

# Research Advertising

## Quick Overview of Ad Development & Approval





# Objective

- Clarify roles in research advertising development, review and approval.
  - Office of Research Integrity (ORI)
  - Institutional Review Board (IRB)
  - Public Relations (PR)
  - Clinical Research-Development & Operations Center (CR-DOC)

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.



# PR Review

# PR Review takes into account:

- ORI Recruitment Guidance Document  
[www.research.uky.edu/ori/SOPs\\_Policies/7-Recruitguidance.pdf](http://www.research.uky.edu/ori/SOPs_Policies/7-Recruitguidance.pdf)
- UK graphic standard  
[www.uky.edu/Graphics/](http://www.uky.edu/Graphics/)
- Required photo releases  
[www.uky.edu/PR/Photo-Image\\_consent\\_form.pdf](http://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
- ✓ Substantive modifications in existing piece.



## 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 revisions to pieces previously reviewed by PR (i.e. phone number).



# Two routes to PR review

1. Investigator develops advertisement piece and submits directly to PR
2. The Clinical Research Development and Operations Center (CR-DOC) develops the piece and obtains PR review on behalf of the investigator.





# Additional CR-DOC services?

CR-DOC makes IRB revisions to tracked ad and will begin promotional activities (listed below) only after receiving a copy of the IRB approval.

[www.ccts.uky.edu/CRDOC/participants.aspx](http://www.ccts.uky.edu/CRDOC/participants.aspx)

- Develop strategies and advertisement for research participant recruitment campaigns
- Radio, newspaper, internet copy writing, cost negotiations and placement
- Layout of advertising flyer, brochures, educational materials for distribution
- Dedicated research wall mounts and websites, metrics available
- New Research Participant Self-referral Database
- Provide UK PR Graphic Standard Policies and FDA compliance assistance
- Coordinate with UK Healthcare for additional promotional campaigns, press releases, etc.
- Research spotlights to promote research studies and physician
- Booth at Community health fairs, festivals, conferences, etc. (Can provide research information to those attending other events.)
- Provide recruitment presentations to investigators and research staff



# IRB Review



# IRB Submission

- The ORI forms website contains all required documents for submission for IRB review.  
[www.research.uky.edu/ori/human/HumanResearchForms.htm](http://www.research.uky.edu/ori/human/HumanResearchForms.htm)
- IRB Form L guides investigators to submit all potential subject recruitment materials for IRB review.
- In addition, it directs investigators to UK Public Relations for review of print and media advertisements that go out to the public.



# IRB Review

- Submit PR approved ad with initial IRB approval (or via modification if study already approved)
- IRB may want the PR marked up version as well as the clean revised version.
- IRB has final say in review process.
- IRB should see/hear final product (print, video, audio).
- IRB may review and approve the wording of the advertisement prior to taping then review final taped message via expedited procedures.



# IRB Advertising Guidelines –

# MUSTS

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
- show RESPECT.



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.

## ***STIPEND PAYMENT - \$ amount***

- For Phase I-III clinical trials and other significant risk research it is not permissible to state the amount to be paid to potential subjects.
- For all other research protocols the IRB will make the decision of whether amount to be paid may be posted in the recruitment materials on an individual protocol basis.



## 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.



# Additional tips for IRB approval

- 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 state that "*study has been approved by UK IRB*" – as could be seen as endorsement.
- Describe all potential recruitment activities in #5 of research descriptions.
- 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 (as outlined in IRB Form N).



# IRB Guide to Identification & Recruitment of Prospective Subjects

[www.research.uky.edu/ori/SOPs\\_Policies/Recruitguidance.doc](http://www.research.uky.edu/ori/SOPs_Policies/Recruitguidance.doc)

- Investigator may approach a potential subject if they have a treatment relationship.
- For hospital based study- seek approval of potential subject's attending physician.
- Outpatients requires approval of potential subject's primary care physician.
- Consistent with state law, UK IRB does not approve finder's fees.
- Cold calls or direct mailings are normally not acceptable.
- Investigator may send IRB approved letter with enclosed card for potential subject to return IF they agree to be contacted.

Describe all recruitment plans  
under #5 of IRB Form B



# Potential Research Participant Resources

# CR-DOC Research Participant Self-referral Database

<http://ccts.uky.edu/Participants/Research.aspx>

The screenshot shows the homepage of the University of Kentucky Clinical Research Self-referral Database. At the top, there is a navigation bar with links for Academics, Athletics, Research, Site Index, and UK HealthCare, along with a search box. Below this is a large banner featuring a photograph of a young girl and a woman. The banner text reads "Research Participants" and "make it possible to imagine a healthier tomorrow treatments". To the right of the banner is the University of Kentucky logo and the text "Clinical Research Development and Operations Center". Below the logo are three buttons: "JOIN", "LOG IN", and "CURRENT STUDIES".

This Web site presents information to help you decide if participating in a research study is right for you. If you are interested in participating in a University of Kentucky clinical research study, please submit your information to the Clinical Research Self-referral Database or email [ukclinicalresearch@uky.edu](mailto:ukclinicalresearch@uky.edu) or call 859-257-7856 for more information.

*We Make Research Happen!*

**Why Participate in Clinical Research Studies?**

- [Understanding Clinical Research Studies \(Trials\)](#)
- [Frequently Asked Questions](#)
- [For Parents: Why Clinical Research Studies in Children are important?](#)
- [Question and Concerns](#)

**Join the Clinical Research Team**

- [What is the Clinical Research Self-referral Database?](#)
- [Privacy Agreement for Self-referral Database](#)
- [How to Find Us](#)
- [Contact Us](#)

**Learn More About Research at UK!**

- [Current Studies](#)
- [View Research Investigator Spotlight](#)
- [Center for the Advancement of Women's Health](#)
- [CenterWatch](#)
- [CISCRP](#)
- [Clinicaltrials.gov](#)

**JOIN NOW!**

facebook | twitter | LinkedIn | CISCRP

# CR-DOC Clinical Research Volunteer website

[www.ukclinicalresearch.com](http://www.ukclinicalresearch.com)

- Provides education material and current study advertising for potential clinical research subjects.

UK UNIVERSITY OF KENTUCKY ACADEMIC PROGRAMS ATHLETICS UK HEALTHCARE RESEARCH SITE INDEX Search UK

UK UNIVERSITY OF KENTUCKY Clinical Research Development and Operations Center (CR-DOC)

Research Participants  
advance future medical treatments

You Can Make Research Happen!  
Please help us to make a difference in advancing tomorrow's health care!

UK Clinical Research Development & Operations Center (CRDOC) UK Research Center for Clinical and Translational Science (CCTS) Research News VP for Research Faculty Research Support Research Grants

Studies currently enrolling at the University of Kentucky

All links are pdf's files

Healthy Volunteer Studies

- Are You Learning or Have Learned Mandarin Chinese
- Brain Stimulation Research Study for Healthy Participants
- Brain Stimulation and Treadmill Training for Stroke Patients
- Fatigue and Muscle Research Study
- Healthy Nursing Mothers Needed for Clinical Research Study
- Healthy Adult Volunteers Needed to Donate Blood
- Healthy Adult Volunteers Needed to Donate Bone Marrow
- Healthy Volunteers Needed for Behavioral Studies
- Individual Needed to Participate in Study on Couple Relationship
- Research Study of Alcohol and Cognitive Processes
- Research Study to Test Effects of Flexibility Training for Mature Populations
- Research Study on Muscle Strength and Body Composition Changes Throughout Life
- Study on the Effects of Alcohol
- Triathletes/Cyclists Needed for a Research Study
- Volunteer for a Study of Voice using Functional MRI
- Is Your Home at Risk for Radon?

UK Clinical Research Development & Operations Center (CRDOC)

Current Studies

UK Research Sites

Volunteer Opportunities

Industry Information

Research Spotlight

Contact Us

How to Find Us

Home

Why Should I Volunteer?

# UK HealthCare

[www.ukhealthcare.uky.edu/patient/clinicalresearch.asp](http://www.ukhealthcare.uky.edu/patient/clinicalresearch.asp)

[For Patients](#) | [For Physicians](#) | [Education](#) | [Research](#) | [Giving](#) | [About UKHC](#) | [For Staff](#)

**UKHealthCare**

Search UK HealthCare

Search

Advanced Search

Ask a Question

[Home](#) | [Our Services](#) | [Find a Doctor](#) | [Make an Appointment](#) | [Health Information](#) | [Directions](#) | [Directory](#)

## UK HealthCare Clinical Research

UK HealthCare Clinical Research Development and Operations Center (CR-DOC) provides valuable services to patients, including the advancement of medicine through ongoing clinical research.

For information on participating in a research study browse our [current list of clinical research studies](#).

Each year, millions of people volunteer to participate in clinical research studies. Without participants, there would be no new therapies for diseases and disorders.

As part of the University of Kentucky's mission to improve medical care and treatment, UK faculty and staff actively participate in numerous clinical research studies for a broad range of medical conditions, such as Alzheimer's disease, asthma, breast cancer, cervical cancer, dental disorders, diabetes, heart failure, HIV AIDS, kidney disease, surgery, and more.

Learn more about clinical research and how you can make a difference in tomorrow's health care by being a research participant.

### Should you participate in a clinical research study?



Find answers to your questions about research studies by reading our informative HealthSmart! publication [Should you participate in clinical research study?](#) >

### CONTACT INFORMATION:

For more information on clinical research studies, e-mail [ukclinicalresearch@uky.edu](mailto:ukclinicalresearch@uky.edu), click one of the links below or call 859-257-7856.

- [Center for Clinical and Translational Science](#)
- [Clinical Research Development and Operations Center](#)
- [Participation](#)

### RESEARCH STUDIES

- [Clinical Research Study Opportunities](#)
- [Women's Health Registry](#)
- [For Kids: Research is Fun](#)
- [Public Trust](#)
- [Research Participant Protection](#)
- [Clinical Research Study Results](#)

### FOR MORE INFORMATION ON RESEARCH

- [CenterWatch Trials Listing Service](#)
- [Clinicaltrials.gov](#)
- [National Institutes of Health](#)
- [National Library of Medicine](#)

# Research

<http://www.research.uky.edu/>

The screenshot shows a Windows Internet Explorer browser window displaying the University of Kentucky Research website. The browser's address bar shows the URL <http://www.research.uky.edu/>. The website header includes the University of Kentucky logo and navigation links for Academics, Athletics, Research, Site Index, and UK HealthCare. A search bar is located in the top right of the header.

The main content area features a large banner with the title "Blindness insight" and a sub-headline: "Ambati team identifies key mechanism in dry macular degeneration, a disease affecting 10 million older Americans and causing blindness in more than 1 million. [Learn More >](#)". The banner image shows a close-up of a human eye with a red retinal scan overlay.

Below the banner is a "NEWS" section with four articles:

- ALLURE OF 'FORBIDDEN FRUIT' CAN STIFLE A ROMANCE**  
Tempted to keep your partner from clicking out a creative idea? Valentine's Day? Your strategy may backfire. [read more](#)
- RESEARCH EXPLORES LITTLE-UNDERSTOOD BRAIN DISEASE**  
Sandera Brown's recent paper on hippocampal atrophy is to be published in *BRAIN* journal. [read more](#)
- PROJECTION TECHNOLOGY DEBUTS WITH 'PORGY AND BESS'**  
New sonic projection technology developed by the UK Center for Visualization and Virtual Environments makes its theatrical debut Jan 28. [read more](#)
- VAN ELDIK AWARDED ALZHEIMER'S DRUG DISCOVERY RESEARCH GRANT**  
Ulrika Van Eldik, Director of the UK Sandera-Brown Center on Aging, received \$750,000 to further her research on a pill to treat Alzheimer's. [read more](#)

At the bottom of the page, there is a link for "more UK research news" and a footer with the text: "University of Kentucky | Updated February 21, 2011 by Alicia Gregory | [Get Adobe Reader for PDFs](#)". The browser's status bar at the bottom shows "Done", "Trusted sites", and a zoom level of 75%.



# ORI Research Participants Website

[www.research.uky.edu/ori/human/participants.html](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.

**UK** UNIVERSITY OF KENTUCKY  
Office of Research Integrity

## Menu

[ORI Home Page](#)

## 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](#)

[Información Sobre la Investigación - en Español](#)

[Contact Information](#)

[What is an Institutional Review Board \(IRB\)?](#)

[What does Accreditation Say About UK?](#)



# Additional Contact Information

- CR-DOC Marketing

Roxane Poskin

Manager, Participant Recruitment and Marketing

(859) 257-7856 Fax: (859) 257-1563

[roxane.poskin@uky.edu](mailto:roxane.poskin@uky.edu)

- PR

Keith L. Hautala

University of Kentucky Public Relations

1A Mathews Building

Lexington, KY 40506-0047

Phone: (859) 323-6363 EXT. 231 Fax: (859) 257-2635

[keith.hautala@uky.edu](mailto:keith.hautala@uky.edu)

- ORI Helene Lake-Bullock, Research Compliance Officer or

Belinda Smith, Research Education Specialist

(859) 257-9428 Fax: (859) 257-8995

[hlbullo@email.uky.edu](mailto:hlbullo@email.uky.edu)

[belinda.smith@uky.edu](mailto:belinda.smith@uky.edu)



# References

- ORI Recruitment Guidance Document  
[http://www.research.uky.edu/ori/SOPs\\_Policies/7-Recruitguidance.pdf](http://www.research.uky.edu/ori/SOPs_Policies/7-Recruitguidance.pdf)
- UK graphic standards  
[www.uky.edu/Graphics/](http://www.uky.edu/Graphics/)
- OHRP Guidebook- Identification and Recruitment of Subjects  
[http://www.hhs.gov/ohrp/archive/irb/irb\\_chapter4.htm#f12](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>