Institutional Review Board (IRB) Review

Research Recruitment & Advertising

Office of Research Integrity

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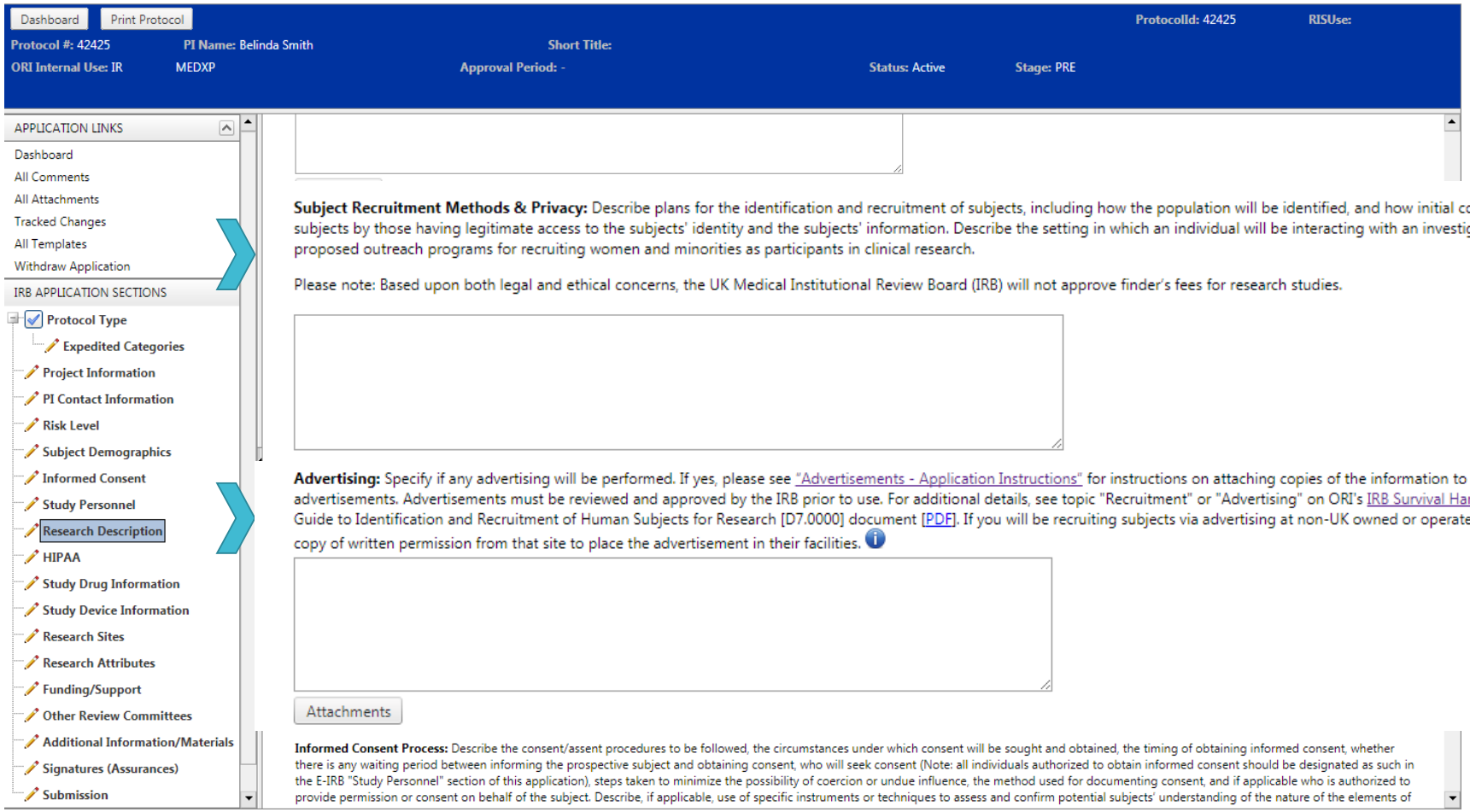
IRB Review

Federal regulations require the IRB to review the methods and material that investigators propose to use to recruit subjects.

Office for Human Research Protection (OHRP) IRB Guidance
www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-written-irb-procedures/index.html

Food and Drug Administration (FDA) Information Sheet
Recruiting Study Subjects
www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

Investigators Propose Recruitment Plans & Advertising Materials in the Research Description section of the E-IRB Application



IRB Guidance

The University of Kentucky provides investigators with practical guidance on developing recruitment plans that:

- respect personal rights to privacy
- promote equitable enrollment, and
- avoid coercion or undue influence of potential subjects.

The following slides provide general information and direction based on the IRB Guidance.

UK IRB Investigator Recruitment & Advertising Guidance
www.research.uky.edu/ori/SOPs_Policies/7-Recruitguidance.pdf

Prohibited Recruitment Practices

Based on legal and ethical concerns, the UK IRB does not approve finder's fees in research studies. Finder's fees are any payments to physicians or other professionals for referring individuals to research studies.

The IRB also prohibits accepting recruitment bonus from sponsors to accelerate recruitment, as the practice may place potential subjects at risk of coercion or undue influence.

Recruitment of Potential Subjects Identified through Review of Private Records

- HIPAA's "preparatory work" option allows individuals who normally have health record access, to view Protected Health Information (PHI) to identify potential subjects. However, PHI may not be removed from the covered entity during the review.
- For hospital based studies an investigator may approach a potential subject if they have a treatment relationship. Otherwise, the investigator is recommend to seek approval from or engage potential subject's attending physician or clinical provider.
- Cold calls or direct mailings from a researcher unknown to the potential subject are generally not acceptable.

Advertising to Public

IRB Review

IRB reviews all recruitment & advertising materials including:

- "Dear Dr." Letters;
- flyers/ads;
- videos;
- radio scripts;
- sponsor's national advertising materials; &
- ads placed on print or social media.

> Audio/Video -Submit text or script initially and follow with final taped audio or video file.

> Print – Submit PR approved copy

Ad Development Do's and Don'ts

- state clearly that the program of study is RESEARCH (insert word '**Research**' before 'study' or 'project');
- show affiliation with University of Kentucky;
- provide contact information;
  - Investigator's name , (i.e. use John Smith, MD instead of Dr. John Smith); and/or
  - Contact instruction, (e.g., phone, email, URL)
- purpose of study; and
- be respectful and appropriate.

MAY

- summarize criteria that will be used to determine eligibility;
- list time or other commitment required;
- list location of research;
- potential benefits; and
- state that subjects will be paid or compensated for their time or travel.

DON'T

- Make safety, effectiveness, superiority claims or imply favorable outcome beyond what is stated in consent;
- state "*New Drug*", "*New Treatment*", etc.;
- state *"study has been approved by UK IRB"* – as may be misconstrued by subject as an endorsement;
- promise "free medical treatment"; or
- emphasize rewards or financial compensation.

Is it permissible to list payment amounts?

The IRB considers whether listing payment amounts could be considered as 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 subjects.

- For other studies, the IRB considers requests to list payment amount on a case-by-case basis.

Other Required Review of Advertising Materials

UK Public Relations (PR) & Marketing Review

Print and media advertisements that will be presented to the public require review by UK Public Relations and Marketing to ensure compliance with UK graphics standards and equal opportunity language. www.uky.edu/prmarketing/

Investigators are responsible for obtaining PR review

- For health-related advertisements: Mallory Powell, mallory.powell@uky.edu.
- For all non-health related, advertisements: Kathy Johnson, kathy.johnson@uky.edu or
- Utilize Center for Clinical & Translational Sciences (CCTS) Marketing -incorporated PR review in ad development process www.ccts.uky.edu/ccts/participant-recruitmentmarketing

Distribution of Print Ads/Flyers

Obtain verbal approval to post advertising/flyers in community settings and letter of agreement when going into a faculty to recruit or conduct recruitment activities.

Using Social Media For Advertising & Recruitment

Applicable policies and guidance

- UK Social Media Policies and Guidelines (AR 10:4).

  If you identify yourself as UK personnel on your personal site, state "views expressed are not necessarily those of the institution".

- UK IRB Investigator Recruitment & Advertising Guidance.

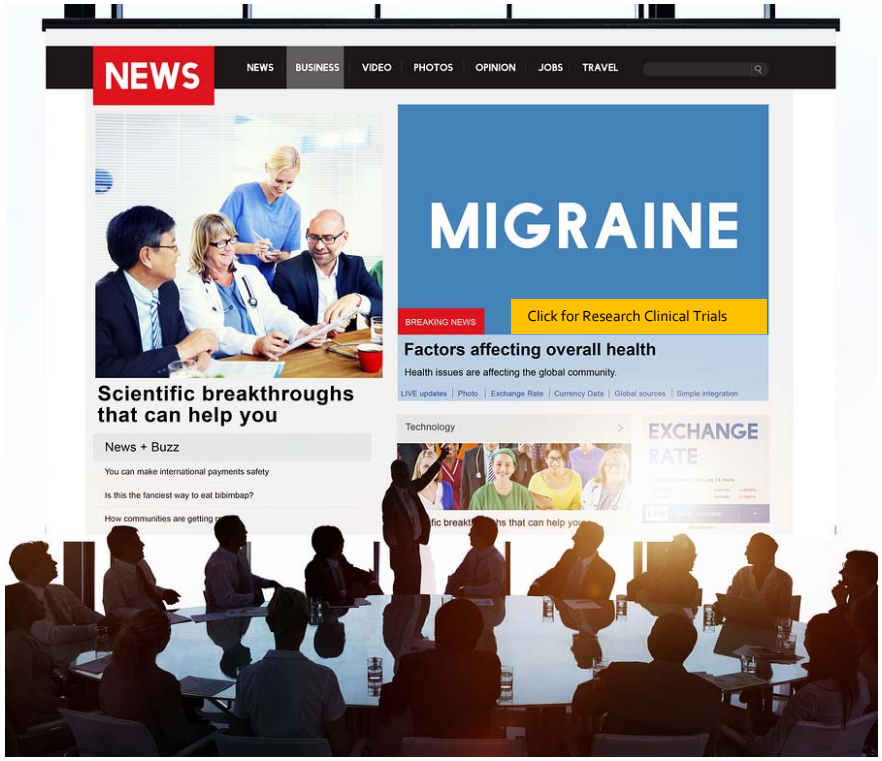
- Online platform's Terms of Use (TOU) and Conditions.

Plan to Monitor Social Media Posts

- Social media can provide an effective tool for reaching potential subject populations. However, postings made in cyberspace may take on a life of their own.
- 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 (e.g., *un-blind treatment, effectiveness claims*).

IRB Review of Social Media Advertising

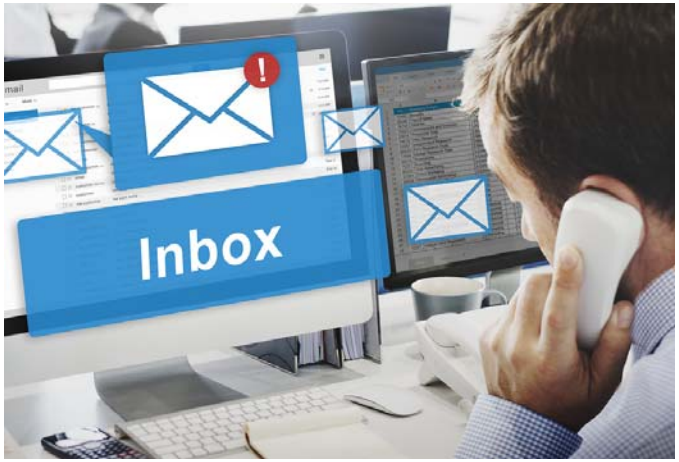
- Provide the IRB with a copy or screen shot of the ad or post including text, images, hashtags…



#drugstudy
#headachetrial
#migraineresearch

Plan for managing response to Advertising

Be available to handle the response to public advertising.



Once enrollment is closed, be sure to remove, replace or disable study-specific advertising.

Pre-Screening of individuals who respond to Advertising

- If using a pre-screening process (e.g., *phone, in- person, email, online*) to assess potential eligibility, describe process and provide script & sample questionnaire for IRB review.
- Provide brief overview and for interested potential subjects, collect information directly related to eligibility & suitability.
- Protect the self-disclosed protected health or private information for those that meet and those that fail to meet pre-screening criteria (e.g., destroy or securely store).
- Obtain permission to retain information for those that fail to meet pre-screening criteria.

Example of Permission to retain & contact for future research

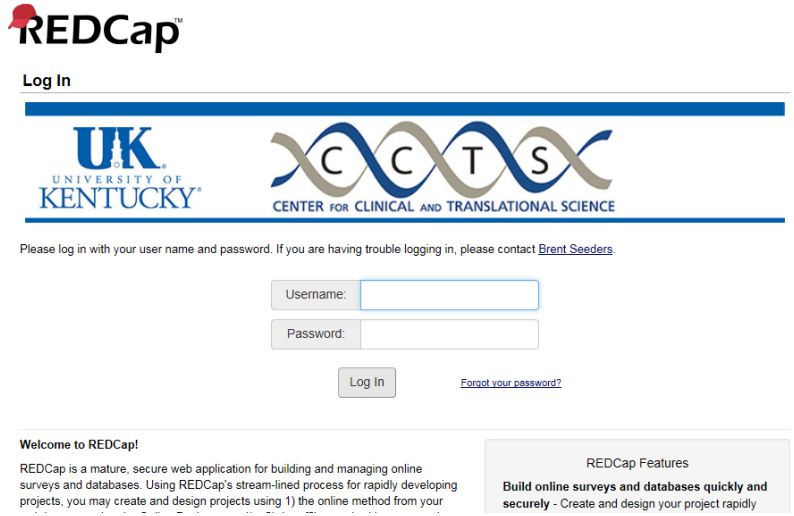
Permission for investigator to retain information and contact individual with future study opportunities (include if applicable):
Do you give your permission for _____(*insert investigator or staff*) to keep your answers on file and contact you regarding your willingness to participate in future research studies about _____(*insert name of disease, condition, or topic area)*?

☐ Yes, _____ may keep my answers and contact information and contact me with future study opportunities.
☐ No. I would like my answers and contact information destroyed when the ____ research study is over.

Online Pre-Screening

Online pre-screening may be efficient for investigator and convenient for potential subjects.

- Instructions for using REDCap Online Pre-Screening www.ccts.uky.edu/ccts/sites/default/files/Prescreening%20using%20REDCap.docx



https://redcap.uky.edu/redcap/

Contacts for IRB Questions

UK Office of Research Integrity (ORI)

- Helene Lake-Bullock, Director
  (859) 257-9428 hlbullo@email.uky.edu
- Belinda Smith, Research Education Specialist
  (859) 323-2446 belinda

CCTS Participant Recruitment Services

The CCTS Participant Recruitment / Marketing services can assist with ad development, distribution, and other recruitment services.

http://www.ccts.uky.edu/ccts/participate-research

CCTS Contacts for Marketing & Advertising Services

UK Center for Clinical and Translational Science (CCTS)

- Roxane Poskin, CCTS Participant Recruitment, Manager, roxane.poskin@uky.edu, 257-7856.
- Mallory Powell, CCTS Communications Director, mallory.powell@uky.edu, 323-6363


THANKS