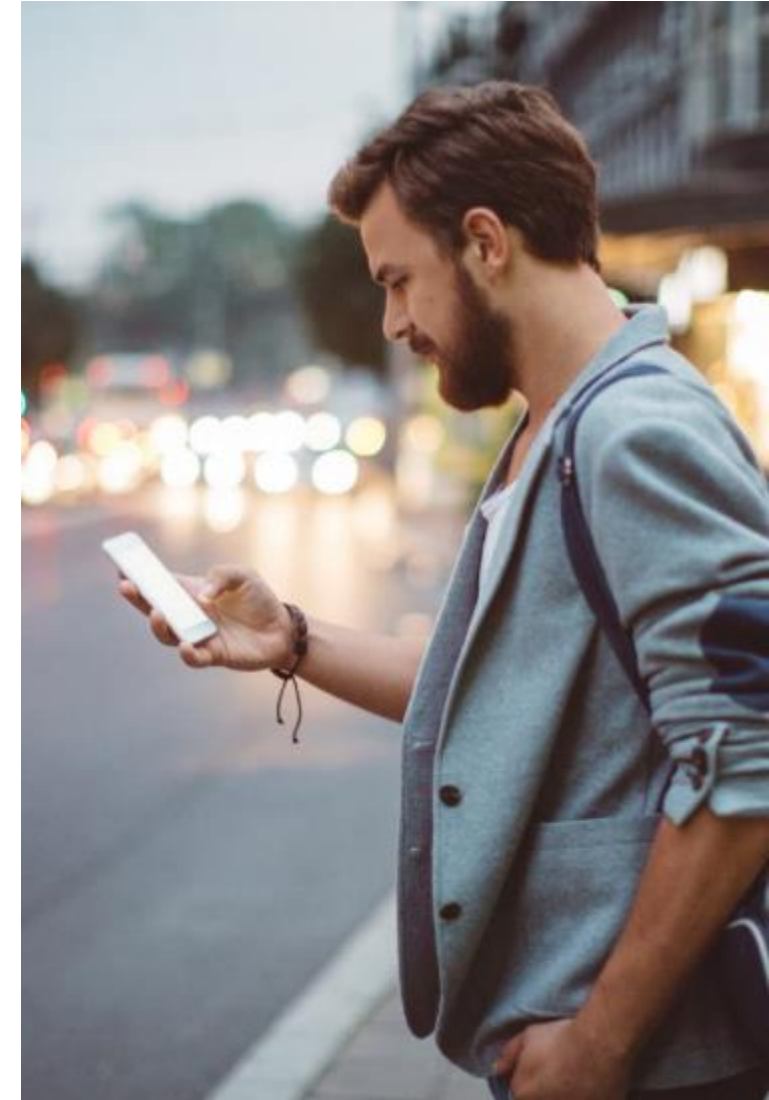


Recruitment for Research Studies

MAY 13, 2021

Topics

- What do the IRB Policies and Procedures and Regulations say?
- What do I need to submit?
- Good recruitment examples
- Social media and recruitment
- Use of the medical record to recruit
- Questions?





What do the IRB Policies and Procedures and Regulations say?



Per the FDA and OHRP regulations, the Emory IRB is charged with ensuring that the recruitment of subjects for research studies is equitable and that participation is voluntary.

The IRB needs to review the *actual materials* that would be used to recruit subjects, including but not limited to:

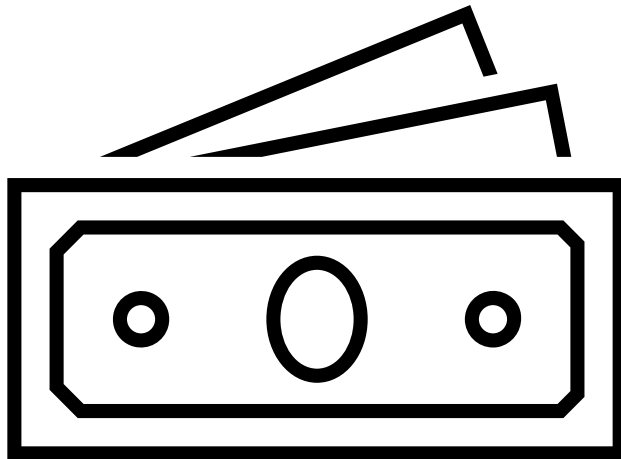
- Flyers and print ads
- Videos or audio presentations regarding the study,
- Final copy of printed advertisements to evaluate the relative size of type used and other visual effects.
- When advertisements are to be taped for broadcast, the final audio/video tape must be submitted.

FDA Guidance

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.

Generally, FDA believes that any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.

Compensation/Reimbursement



Guidance

- Federal regulations do not provide clear guidance on how research subjects should be compensated.
- Under Federal regulations (45 CFR 46.116), for research involving more than minimal risk, there must be an explanation as to whether any compensation will be provided.
- For FDA-Regulated Research, the IRB must not allow compensation for participation in an FDA-regulated trial to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

Raffles, Contests & Lotteries

Any incentives for study subjects that involve giveaway's, chances to win prizes, lotteries, etc. must conform to all state laws regarding games of chance and gambling. In general, under Georgia law, lotteries and games of chance are prohibited.

A license is required in Georgia to offer raffles

If you allow anyone to participate in the raffle, even if they don't join the study, it may be acceptable

Compensation for conduct of a study should not exceed the fair market value of the services provided.

Georgia Code § 16-12-22.1

<http://statelaws.findlaw.com/georgia-law/georgia-gambling-laws.html>



What do I need to submit?

Recruitment is the beginning of the informed consent process...

So, all recruitment consent must be IRB approved!

- Submit materials in their final formatting (font, color, etc.)
- If advertisement will be in video or audio (e.g. a radio or tv ad), submit language for approval first
- Important: Compensation must not be **highlighted**/*accentuated* beyond the other information about the study.





Information to Include

Examples of Good and Bad

DO



Include:

- Name, address, and contact info of study site/study team
- Condition under study or purpose of the research
- Eligibility criteria
- Time or other commitment required
- Participation benefits, if any (e.g., a no-cost health examination, participation in a nutrition program, etc.)

DON'T



- Emphasize compensation in any way.
- Overstate benefits to participation.
- Make claims about an investigational test article

Examples

Both Good and Bad

Online Ad Submission Example

The Child and Adolescent Mood Program (CAMP) is currently conducting research investigating a type of treatment called Behavioral Activation (BA) Therapy with adolescents.

One aim of this study is to examine how brain functioning changes over the course of this treatment. Participants will undergo functional Magnetic Resonance Imaging (fMRI) scans throughout the 16 weeks of treatment.

Follow the link below to learn more and see if your teen qualifies!
<http://www.treadlab.org/participate-in-a-study/>

The above language may be paired with one of the following images.



Thanks to the TREADLAB for sharing their submission!



"The blood draw didn't even hurt and I was able to save lives"
- Participant AB

Together, we can chart a new course for humanity!

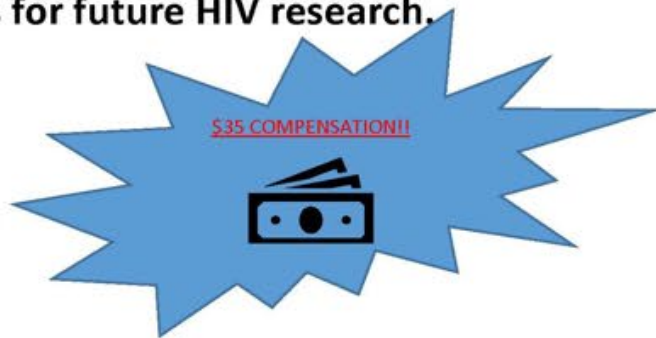
Research Volunteers Needed in this EPIC Biorepository Study!

We are collecting blood samples for future HIV research.

You may qualify if you are:

- ✓ age 18-19 or age 35 & older
- ✓ HIV negative man who has sex with men
- ✓ Not currently taking PrEP

Contact us at EMORYIRBRECRUITMENT@example.edu





"The blood draw didn't even hurt and I was able to save lives"
- Participant AB

Together, we can chart a new course for humanity!

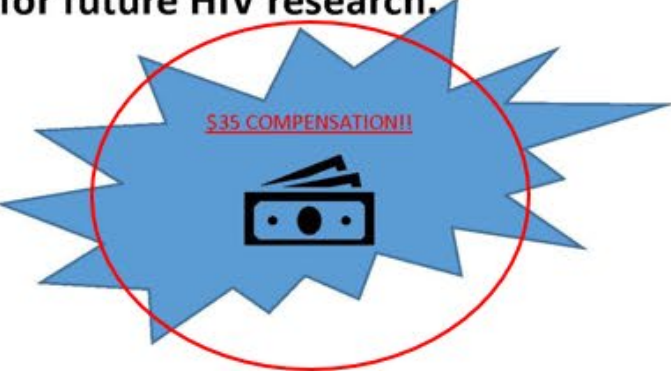
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TROUBLE SLEEPING? Try a new drug for insomnia!



So far, in patients we have studied, we believe Exonopin™ can reverse damage caused by lack of sleep.

PARTICIPANTS RECEIVE A FREE SLEEP STUDY!!

Contact the Study Coordinator for more information:
FDA.worstnightmare@example.edu

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Social Media

Compliance Considerations:

- It is the responsibility of the research team, when designing a protocol, to understand the social media site terms of use (TOU), as well as university policies and applicable laws. In addition, study teams should be aware of any research or recruitment-related restrictions on the social media sites through which they intend to conduct their recruitment activities



Type of Recruitment

Private messaging for recruitment:

This is defined as two-way communication between a research team member and a potential research subject using private message features on social media sites (e.g., Facebook messages or messenger, Twitter direct messages), . The IRB may approve this strategy on a case-by-case basis. The preference is that the potential subject previously approved of such communication (for example, a general post was created, and the potential subject gave permission for a personal message). This approach requires a robust plan for managing interactions.

Interactive recruitment materials:

Include any post or paid advertisement that permits liking, commenting, sharing or other public interactions with potential participants on the social media site. The plan for managing interactive recruitment materials must be clearly delineated in the social media management plan.

Static recruitment materials:

Post or paid adds that do not permit interactions with potential participants (e.g., liking, sharing, etc.). If you link to IRB approved destination, no need to submit a plan for managing interactions.

Recruiting via public and private groups:

This practice of is permitted but research teams must be aware of any site restrictions on recruiting participants via groups. If this method is used, research teams must identify if there is a group moderator and request permission to communicate with and recruit group members. It is acceptable to take this step prior to requesting IRB approval. As part of the IRB approval process, research teams must submit to the IRB the text of the recruitment materials that will be shared with group members along with any approval obtained.

Levels of Review	Examples of Study Recruitment Activities
<p>Simple: Social media recruitment channels that have been pre-vetted by the Emory Privacy, Information Security and General Counsel's offices.</p>	<ol style="list-style-type: none"> 1. Posting recruitment materials through the an official Emory Healthcare or Emory University Facebook account. 2. Purchasing static (right-column) advertisements through any official Emory Healthcare or Emory University Facebook account (the protocol submitted to IRB for approval must also include a screenshot of an email or other communication indicating that the social media account manager has approved purchasing ads through the account).
<p>Complex: Social media recruitment activities that <u>may</u> require ad hoc or ancillary reviews as requested by the IRB.</p>	<ol style="list-style-type: none"> 1. Posting <i>interactive</i> recruitment materials through any official Emory or Emory Health Facebook account (the protocol submitted to IRB for approval must include a screenshot of an email or other communication indicating that the social media account manager has approved posting materials through the account). 2. Posting recruitment materials to Facebook groups. 3. Recruiting via private messaging (i.e., direct messaging to prospective participants for recruiting without the exchange of additional communication) on a social media site (e.g. Facebook messages, Facebook messenger, Twitter direct messages). 4. Collection of any identifiable data through a social media site during the recruitment process. 5. Use of social media sites other than Facebook for study recruitment.



Personal social media accounts cannot be used to purchase or place initial recruitment materials for Emory related studies.

Members of the research team are permitted to share recruitment materials that are posted through official Emory-approved accounts to their personal pages and accounts, without changing the post or adding comments.

Georgia CTSA Facebook account (streamlined submission/approval).

The Georgia CTSA Recruitment Center co-manages the official “Georgia CTSA” Facebook page as a channel through which investigators can post recruitment materials. The Georgia CTSA Recruitment Center will facilitate the posting of IRB-approved ads through the Georgia CTSA Studies Facebook page. <https://georgiactsa.org/research/recruitment-center.html>

Official Emory University and Emory Healthcare social media accounts.

If a research team has its own official Emory social media account or has received permission from a social media manager to post recruitment materials through an official Emory social media account maintained by a different unit, investigators may instead seek approval to post IRB approved recruitment materials through those accounts.

Note: Any costs incurred will be the responsibility of the research team

Official Emory Accounts



Social Media Management Plan

*What to
Include in the
management
plan...*

- A list of all social media sites that will be used for recruiting:
 - Indicate if official accounts will be used for posting and whether you will target public or private groups/
- Attestation statement addressing the team's plan to comply with all policies as applicable on the respective platform.
- Final mock-ups of all materials.
- Details on where any links may lead.
- Plans for managing any postings, monitoring and responses to recruitment-related communication

Recruiting Subjects via Review of Medical Records or Prior Research Data

In order 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.



'Cold Calling'

Providers that have a treatment relationship with the patient are, however, able to approach their patients about their research studies.

Generally, Emory does **not** allow 'cold calling' of patients (or former patients) based on information contained in their medical records, due to sensitivity around privacy.



No Treating Relationship?

Inform

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.

Seek Permission

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.

Front-Door Authorization

In 2015, Emory Healthcare rolled out the “front-door authorization”. The goal was to seek approval prospectively for contact about research study participation.

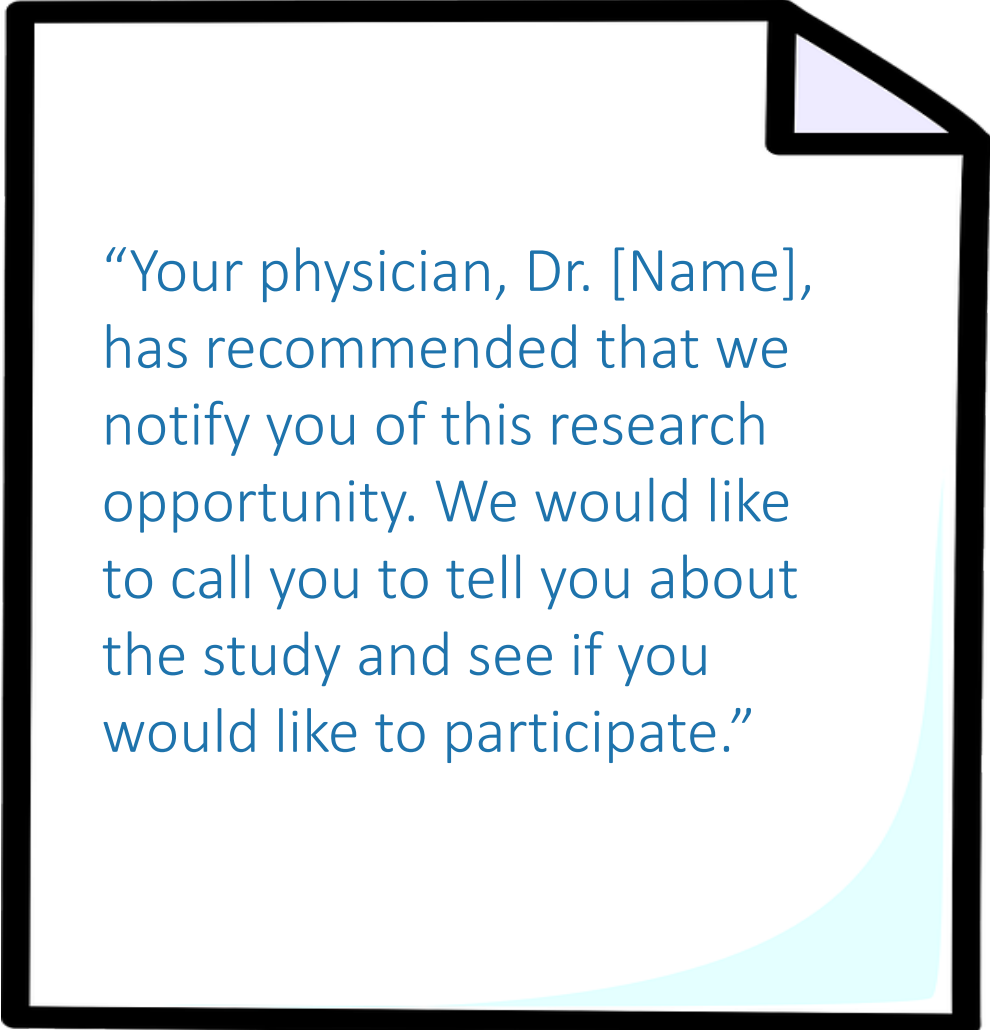
- Teams can contact eligible patients from the Emory medical record/Clinical Data Warehouse **IF AND ONLY IF** they have signed the front-door authorization to be contacted for research studies (see the relevant flag in the patient’s medical record).
- Remember: you must have IRB approval for the research 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.

Remaining Options

When Prior Scenarios Don't Apply

If none of the prior options 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 be informed about the research opportunity.



“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.”

References

- Emory IRB P&Ps, Chapter 76-Recruitment of Subjects
- Emory Communication and public affairs site:
<https://communications.emory.edu/resources/identity/index.html>.
 - <https://communications.emory.edu/resources/identity/social-media-guidelines.html>
- OHRP Guidance on Institutional Review Board Review of Clinical Trial Websites
- FDA Guidance- Recruiting Study Subjects
- Emory IRB Guidance
 - Advertising and Recruitment: Guidance & Information
 - FDA guidance on payment for participation
 - Guidelines for Using Social Media to Recruit Research Participants