Participant Recruitment Services: Need Advertising?
March 16, 2015

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http://ccts.uky.edu/ccts/participant-recruitmentmarketing
Objectives:

- Overview of UK ad development & approval process
- FDA/IRB Guidelines: Mays, Musts and Don’ts
- Visually appealing ads and branding
**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: staciebebout@uky.edu

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**Radio copy template**

*You are willing to undergo* two blood draws. Snacks provided.

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**Study Flyer**

**Study Brochures**

**Current Studies: UKclinicalresearch.com**

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**UNIVERSITY OF KENTUCKY RESEARCH**

**How high is the fat in your blood after a meal?**

Research Investigator Philip Kern, MD, at the University of Kentucky College of Medicine is conducting a clinical research study to understand the connection between a high-fat meal with inflammation and the possible development of diabetes.

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);
- do not have diabetes.

You will be compensated at the end of the study.

For more information, please contact Stacie Bellout: (859) 323-9987 or email staciebebout@uky.edu.

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**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 would 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 859-221-9476 or email pregnancykv@gmail.com by Nov. 15.
Development of Advertising Materials

Flyers! Radio scripts! Print ads! Billboards! And more!

Two options:

1. You can do it yourself!
   - Flyer templates are available on the CCTS website
     http://ccts.uky.edu/ccts/participant-recruitmentmarketing

2. We can do it for you!
   - Complete a CCTS Service Request form
     http://ccts.uky.edu/ccts/ccts-service-request-forms
   - Select “Participant Recruitment”
Research Advertising Approval Process

TWO approvals needed for research advertising:

1. UK Public Relations and Marketing approval
2. IRB approval
UK Public Relations Approval Process

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
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 Approval Process

• Advertisements must be reviewed and approved by the IRB prior to use.
• Generally, the IRB is not required to review clinical trial website postings unless the information goes beyond directory listings of basic descriptive information.

Section 1, Form B, #5: Subject Recruitment Methods and Privacy
“Describe plans for the identification and recruitment of participants”
*CCTS has standard language available for your convenience.*

Section 4, Form L. Advertisements
research.uky.edu/ori/FormsHelp/S4L.htm
“If any materials will be used to recruit subjects for your research study, attach copies of the materials to be used (e.g. flyers, videos, radio scripts, sponsor’s national advertising materials, etc.).”
FDA/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
  • Email, and/or
  • URL address
• List purpose of study; and
• Show RESPECT.

research.uky.edu/ori/ORIForms/89-research-advertising-for-web.pdf
Recruitment material/advertising may
• Summarize criteria that will be used to determine eligibility;
• List time or other commitment required;
• List location research;
• Briefly list participation benefits;
• The time or other commitments required; and
• State that subject 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.
Examples of Compensation Levels Offered to Study Volunteers

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Visits</th>
<th>Compensation Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthritis</td>
<td>1-24</td>
<td>$100- $1,450</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>5-45</td>
<td>$150 - $1,350</td>
</tr>
<tr>
<td>Depression</td>
<td>1-50</td>
<td>$200 - $1,036</td>
</tr>
<tr>
<td>Type II Diabetes</td>
<td>2-28</td>
<td>$50 - $1,300</td>
</tr>
<tr>
<td>HIV</td>
<td>4-16</td>
<td>$50 - $1,160</td>
</tr>
</tbody>
</table>

Source: CSCR, 2013
IRB/FDA Advertising Guidelines – Don’ts

Must not

• 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, (e.g., 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 viewed by subject as an endorsement.
• Describe ALL potential recruitment activities in #5 of Research Description, Form B. (Example provided)
• 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).
Find 10 things wrong...

• Claims new, improved, safe
• Free medication (at no cost)
• Superior drug
• Coercive
• Phase II - $1,500
• An Equal Opportunity University (UK PR)
• Research study
You had me at…

- You have approximately 3 to 6 seconds to catch a person's attention.
- Ask a question in your opening title
- Visually engaging images
- Tone down the scientific language: 6th to 8th grade reading level.
- Know your audience, learn their demographics
- Brand and image – UK (TRUST)
- Where do willing participants find studies at UK?
Researchers are inviting you or your child to participate in a study to understand the effects of high body weight on the normal contraction in the heart.

The purpose of this study is to examine the function of the heart in children with high body weight compared to children with normal weight. Ultimately we are trying to understand why people who are overweight are more likely to suffer from heart disease.

You may be eligible to participate if:
- you are 8-18 years of age
- you are in the 95th percentile of weight for your age group
- you do not have diabetes
- you do not have any known chronic diseases (high blood pressure is ok)
- you do not have any metal implants or claustrophobia which would prevent you from being able to undergo magnetic resonance imaging (MRI)

For more information or to participate:
Call: 859-218-1611
Email: pedresearch@uky.edu
Website: www.ukclinicalresearch.com
Top Ways that People Report Finding out About Clinical Trials

- Internet: 46%
- The Media (TV, Radio, Newspapers): 39%
- eMail: 32%
- Research Center Ads: 28%
- My Physician or Nurse: 23%
- Mail: 21%
- Family/Friends: 13%

Percent Mention

Source: CISCRP, 2013; N=5,701 people worldwide
Patient-reported top sources of clinical trial information

- **Clinicaltrials.gov**: 38.2%
- **CenterWatch**: 27.6%
- **Health Associations Sites**: 11.1%
- **Commercial Health Portals**: 10.6%
- **SCT (CISCRP)**: 10.5%
- **Gov agencies**: 1.8%

CCTS is on 3 of these sites

Source: CenterWatch 2010 Survey, N=1,023 patients
Top Reasons People Choose to Participate in Clinical Trials

- To advance medicine: 33%
- To help improve the lives of others: 29%
- To help improve my condition: 15%
- To earn extra money: 5%
- To receive free medical care: 3%

Source: CSCR, 2013; N=5,701 people worldwide
Most Volunteers Who Are Ineligible for a Clinical Trial Don’t Search for Another

Source: CISCRT, 2013; N=4,425 people worldwide
Placement of Recruitment Materials

- Obtain population demographics
- Negotiate vendor costs
- Place ads on free locations
- Place ads on vendor locations
- Metrics on placement of materials
CCTS can also help you with…

- Developing and implementing a comprehensive recruitment plan
- Advertising your study through a variety of free and paid options, including:
  - Websites: UK Current Studies/Research Spotlights, CenterWatch
  - UK Public Relations: UKNow, Herald Leader Your Health Columns, media outlets
  - UKHealthCare Marketing: social media, patient mailings

[ccts.uky.edu/ccts/participant-recruitmentmarketing]
Please complete a CCTS Participant Recruitment Services request form, located on the CCTS Home page: ccts.uky.edu.

Help us spread the word about research!! Like us on Facebook, Twitter, and YouTube.
Upcoming CCTS Recruitment Lunch and Learns:

April 30, 2015
“How to have conversations with your patients about research”
John Slevin, MD, Neurology

May 11, 2015
Feasibility Searches & Recruitment Registries and Resources
Tammy Harper/Roxane Poskin

June 2015
Launch of Participant Recruitment Services Core
Phil Kern, MD
QUESTIONS?

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