

Subject Recruitment Advertisements and eIRB Transition Updates

October 10, 2019

Topics to Cover



Advertisement Dos and Don'ts



Submission Suggestions



Reviewing Medical Records for Recruitment



Requirements for Drug and Device Studies



Examples



eIRB Transition Update



Questions

Posting Advertisements



Recruitment advertisements must be IRB-approved

- Recruitment is the beginning of the informed consent process
- 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
 - Once the wording is vetted by the IRB and you record the ad, submit the final copy/video to the IRB for approval

Advertisement Dos

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.)

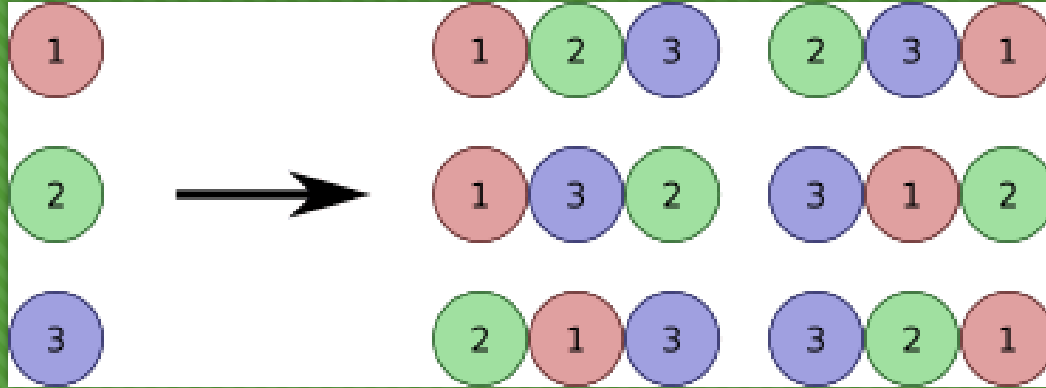


Advertisement Don'ts



Don't

- Emphasize compensation in any way
 - No bolding, italicizing, underlining, or different colored text
- Overstate benefits to participation
 - Keep the scope of the research question in mind
- Gloss over risks



Online Ads

Submission Suggestion

Submit one layout example of your ad

Include another file with the different images, taglines, and text options

Allows for faster refreshing of ad content

- The IRB can approve one submission for ads that can include any permutation of the submitted information

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!

Submission Suggestion



- Provide passwords if multimedia content is password protected
- Only subject-facing recruitment materials should be uploaded in the “Recruitment and Payment” section.
- Please archive any old advertisement materials by labeling files

But what if participants want to share their experience in recruitment materials?

If you intend to use previous subjects' quotes, video, or audio for recruitment, it must meet IRB expectations

- You must edit appropriately
- It may not be possible for participants to share their perspective on study risks and benefits without appearing coercive



Reviewing Medical Records for Recruitment



Must have IRB approval first and be granted a partial HIPAA waiver

Allows researchers in a covered entity to review medical records in advance of research



Once population identified- NO COLD CALLING

Providers with a treatment relationship should make contact

Avoid concern: how did you get my health information?!

More info in [Recruitment Guidance](#)

Reviewing Medical Records for Recruitment

Find a treating physician willing to make contact

- Can ask patient's permission to pass along contact info
- Permission should be recorded in the medical record by treatment provider
- Remember- passing along info about the study or providing a blank informed consent is not engagement in human subjects research
 - No need to list treating physicians on the study if not engaged
- Last resort: researchers may obtain permission from physicians to contact their patients directly
 - Must make it clear that physician was consulted in introduction



Requirements for Drug and Device Studies



- Comes from FDA: [Recruiting Study Subjects, Guidance for IRBs and Clinical Investigators](#)
- No claims should be made that test article is safe or effective for the purposes under investigation- including by research subjects (if applicable)
- Should not use terms like “new treatment”, “new drug”, etc., without explaining the test article is investigational
- Ads shouldn’t promise “free medical treatment” when the intent is to say subjects won’t be charged for taking part in investigation

Public Listings of Clinical Trials in Registries or Research Websites

○ IRB review not required when information limited to basic trial information:

- Study title
- Purpose
- Protocol
- Summary
- Basic eligibility criteria
- Study site locations
- Contact information



Examples for Improvement



"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

\$35 COMPENSATION!!





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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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System upgrade updates



Reminder about submission slowdown- anticipated dates January 7-January 31

- Reportable events are processed as normal
- VERY LIMITED submissions of new studies and amendments
- NO CONTINUING REVIEW PROCESSING WHATSOEVER

What this means for continuing review...

If your study approval expires between January 1, 2020, and February 21, 2020, plan to submit CR early

- Studies that require full board review- deadline to submit by November 1, 2019
- Studies that receive expedited review- deadline to submit by November 15, 2019
- [Review this list](#) to see if your study is affected.
- Contact your study analyst or IRB Listserv with questions- irb@emory.edu

Questions?

