Objective

- Clarify roles in research advertising development, review and approval.
  - Office of Research Integrity (ORI)
  - Institutional Review Board (IRB)
  - Public Relations (PR)
  - Center for Clinical and Translational Science (CCTS)

These units collaborate to facilitate compliant subject advertising and streamline both the PR and IRB approval process by incorporating a number of checks and balances to promote compliant ad development, preferably at the front end.
Recruitment Advertising Materials

Study Flyers

TV/Cable ads

Bill Boards

and More…

Brochures

Internet ads

Newspaper ad

Radio scripts

An Equal Opportunity University

This study is performed by:
• University of Kentucky
• Vanderbilt University

This study is funded by:
• National Institutes of Health
• American Heart Association
• American Diabetes Association
• American College of Sports Medicine

You may be eligible to participate if you:
• are a male or female between the ages of 21-65;
• lean or obese (BMI 20-40); or
• do not have diabetes.

You will be compensated at the end of the study.

For more information, please contact Stacie BeBout: 859-323-9987 or email staciebebou@uky.edu

University of Kentucky College of Medicine
www.UKclinicalresearch.com

Getting Back in Groove for Health

Research Investigator Karyn Esser, PhD, at the University of Kentucky College of Medicine is conducting a clinical research study to understand the normal rhythms of sleep, wake, eating and physical activity that people go through on a daily basis.

You may be eligible to participate in this study if you are:
• generally Healthy or Diabetic;
• overweight or obese;
• ages 50-70;
• able to do at least light physical activity.

For more information about this study, contact: Stacie BeBout
Phone: 859.323-9987
Email: staciebebou@uky.edu

Newspaper ad:

Version 1:
Is this your first pregnancy? Would you like to participate in a study about birth decisions and preterm birth? The March of Dimes and researchers at the University of Kentucky want to understand what women know about preterm birth and how women make birth decisions.

What would I have to do to participate?
You would need to attend a focus group with other pregnant women and talk about giving birth and preterm birth. The focus group lasts approximately an hour.

You will receive a $10 gift card for participating. Snacks provided.

To learn more, please call or text Sarah Vos at 895-221-9476 or email pregnancyky@gmail.com by Oct. 31.

Version 2:
Is this your first pregnancy? Would you like to participate in a study about birth decisions and preterm birth? The March of Dimes and researchers at the University of Kentucky want to understand what women know about preterm birth and how women make birth decisions.

What would I have to do to participate?
You would need to attend a focus group with other pregnant women and talk about giving birth and preterm birth. The focus group lasts approximately an hour.

You will receive a $10 gift card for participating. Snacks provided.

To learn more, please call or text Sarah Vos at 895-221-9476 or email pregnancyky@gmail.com by Nov. 15.

Version 3:
Attention new moms: Did you have a C-section or an induction before 39 weeks? Would you like to participate in a research study?

The March of Dimes and researchers at the University of Kentucky want to understand how women make birth decisions and what women know about preterm birth.

What would I have to do to participate?
You will need to take part in an interview, where you would talk about your pregnancy and your birth experience. The interview lasts approximately an hour and can be scheduled at a time and place convenient to you.

You will receive a $10 gift card for participating.

To learn more, please call or text Sarah Vos at 895-221-9476 or email pregnancyky@gmail.com by Nov. 15.

Newspaper ad:

Internet ads

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www.UKclinicalresearch.com
TWO approvals needed for research advertising:

1. UK Public Relations and Marketing approval
2. IRB approval
PR 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.

- For health-related advertisements: Mallory Powell, mallory.powell@uky.edu.

- For all non-health related, advertisements: Kathy Johnson, kathy.johnson@uky.edu
PR Review takes into account:

- ORI Recruitment Guidance Document
  www.research.uky.edu/ori/SOPs_Policies/7-Recruitguidance.pdf

- UK graphic standard
  www.uky.edu/Graphics/

- Required photo releases
  www.uky.edu/PR/Photo-Image_consent_form.pdf
Advertising that needs review by PR:

- Any piece referencing UK or UK researchers;

- Any piece that will be distributed to the general public via mass media or grassroots distribution;

- Any piece that will be distributed within campus (i.e. Flyer posted in break room for questionnaire study of employee satisfaction); or

- PR will only review initial ad, modifications will not need PR review.
Exception from PR requirement:

- Nationally developed campaign pieces where only mention of UK is in the attached contact information (i.e. National advertising for multi-site sponsored trial with central call center and/or local site contact info);

- Recruitment Letters; or

- Minor changes such as changes to phone, email, or coordinator name.
Submit clean and PR stamped ad to IRB.

Once approved use clean copy of ad for recruitment.

Are you an athlete who has been injured in the past?

Researchers at the University of Kentucky are currently enrolling participants in a research study in investigating the effect of injury on return to activity in athletics. We are recruiting collegiate athletes who have been medically cleared for sport participation to be monitored for the occurrence of injury over 1 year.

You may be eligible to participate if you:

- Are a collegiate athlete between the ages of 18-35
- Have been medically cleared to participate in your sport

For more information, please contact
Research Investigator: Tim Uhl, PhD, ATC, PT, FNATA
Phone: (859) 218-0858
Email: tluhl2@uky.edu

OR

Co-Investigator: Aaron Sciascia, MS, ATC, PES
Phone: (859) 258-8506
Email: aaron.sciascia@uky.edu

www.UKclinicalresearch.com
IRB Review
IRB Review of Recruitment Plans

IRBs review recruitment plans to ensure methods are fair, equitable, avoid undue influence, and protect privacy.

- The *IRB Guide to Identification & Recruitment of Prospective Subjects* outlines recruitment strategies permitted or prohibited by the IRB and includes guidance on development of recruitment materials.
For hospital based studies an investigator may approach a potential subject if they have a treatment relationship. Otherwise it is best to seek approval of potential subject's attending physician.

UK IRB policies prohibit use of finder’s fees or recruitment bonuses.

Cold calls or direct mailings are generally not acceptable for privacy reasons.

Investigator may send IRB approved recruitment letters with response card for potential subject to return IF they agree to be contacted.
Submit recruitment plans

- Describe plans for the identification and recruitment of participants in IRB Research Description, **Form B**, #5: Subject Recruitment Methods and Privacy.

- Include contingency recruitment plans for approval in case initial strategies are not sufficient to complete enrollment.

* For your convenience, the CCTS has sample language available describing numerous recruitment strategies including available CCTS advertising services.
IRB Ad Review Requirement

The IRB reviews advertising materials to assure that they are not unduly coercive and do not promise results beyond what is outlined in the consent and the protocol.

- Advertising materials must be reviewed and approved by the IRB prior to use.

- Such materials include PR approved flyers/ads, videos, radio scripts, sponsor’s national advertising materials, etc.
Ad submission forms

Submit with initial IRB approval (Form L) or as a protocol Modification Request for approved studies.

The IRB Form L:
- guides investigators to submit all potential subject recruitment materials for IRB review;
- directs investigators to UK Public Relations for review of print and media advertisements; and
- provides links to optional CCTS flyer development and marketing services available upon request to UK investigators at no cost.
Advertising Guidelines –

Ads must

- state clearly that the program of study is research;

- show affiliation with University of Kentucky;

- provide contact information;
  - Investigator's name, and/or
  - Person to contact, and/or
  - Contact's phone and/or
  - e-mail, and/or
  - URL

- list purpose of study; and

- be respectful and appropriate.
Recruitment material/advertising may

- summarize criteria that will be used to determine eligibility;
- list time or other commitment required;
- list location of research;
- briefly list participation benefits;
- the time or other commitments required; and
- state that subjects will be paid or compensated for their time or travel, but should not emphasize payment.
Must Not:

- include coercive language;

- claim, either explicitly or implicitly, that the test article is safe or effective for the purpose under investigation; or that it is equivalent or superior to any other treatment;

- state “New Drug”, “New Treatment”, “New Device” etc without explaining that test article is investigational;

- promise “free medical treatment” if only providing study related care at no cost; or

- emphasize rewards or list dollar amounts for Phase I-III clinical trials or other significant risk research.
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.
Additional ad development & approval tips

- Use staff credentials vs. title (i.e. use John Smith, MD instead of Dr. John Smith).

- Insert word ‘Research’ before ‘study’ or ‘project’.

- Do not include statement that “study has been approved by UK IRB” – as may be viewed by subject as an endorsement.

- Submit text for taped advertising to the IRB initially and follow with final taped audio or video file.

- Get verbal approval to post advertising/flyers in community settings and letter of agreement when going into a faculty to recruit or conduct recruitment activities.
Potential Research
Participant Resources
Click on the CCTS Service Request Form, and select Participant Recruitment located in Clinical Services.
Participant Recruitment Resources

Participant Recruitment and Marketing provides compliant advertising recruitment materials for studies and develops a strategic ad campaign with the PI using various free and at cost media methods.

To discuss services, please contact:

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

ccts.uky.edu/ccts/participant-recruitmentmarketing
Participate in Research

www.ukclinicalresearch.com

Registries:
ResearchMatch
Ky Women’s Health Registry

Recruitment Websites:
UK Current Studies
UK HealthCare_Clinical Trials
CenterWatch.com

Recruitment Videos:
5 Clinical Trial Videos

Wall Mounts:
5 recruitment wall mounts
In Ky Clinics and Hospitals

You can make a difference through research.
Did you know that you can help others by participating in research? Health research affects every aspect of our daily lives, from the over-the-counter medications we take to the diets we follow and the health of our environment. But research needs healthy participants as well as those with medical conditions in order to move forward. All too often, studies are forced to end early because there aren’t enough volunteers, which means that many important questions go unanswered and treatment options remain limited.

You can make a difference through participating in research. Health research is much more than clinical trials for rare diseases and sometimes it’s as simple as a questionnaire or a screening. There are two ways for you to learn more and get involved: You can join ResearchMatch, which connects potential volunteers with researchers, and you can also see Current Studies at UK.

ResearchMatch helps researchers and potential volunteers to connect.

ResearchMatch is an easy-to-use, secure, research participant registry that brings together volunteers who are interested in research, and researchers who are looking for participants for their studies. Joining is free and takes just a few minutes. Simply register and wait to be contacted, or “matched,” to studies that might interest you. You always have the chance to participate or not. You can also search for specific medical conditions and studies on the “About” or “Volunteers” page. Individuals under the age of 18 must be enrolled by a parent or guardian.
The CCTS helps investigators with their participant recruitment efforts. Including customized recruitment plans and the use of ResearchMatch.

ResearchMatch is a national NIH/CTSA registry operated by Vanderbilt University University a partner of the UK CCTS. It is a free recruitment tool and feasibility analysis resource that connect participants with researchers.

ResearchMatch.org/uky
UK HealthCare
http://ukhealthcare.uky.edu/Patients/trials/

Participate in research

You can make a difference through research.

Research positively impacts the lives of millions of people every day, but research needs you to keep it moving forward – for your family, community and the health of people everywhere. When researchers and volunteers connect, it accelerates the recruitment process of research studies. This can make a big difference in obtaining successful research outcomes that may lead to future medications, treatments and healthier lives for everyone.

ResearchMatch helps researchers and potential study volunteers connect.

What is ResearchMatch.org?

ResearchMatch is an easy-to-use, secure, volunteer research participant registry that brings together two groups of people who are looking for one another: (1) willing volunteers who are trying to find research studies, and (2) researchers who are looking for people to participate in their studies. (Individuals under the age of 18 must be enrolled by a parent or guardian.)

Consider making a difference by volunteering as a research participant through ResearchMatch.org. Joining is free and takes just a few minutes. Registering for ResearchMatch does not require you to participate in any study of any kind. Instead, you simply register and wait to be "matched," or contacted, about studies that might interest you. If you are contacted about participation in a study, researchers will fully explain to you what the study is about and what your participation will require. At that time you can decide if you want to participate.

Current Studies at the University of Kentucky
Research
http://www.research.uky.edu/
ORI Research Participants Website
http://www.research.uky.edu/ori/human/participants.html

Provides resources and education material for potential research participants. Includes materials for parents, Legally Authorized Representatives and Spanish education materials.

Research Participants

Research involving human subjects is based on a commitment to advance human welfare, knowledge and understanding, and to examine cultural dynamics. Researchers, universities, governments and private institutions undertake or fund research involving human subjects for many reasons: for example, to alleviate human suffering, to validate social or scientific theories, to dispel ignorance, to analyze policy, and to understand human behavior and the evolving human condition. [Interagency Advisory Panel on Research Ethics]

Someday, you or a family member may want to take part in a research study. If this happens, the information here may help you make the right decision.

To jump to a topic, click on your choice in the menu below:

Information about Participating in Research

What is a Clinical Trial?

For Parents

Contact Information

What is an Institutional Review Board (IRB)?

What does Accreditation Say About UK?

Información Sobre la Investigación - en Español
Contacts

- **UK Office of Research Integrity**
  Helene Lake-Bullock, Research Compliance Officer
  (859) 257-9428 hlbullo@email.uky.edu

  Belinda Smith, Research Education Specialist
  (859) 323-2446 belinda.smith@uky.edu

- **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
References

- ORI Recruitment Guidance Document
  http://www.research.uky.edu/ori/SOPs_Policies/7-Recruitguidance.pdf

- UK graphic standards
  www.uky.edu/Graphics/

- OHRP Guidebook- Identification and Recruitment of Subjects
  http://www.hhs.gov/ohrp/archive/irb/irb_chapter4.htm#f12

- FDA Guidance on Recruiting Study Subjects
  http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm