

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

The screenshot displays the E-IRB application interface. At the top, a blue header bar contains navigation links for 'Dashboard' and 'Print Protocol', along with protocol details: 'Protocol #: 42425', 'PI Name: Belinda Smith', 'Short Title:', 'Approval Period: -', 'Status: Active', and 'Stage: PRE'. Below the header, a sidebar on the left lists 'APPLICATION LINKS' and 'IRB APPLICATION SECTIONS'. The 'Research Description' section is selected and highlighted with a blue arrow. The main content area is divided into two sections. The first section, titled 'Subject Recruitment Methods & Privacy', contains a text box with the following text: 'Describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information. Describe the setting in which an individual will be interacting with an investigator. If applicable, describe proposed outreach programs for recruiting women and minorities as participants in clinical research.' Below this text box is a note: 'Please note: Based upon both legal and ethical concerns, the UK Medical Institutional Review Board (IRB) will not approve finder's fees for research studies.' The second section, titled 'Advertising', contains a text box with the following text: 'Specify if any advertising will be performed. If yes, please see "Advertisements - Application Instructions" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment" or "Advertising" on ORI's IRB Survival Handbook web page for the PI Guide to Identification and Recruitment of Human Subjects for Research [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.' Below the text box is an 'Attachments' button. At the bottom of the page, the 'Informed Consent Process' section is partially visible, starting with the text: 'Describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent (Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application), steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of

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

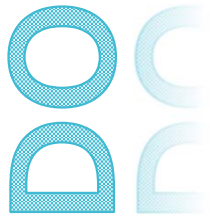
IRB reviews all recruitment & advertising materials including:

- “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
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

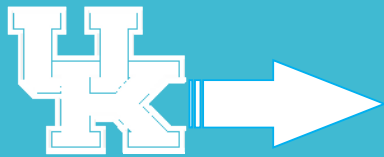
UK Public Relations (PR) & Marketing Review

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 facility to recruit or conduct recruitment activities.





Using Social Media For Advertising & Recruitment


Applicable policies and guidance

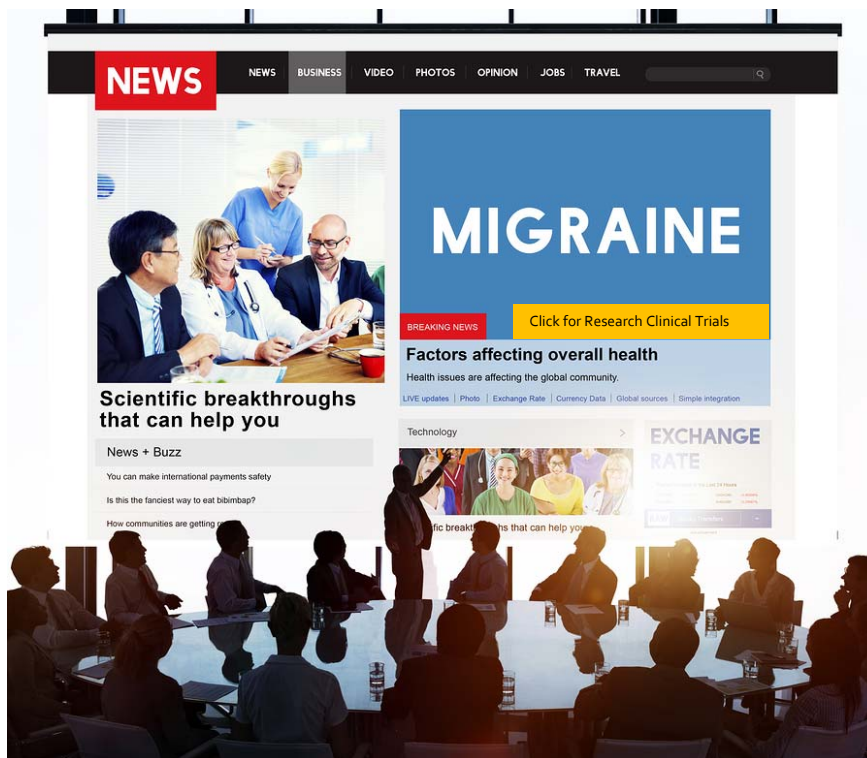
- UK Social Media Policies and Guidelines (AR 10:4).
If you identify yourself as UK personnel on your personal site, state "views expressed are not necessarily those of the institution".
- UK IRB Investigator Recruitment & Advertising Guidance.
- Online platform's Terms of Use (TOU) and Conditions.

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):

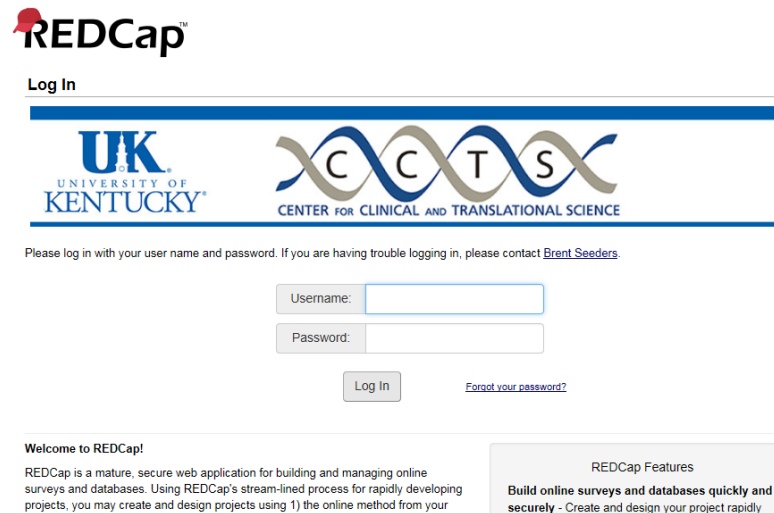
Do you give your permission for _____ (*insert investigator or staff*) to keep your answers on file and contact you regarding your willingness to participate in future research studies about _____ (*insert name of disease, condition, or topic area*)?

- 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



The screenshot shows the REDCap login interface. At the top left is the REDCap logo. Below it is a "Log In" link. A blue horizontal bar separates the header from the main content. Below the bar are the logos for the University of Kentucky and the Center for Clinical and Translational Science (CCTS). Below these logos is a login form with fields for "Username:" and "Password:", a "Log In" button, and a "[Forgot your password?](#)" link. At the bottom, there is a "Welcome to REDCap!" message and a "REDCap Features" box with the text: "Build online surveys and databases quickly and securely - Create and design your project rapidly".

<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.



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About Us

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Education & Career
Development

Funding
Opportunities

Cores

Research
Networks

Participate In
Research

Participate In Research

You can make a difference through research

Researchers are working hard to identify new treatments and strategies to improve health and to understand the diseases that make us sick, but in order to succeed they need both healthy research participants and participants with medical conditions. You can make a difference by participating in research. Health research ranges from simple questionnaires and screenings to clinical research studies (clinical trials) of investigational drugs and devices.

Join us in discovery.

There are three ways for you to learn more and get involved in research studies at the University of Kentucky: You can see Current Studies at UK, join ResearchMatch, which connects potential volunteers with researchers, and you can Learn more about participating in research.



Featured Studies



<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

