USING SOCIAL MEDIA FOR PARTICIPANT RECRUITMENT

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SETTING THE STAGE: WHAT IS **INTERNET RESEARCH**?

- **Internet used as a tool for conducting research**
  - Examples: online survey, **subject recruitment**, email or chat interviews

- **Internet as a location or site for conducting research**
  - Examples: Collecting data about or observing online environments such as chatrooms, gaming sites, virtual worlds

- **Internet as a source of information**
  - Examples: data mining from social media site; collecting data from online datasets, databases, repositories
SOCIAL MEDIA & RECRUITMENT

- Regulatory and IRB issues related to the use of social media for participant recruitment
- Participant recruitment and social media at UK
- Leveraging social media for recruitment
- Case study: BioMotion Lab Facebook page

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
WHAT IS SOCIAL MEDIA AND WHY IT IS IMPORTANT?

The internet brings an entire new dimension to clinical research by offering a widely available medium in which the public, participants, and healthcare professional can:

1- Extend their reach
2- Exchange information
3- Build engaged communities

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
72% of internet users say they looked online for health information within the past year

18% of internet users have gone online to locate others with similar health concerns

52% of smartphone owners have used their phone to look up health or medical information

35% of adults have used the internet to try to determine what medical conditions they have

Source 2014-2012: pewinternet.org/fact-sheets/health-fact-sheet/
WHAT IS SOCIAL MEDIA?

An **Interactive** platform for electronic communications, used by groups of people to create, share, and exchange information.

This ability to identify, connect, and potentially align individuals can significantly amplify messages communicated through social media.
ALS ICE-BUCKET CHALLENGE

- 3 friends were all diagnosed with ALS, or Lou Gehrig’s disease.

- **Posted on Facebook:**
  - Families and friends (Cold Water) - mid 2013 to 2014
  - Golf Channel, Morning Drive - June 13, 2014
  - The Today Show: golfer Greg Norman challenged Matt Lauer, July 15.

- Millions saw and accepted the challenge or they wrote checks.

- Estimated $220 million when to organizations benefiting ALS.

“The ALS Organizations learned... social media is huge and potentially helpful force not to be ignored and it is critically important to how they engage with people in new and different ways. “

-- Meryl Weinberg, CEO of the National Health Council, non-profit patient advocacy group

*Source: CenterWatch Monthly January 2015*
#SAVE JOSH

Josh Hardy was a cancer-stricken 7 year old who had developed a serious viral infection with no acceptable treatments...

#SaveJosh social media blitz resulted in a new Phase III clinical trial within 4 days!
SOCIAL MEDIA CAN NETWORK TRANSPLANT PATIENTS

Doctors at The Ohio State University Wexner Medical Center say there's a critical shortage of viable organs.

So more patients are seeking organ donors and support online.

Quickly creating communities dedicated for a cause!

HOW DO WE CONNECT?

Research communities can connect through social media.

Facebook: 1 Billion users
YouTube: 1 Billion users
Twitter: 500 Million users
Instagram: 300 Million users
Pinterest: 70 Million users
RESEARCH SOCIAL MEDIA HAS BEEN SLOW STARTING

Why?

Lack of certainty in terms of:
• Review and approval
• Enforcement
• Effect on study integrity
• Return on investment
• Understanding of technology

The FDA is watching social media closely.

FDA cited ThermaSolutions for Off-label promotion on the basis that its tweets were broader than the clear indications

FDA cited AMARC Enterprises for Off-label promotion for using its product Facebook page to ‘Like’ an external post describing off-label use

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
WHAT ARE THE BOUNDARIES?

From the Nuremberg code of 1950 to now, there are no new regulations for social media.

We only have BROAD principles, like:
• IRB’s authority to review and approve all research activities
• Requirements to ensure that informed consent is appropriately sought
• Requirements to ensure that adequate provisions are taken to ensure the privacy and confidentiality of participants

1998 FDA guidance: Recruitment of participants using TV, radio and receptionist – very conservative on what needs IRB review and approval and treats all newer methods of advertisements as if print materials.

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
LIMITED DIRECTION ABOUT SOCIAL MEDIA FOR RECRUITMENT

In 2014, the FDA issued three draft guidance documents concerning the use of social media with the promotion of approved products. None are specific to research.

Main Takeaways include:

- Cannot blame the platform
- Responsible for all communication under your control
- Have to keep FDA informed of all your activities

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
HHS AND OHRP ON INTERNET RESEARCH

Health & Human Services:
The HHS protection of human subjects regulations do not specifically reference Internet research.

Office for Human Research Protections:
OHRP has no formal written guidance specifically on Internet research. They consider direct subject recruitment as part of the informed consent process, which is subject to IRB review.

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
What forms of online recruitment are used and what is reviewable by an IRB?

Recruitment tools include Web ads, Twitter streams, blog postings, YouTube videos, and push methods, such as email solicitations and texts. Links to online recruitment sites (e.g., Patients Like Me, Inspire) may also be provided in other media (television, newspaper, classified, public transit posters, robo-calls, etc.).

OHRP considers direct subject recruitment part of informed consent, which is subject to IRB review.

REGULATORY ISSUES RELATED TO INTERNET RESEARCH USING SOCIAL MEDIA

- What is “private”? 
- What is “identifiable”? 
- How to protect subjects’ privacy and confidentiality interests? 
- Minimizing risk when using sensitive online data
  - Current sensitivity vs. future sensitivity

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
WHAT IS REVIEWABLE SUBJECT MATTER?

• Any communication specific to a particular study that is clearly directed at current or future participants.

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
Recruitment using social media

- Using social media and online techniques must be approached with caution and regard for applicable policies and guidance such as the UK Social Media Policies and Guidelines (AR 1-.4) and the online platform’s Terms of Use (TOU) and Conditions or established policies and procedures.

- IRB review and approval prior to implementation of social media or online advertising is required. Describe specific platforms intended for use.

- Investigators must identify and comply with the TOU or policies and procedures of any social media platform or online advertising venue. Privacy policies, prohibited content, and limitations on location and frequency of postings are sometimes found in the user instructions or Frequently Asked Questions (FAQ) instead of the TOU (e.g., Craigslist FAQ).

- Research Advertising: research.uky.edu/ori/ORIForms/89-research-advertising-for-web.pdf

Source: http://www.research.uky.edu/ori/SOPs_Policies/7-Recruitguidance.pdf
Recruitment Materials

- Direct advertising for study subjects is the start of the informed consent and subject selection process and IRB review is required for direct recruitment materials that are intended to be seen or heard by prospective subjects to solicit their participation in a research study.

- The IRB reviews the final copy of printed advertisements. The IRB assures that the advertisements do not state or imply a favorable outcome or other benefits beyond what is outlined in the consent document and the protocol, or include exculpatory language.

- Advertisements to recruit participants are limited to the information the prospective participants need to determine their eligibility and interest. Examples of direct advertisement include: newspaper, radio and television advertisements, bulletin board announcements, recruitment posters, flyers, dear doctor letters, video recruitment tapes, and Internet postings.
Volunteers ages 60 to 75 needed for study of aerobic exercise

DYNATHAN J. JOHNSON
Contributing Gourmet
June 19, 2015

"Those who think they have not time for bodily exercises will sooner or later have to find time for illness."

That’s what British statesman Edward Stanley advised in 1673.

Sometimes we just have to do what we have to do.

Regular exercise has long been linked to stress reduction, improved mood, and the prevention or delay of disease and disability. Yet despite the well-known health benefits associated with physical activity, many of us find it difficult to exercise regularly. We say we’re too busy or too busy.

When we think of the benefits of exercise, we often focus on weight loss and weight management, but regular exercise has a positive effect on nearly every part of the body, from brain function to vision.

Quite simply, if your brain is not functioning well, the rest of your body won’t function well.

Recent research at the University of Kentucky College of Health Sciences might prompt us with another reason to jump into the pool, pound the pavement or push the pedals this summer. We discovered that older adults who are aerobically fit have better and stronger connections among some brain regions. These findings build on previous evidence demonstrating beneficial effects of exercise and aerobic fitness on the volume of the brain’s gray matter (nerve cells) in healthy older adults. We added to this evidence by demonstrating that the wires (axons) connecting these nerve cells, commonly referred to as “white matter,” appear to be more structurally similar in adults who exercise regularly. More cognitive abilities, such as being able to flexibly switch attention between tasks, have been linked to the structural makeup of these areas.

Building on these findings is a recently completed UK study demonstrating a link among heart function, aerobic fitness and blood flow to regions of the brain that is susceptible to Alzheimer’s disease. These findings are promising, and in order for UK to further establish these relationships, we need to show that aerobic training is the primary contributor to increased blood flow to these regions. The researchers recruited a group of volunteers, 60 to 75 years old, who are willing to participate in an individualized training program to improve aerobic fitness. Participants will receive 21 training sessions over the course of 11 weeks. The sessions will include free assessments of heart health, tone, memory, coordination and brain function. If you’re interested in participating, contact Barbara Martin or Nathan Johnson at (859) 323-6498, or email nathan.johnson9@gmail.com to meet and assess you.}

Nathan F. Johnson is an assistant professor in the Division of Physical Therapy at the University of Kentucky College of Health Sciences.

You could help UK study heat treatments for cancer

BY JEREMAHIN MARTIN
Contact: October 17, 2016

Thermal therapy, or hyperthermia, has been used for medical treatments for centuries. Modern research has demonstrated that high temperatures can damage and kill cancer cells, helping to shrink tumors with minimal injury to healthy cells. Heat exposure can also make cancer cells more sensitive to radiation and chemotherapy, potentially increasing the effectiveness of these treatments.

In hyperthermia treatments, doctors closely monitor a patient’s body temperature to be sure that the desired temperature is reached, but not exceeded. Hyperthermia is generally used in combination with other cancer therapies, such as radiation and chemotherapy.

Currently, approved uses of hyperthermia for cancer treatment include local and regional hyperthermia. For local hyperthermia, high heat is applied to a small area, such as a tumor near or on the skin. In some cases, it can be applied externally to treat tumors that are just below the skin, or can be applied internally to treat tumors deep within the body or near body cavities.

Regional hyperthermia, which involves lower temperatures and is often combined with anticancer drugs, uses various methods to heat large areas of tissue, such as a body cavity, organ or limb.

Whole body hyperthermia is being studied as a way to treat metastatic cancer that has spread through the body. One type of whole body hyperthermia involves external heat, delivered through radiant heat devices that utilize infrared radiation in a noninvasive manner. However, the effectiveness of radiant heat is compromised because it is difficult for external heat to reach the organs, which are the most common location of metastases. External heating can also cause burns and pain.

An alternate to external heating is the use of perfusion circuits, which heat a patient’s blood. This procedure is invasive, but provides steady internal heating with no adverse skin burns. These perfusion circuits also heat the body more quickly, which is associated with more effective killing cancer cells.

Doctors at the University of Kentucky are currently conducting a study to investigate perfusion whole body hyperthermia for treatment of late stage lung cancer. If you or someone you know would like to learn more about this clinical trial, please contact the Division of UK Cardiothoracic Surgery at (859) 323-6498 for a free screening. You can also find information at UKCancerResearch.com.

Dr. Jeremahin Martin is an assistant professor of surgery at the University of Kentucky and a member of the lung and thoracic cancer team. He was listed on one of the Best Doctors in America in 2016.
FACEBOOK AND TWITTER RESEARCH POSTS

CCTS and UK HealthCare will promote your studies, pending IRB approval!
FACEBOOK AND TWITTER RESEARCH POSTS

At the end of your study, mention the UK Current Studies website or provide a brochure and ask them if they are interested in sharing the UK Current Studies: [UKclinicalresearch.com](http://UKclinicalresearch.com)

All IRB approved study flyers are posted on UK Current Studies, if it is stated as a recruitment method in your Form B. [UKclinicalresearch.com](http://UKclinicalresearch.com) and [www.facebook.com/UKCCTS](http://www.facebook.com/UKCCTS)

Ask for our example: Research Description, Form B, Section 5. Subject Recruitment Methods

Most people have 120 Facebook friends and anywhere from 3-4 other social media sites.
Three year grant to study potential environmental reasons for the high lung cancer rates in Eastern Kentucky.
STANDARDS FOR REVIEW

Undue influence:

The IRB looks for the same things in social media language as in printed materials and generally centers on communications that could be either inaccurate or misinterpreted as presented – Therapeutic Misconception

Issues:

✧ Limited amount of information you can convey some platforms.
✧ Use of the word TREATMENT, which implies certain benefit
✧ Use of the words payments or free medical care or overly optimistic language.

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
GENERAL EDUCATIONAL RESEARCH MATERIALS

• **General research:** Articles, Facebook, Twitter posts, YouTube videos, etc that intend to foster participant engagement, *not* enrollment into specific studies. The public finds this information useful.

• **In line with FDA guidance:** It’s difficult to make the argument that to review these types of materials would provide any additional protection to participant with regards for their rights, safety, or welfare.

• **But, the IRB could ask to review.**

*Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney*
Example: Research Description, Form B, Section 5:
Subject Recruitment Methods

General Educational Research Articles: UK PR Boilerplate language

*You can make a difference through participating in research and discovery. To find more information, including a list of current studies at UK and access to studies nationwide, please visit UKclinicalresearch.com or call 859.257.7856.*
Gregory Jicha, MD
Professor of Neurology, Center on Aging
Talks about the importance of bringing research from the lab to the people.

NOTE:
UK Public Relations consent form
Participant must sign to give approval to use their photo, video, etc.
HOW TO SUBMIT FOR **IRB REVIEW & APPROVAL**

Social Media is handled like all other participant recruitment materials. Documentation is required for everything.

- A **hard copy** of final mock-up, including images
- **All** study-specific home pages, posts, tags, and ads
- If you make changes to recruitment materials during course of the study these **changes must be submitted for IRB review**.
- Changes are **normally** quick turnarounds using the expedited review process.
You may be eligible for this research if you:

• are 65 years old or older
• have normal or controlled blood pressure
• do not have diabetes
• do not have any known heart, muscle or nerve disorders
• are able to participate in an exercise program

Researchers at the University of Kentucky are conducting a study to see if inflammation in the fat and blood causes a tendency toward pre-diabetes. You may be eligible to participate if you are between the ages of thirty-five to sixty-five, are normal weight or overweight, have a family history of diabetes, slightly abnormal blood sugar, and high blood pressure or cholesterol. Please contact research coordinator at eight-five-nine-three-two-eight-five-nine or visit UKCLINICALRESEARCH.COM.

Contact:

Doug Long
delong2@uky.edu
859-323-5438

Researchers at the University of Kentucky are studying how a widely prescribed medication may enhance your ability to benefit from resistance exercise. You may be eligible to participate if you are 65 years or older. You will be compensated for your time.

Contact:

Doug Long
delong2@uky.edu
859-323-5438
Online newspaper banners

UNIVERSITY OF KENTUCKY RESEARCH
Study on Inflammation in the Fat and Blood

Researchers at the University of Kentucky are evaluating knee strength and functional performance in people who have had an ACL reconstruction in the past 5-20 years. Participants will be compensated for their time and we can share your evaluation performance with you. If interested please contact allie.romines@uky.edu

Please help us spread the word about this research study!

http://ccts.uky.edu/ccts/acl-reconstruction-study

Emails to listservs

Exercise Training Study

You may be eligible for this research if you:
- are 65 years old or older;
- have normal or controlled blood pressure;
- do not have diabetes;
- do not have any known heart, muscle or nerve disorders; and
- are able to participate in an exercise program.

Researchers are studying how a widely prescribed medication may enhance your ability to benefit from resistance exercise. Participants should not be currently performing weight lifting exercises and will be required to pass a physician exam. All study procedures including the exercise program will be free of charge. Participants will receive valuable information about your health, free personal training, and compensation for your time.

ResearchMatch email/advertisement:
- In initial email contact - No contact information
- Once volunteers responses “Yes”
- You can contact volunteer with more information

Link advertisement to online submit flyer, UKclinicalresearch.com and REDCap.
ADDITIONAL CONSIDERATIONS:

A RECRUITMENT PLAN

Include a formal social media management plan in your IRB and remove the mystery!

- Develop a clear strategy and integrated presence
- Define what will be submitted for review and what will not
- Create a matrix of responses to anticipate user-generated content

Provide a complete picture:
1. Rationale for use
2. Privacy concerns
3. Vetting communications for appropriateness
4. Vetting for IRB-reviewable subject matter
5. Monitoring user-generated content

Example: Form B, Research Description, Section 5. Subject Recruitment Methods
ADDITIONAL CONSIDERATIONS:
IF YOU ARE CREATING YOUR OWN FACEBOOK PAGE

Review may extend beyond the specific communications

The “About” tab in Facebook allows for specific communications
• Purpose of research
• Purpose of account
• How page will be monitored
• Any limitations on how the page should be used

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
SOCIAL MEDIA WILL BECOME MORE PREVALENT

Source 2015: Quorum Review IRB presentation by Dominic A. Chiarelli, JD, CIP Regulatory Attorney
SOCIAL MEDIA – WHAT’S NEW?

Apple Research Kit and HealthKit

Twitter chats, promote Tweets
Twitter Periscope – live video broadcast,
Boost Facebook page,
Social Media Listening
Pinterest, Instagram
YouTube, Apps

Genes for Good

Markey Clinical Trials App
RECRUITMENT WORKGROUP

CCTS Contacts:
Communications: Mallory Powell, mallory.powell@uky.edu
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Biomedical Informatics: Tamela Harper, tjharp00@uky.edu
Study advertisements: Nahal Hosseini, nho222@uky.edu