

Monitoring Patient Recruitment Campaigns for Compliance

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Agenda

- Background
- Do's and Don'ts
- Acronyms
- Online Advertising and Social Media

Landscape

- Patient recruitment accounts for a quarter of the time spent conducting a typical clinical trial.
- Presently, nearly 86% of clinical trials conducted in the United States fail to meet established enrollment timelines.



Pop Quiz: Are These Statements Acceptable in Ads?

- Study participants will be helping doctors find out if symptoms return when patients stop taking medication.
- The drug used in this study has been approved by the Food and Drug Administration.
- You will be treated by a personal physician who is an expert in this disease.
- Are you suffering from this disease? We may be able to change that.
- You will be paid for your participation in this study.

NO

What are the Rules?



- FDA Information Sheet (1998)
 - FDA considers direct advertising for study subjects to be the start of the informed consent and subject selection process.
- 21CFR312.7(a)
 - An investigational new drug shall not be represented in a promotional context
 - Restricts promotional claims of safety and effectiveness of the drug to preclude commercialization of the drug before it is approved for commercial distribution
- HIPAA



Background: Types of Advertisements Used for Clinical Trial Recruitment

The types of advertisements include but are not limited to:

- Newspaper
- Radio
- Television
- Bulletin boards
- Posters
- Flyers
- Telephone recruiter scripts
- Internet (one exception – clinicaltrials.gov)
- Letters
- Receptionist Scripts



Study Recruitment Advertisements – Do's:

- Mention that study is a research study – never downplay the investigational nature.
 - For example – “Conducting a research study with an investigational drug..”
 - This applies *even if the product is approved*, when studied in new indication, formulation, dosage, etc. (other than approved label)
- If there is a placebo arm, it is recommended that this be referenced.
- Information should include what prospective subjects need in order to determine if they are interested and/or eligible.
- Provide close oversight over any recruitment vendors. They are often unaware of many risks discussed and have a different focus: to efficiently recruit subjects (Recall the landscape).

Study Recruitment Advertisements – Do's:

- When appropriately worded, materials can contain:
 - Name and address of the clinical investigator or research facility
 - The condition under study or the purpose of the research
 - A summary of the criteria used to determine eligibility for the study
 - A brief list of participation benefits, if any (e.g., a no-cost health examination)
 - Time or other commitment required of subjects
 - The person or office to contact for further information



Study Recruitment Don'ts Advertisements Should Not Be:

Promotional / use branding



Avoid using information that may be deemed as promotional for the product:

- Branded name
- Generic name (in certain cases)
- Use of company-internal product code
- Terms used to describe the product that only one product would meet
 - Example – use of dosing strength that is very specific to a product
- “FDA-approved”
- Similar color schemes between product website and marketed product advertisements
- Tag lines
- Similar/same graphics
- Similar story lines

Ask Yourself...

- Are the materials completely distinct, in a perceptual sense, from the marketing campaign?



+ Quack =



Study Recruitment Advertisements Should Not:

Misrepresent the Facts by Including Statements About:

- a broadened or misleading indication
- special/personalized medical care or attention
- state that the product is FDA approved when it is approved for a different indication than the one under study



Do Not Be:

Unduly influential

- Does the advertisement state that the investigational product is known to be the equivalent or superior to any other drug, biological, or device?
- Is the word “benefit” used to describe receipt of study procedures?
 - If yes, it must contain mention of the risks.
- Does the advertisement use terms such as, “new treatment”, “new medication”, or “new drug”?
 - The term “new” should **not** be present in this context, as it indicates false promises (e.g., “receive new treatments” leads study subjects to believe that they will be getting improved products of proven worth).

Do Not Be:

Unduly influential

- Does it promise “free medical treatment”?
- Does it use language such as:
 - “Earn cash”
 - “You will be paid”



Do Not Use:

Coercive language

- “We need your help”
- “Call today”



Do Not Be:

Overly reassuring

- Does the ad contain comments that would make someone think that they will be healthier or cured if they participate?
- Does it state that the investigational product is safe or effective for the purposes under investigation?
- Does it state “FDA approved” or “approved”?



Study Recruitment Advertisements – Study Acronyms

Is an acronym associated with the study?

- Best Practice: Encourage study teams to speak with Compliance from the start.
- Upon the acronym's first use, include the official title of the study or a brief explanation.
 - For example: The ADHD TEMPO Study - This clinical research study is gathering data to help doctors determine the best time of day to administer the investigational non-stimulant medication in order to best address children's ADHD symptoms.

Points to Consider – Web-based advertising

facebook

Internet advertising

- The industry has no specific guideline or regulatory agency recommendations on this topic (Reminder: GCP applies here as well).
 - FDA public hearing of November 2009 did not result in additional guidance
- Compliance should be continually involved in review of web-based advertising and providing recommendations on a case by case basis

Google

YouTube

craigslist
online community

Meetup

myspace.com
a place for friends

twitter

Shire

To be as brave as the people we help

Points to Consider

- 61% of Adults look online for medical help
- The various social media outlets account for a total of BILLIONS of people





RISKS

IF YOU NEVER TRY ANYTHING NEW,
YOU'LL MISS OUT ON MANY OF LIFE'S GREAT DISAPPOINTMENTS.

www.despair.com



To be as brave as the people we help

Points to Consider – Web-based advertising

Risks Involved:

1. Advertising versus Promotion
2. Posting on sites controlled by third parties – no control on where your ad ends up (eg. website reputation, other adjacent ads etc.)



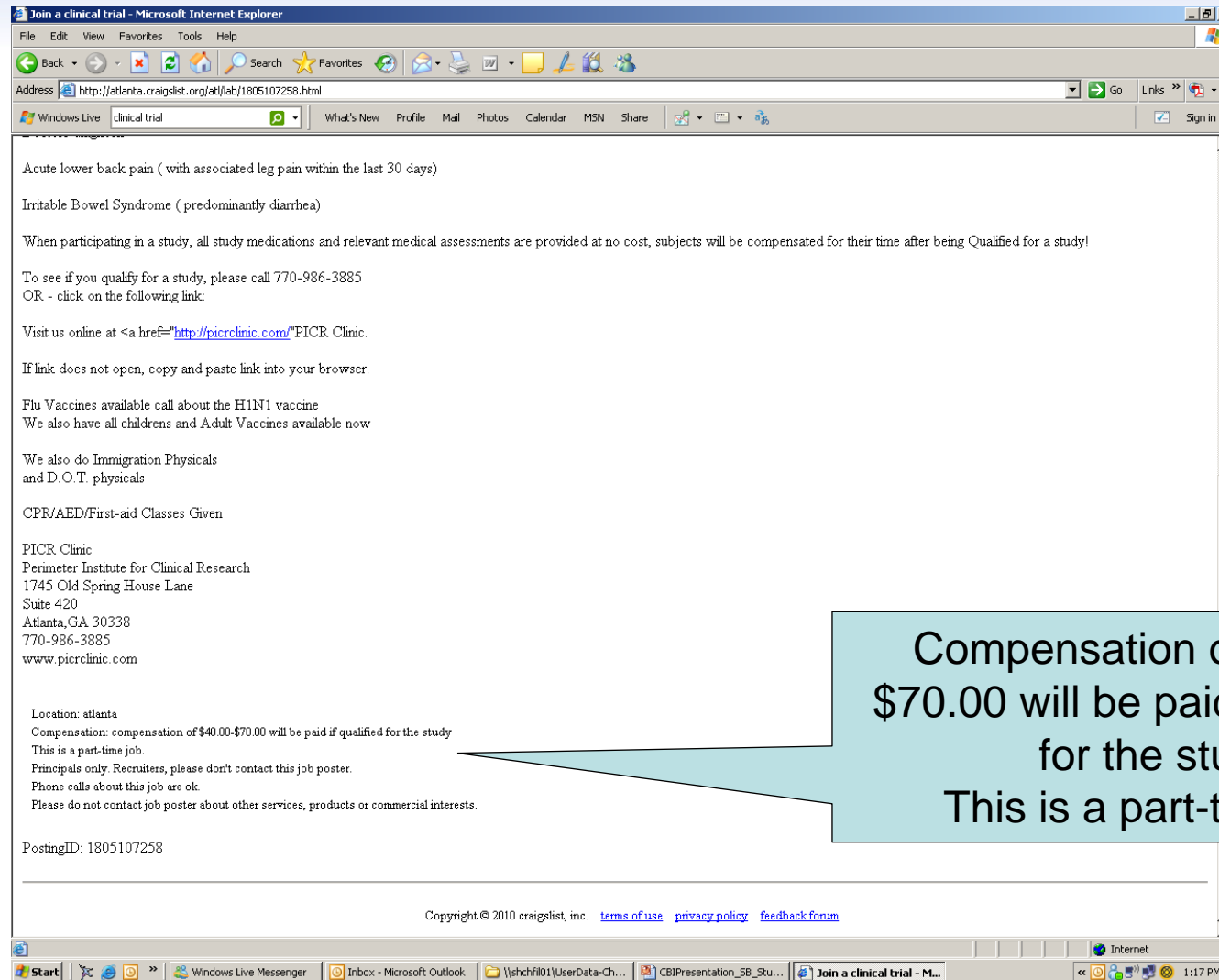
Points to Consider – Web-based advertising

3. Adverse Event Monitoring and Reporting
4. Risk of Data Contamination
5. Confidentiality/Privacy Issues (“Scraping”)
6. Accounting for Minors/Location of Subjects



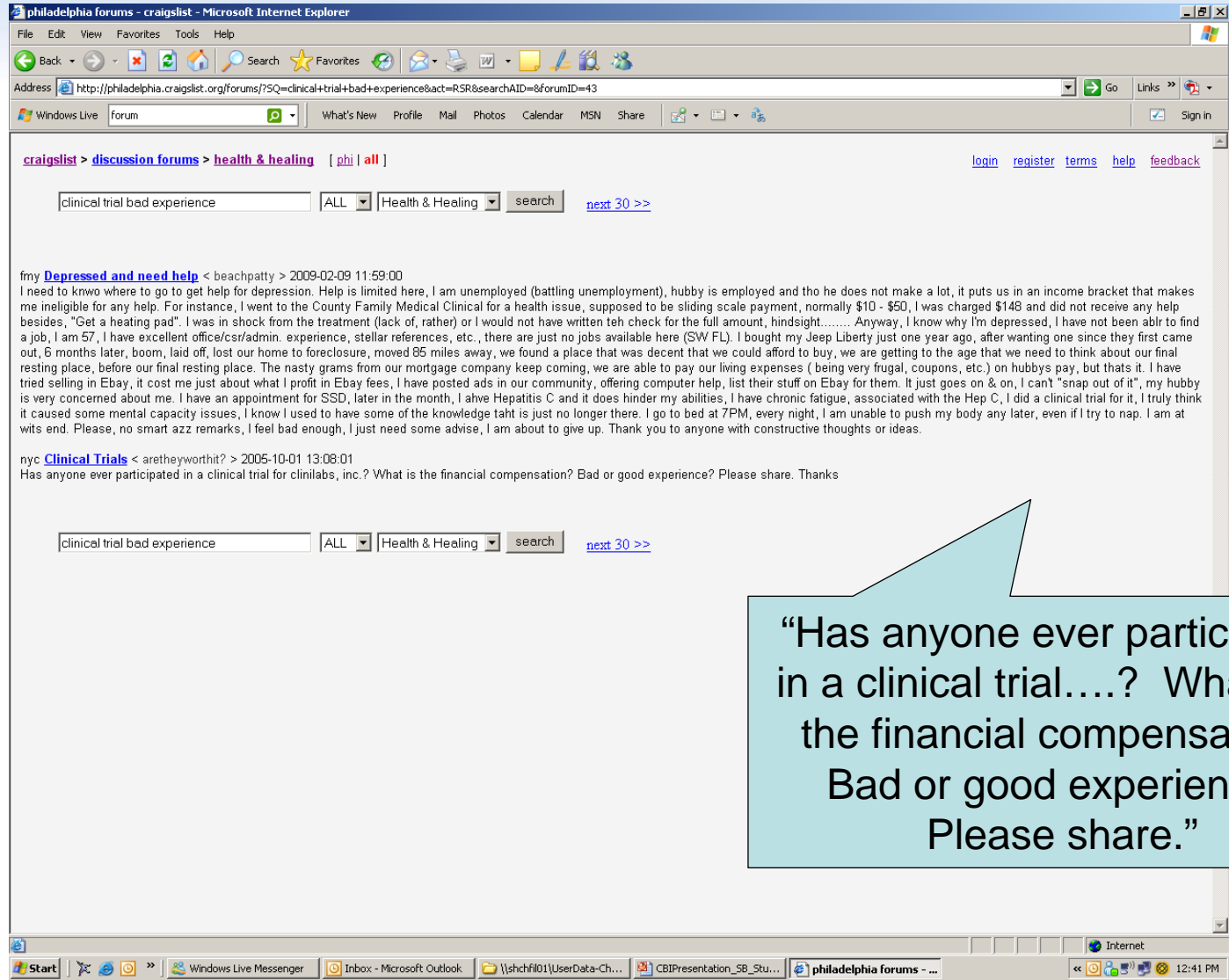
Note: Not all disease trials are ideal for online recruitment. For example, chronic disease patients are mostly offline.

Example: Social Media Recruiting



Compensation of \$40.00-
\$70.00 will be paid if qualified
for the study
This is a part-time job.

Example: Blogging



“Has anyone ever participated in a clinical trial....? What was the financial compensation? Bad or good experience? Please share.”



To be as brave as the people we help

SPD503-314 Sponsored Links

Google

adhd child Search Advanced Search Preferences

Warning: This page is a tool for AdWords advertisers to test their ads. For full Google functionality [return to the Google homepage](#).

Web [Show options...](#) Results 1 - 10 of about 1,300,000 for [adhd child](#). (0.11 seconds)

ADHD
[www.focusonadhd.com](#) Learn About The Symptoms Of ADHD In Children.

ADHD Information
[www.adhd360.com](#) For Healthcare Professionals - Find Information On ADHD In Children.

ADHD In Kids

Sponsored Links

A Clinical Research Study
For The Treatment Of ADHD
Symptoms In Children Ages 6-17.
[www.FocusingOnADHD.com](#)

If your child has ADHD

We're conducting a research study that may help with their symptoms.

[www.ADHDTEMPOStudy.com](#)

ADHD treatment options

Evaluating a non-stimulant medication for children aged 6-12.

[www.ADHDTEMPOStudy.com](#)

A clinical research study

for the treatment of ADHD symptoms in children aged 6-12.

[www.ADHDTEMPOStudy.com](#)

A clinical research study

of a non-stimulant medication for children aged 6-12 with ADHD.

[www.ADHDTEMPOStudy.com](#)

A clinical research study

that may help parents to address the symptoms of their child's ADHD.

[www.ADHDTEMPOStudy.com](#)

When it comes to ADHD

and its potential treatments, it's important to know all your options.

[www.ADHDTEMPOStudy.com](#)

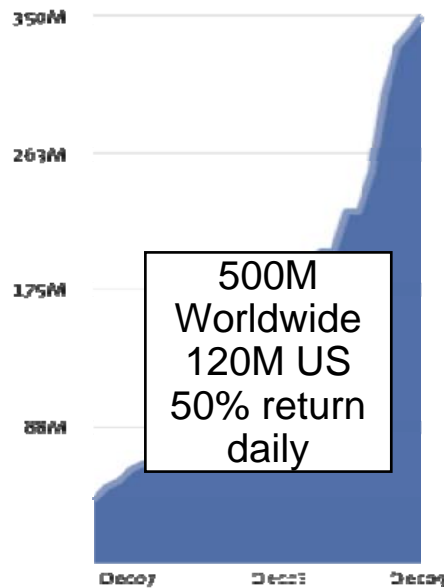
SRP Example

Copyright © 2009 BEK Healthcare, Inc. (d/b/a BEK Worldwide) and TCN e-Systems, LLC. All rights reserved.

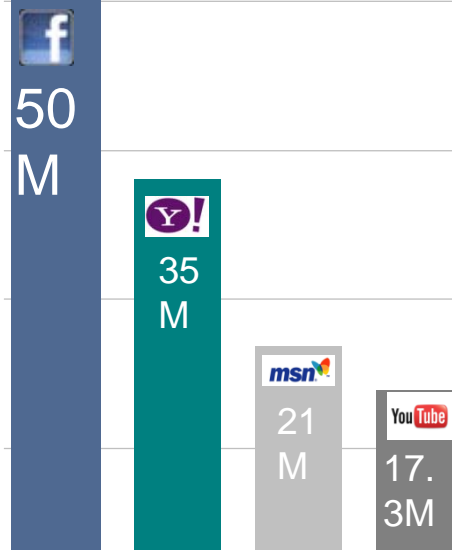
Why Consider Social Media?

Facebook Scale

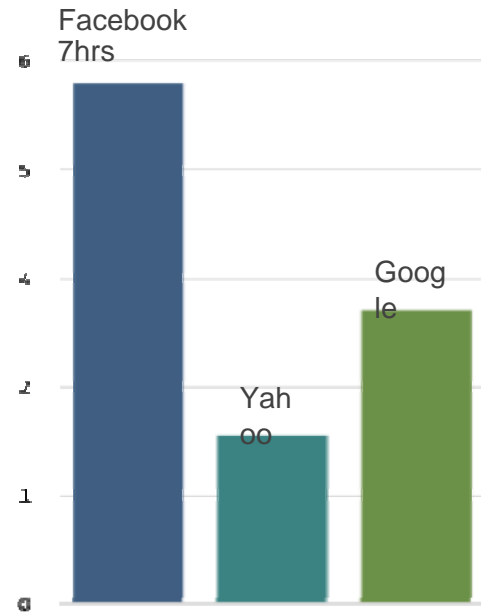
Rapid



#1 Daily



#1 in Time Spent



Source: Compete.com, US 30 day active, Oct 09

Source: Nielsen, Jan 2010

Advertising & Social Media

- If social media are used for trial ads, be aware:
- Agencies (eg. FDA) apply the same set of rules regardless of the media used (traditional vs. internet)
 - Sponsored or controlled sites provide for more opportunity to minimize or mitigate risk
- Bloggers can generally say anything about a company's products, processes, standards
 - trying to correct wrong information – is it beneficial?
 - do you know who posts as a patient or HCP?
- How would that impact adverse event reporting and our responsibilities? What are our monitoring responsibilities?

Lack of awareness is never an excuse!

So What's the Solution?



- Same criteria in place for content regardless of information venue
- Begin allowing one/few social media venue at a time, noting all ways that interactivity must be disabled
- Strict Criteria Regarding Settings and Approval Process (extra steps)
- Provide written guidance for instructions regarding settings necessary
- Close vendor oversight is required; the fewer vendors are used across the company, the better
- Emergency Takedown Procedures: ads must be immediately removable as necessary

- Standard ads only
- “Liking” still possible on non-standard ads = Connectivity
- No video, streaming, polling, etc.
- Hyperlinks may be included that direct potential study subjects to the study center’s landing page.
- Since Facebook does not have a test environment, Compliance must be notified as soon as the advertisement is posted and a confirmation review will be conducted.
- Interactivity will only be one way only from company/study center to individuals acting as an “information concierge” rather than full social media network.
- Ads targeted by age, gender, and keyword
- Can view traffic driving to recruitment website (assess)

- When posting a classified ad, you must first click – “post to classifieds” then click – “community”, then “volunteer”. **Ads may only be classified under the “volunteer” category.**

The screenshot shows the Craigslist Philadelphia homepage. The 'community' category is selected, and the 'volunteers' sub-category is highlighted with a red circle. The page layout includes a left sidebar with navigation links, a main content area with various category lists, and a right sidebar with location links.

Left Sidebar:

- post to classifieds
- my account
- help, faq, abuse, legal
- search craigslist
- for sale
- event calendar
- haiti earthquake relief
- avoid scams & fraud
- personal safety tips
- craigslist blog
- craigslist factsheet
- best-of-craigslist
- craigslist (tv)
- craigslist movie & dvd
- craigslist foundation
- system status
- terms of use about
- privacy help

Main Content Area:

- community**
 - activities
 - artists
 - childcare
 - general
 - groups
 - pets
 - events
 - lost+found
 - musicians
 - local news
 - politics
 - rideshare
 - volunteers**
 - classes
- housing**
 - apts / housing
 - rooms / shared
 - sublets / temporary
 - housing wanted
 - housing swap
 - vacation rentals
 - parking / storage
 - office / commercial
 - real estate for sale
- for sale**
 - appliances
 - antiques
 - barter
 - bikes
 - boats
 - books
 - business
 - computer
 - free
 - furniture
 - general
 - jewelry
 - materials
 - ns
 - sporting
 - tickets
 - tools
 - wanted
 - arts+crafts
 - auto parts
 - baby+kids
 - beauty+hhh
 - cars+trucks
 - cds/dvd/vhs
 - cell phones
 - clothes+acc
 - collectibles
 - electronics
 - farm+garden
 - garage sale
 - household
 - motorcycles
 - music instr
 - photo+video
 - toys+games
 - video gaming
- services**
 - beauty
 - creative
 - computer
 - cycle
 - event
 - financial
 - legal
 - lessons
 - marine
 - pet
 - automotive
 - farm+garden
 - household
 - labor/move
 - skill'd trade
 - real estate
 - sm biz ads
 - therapeutic
 - travel/vac
 - write/ed/hb
- discussion forums**
 - 1099
 - apple
 - arts
 - atheist
 - autos
 - beauty
 - bikes
 - celebs
 - comp
 - crafts
 - diet
 - divorce
 - dying
 - eco
 - educ
 - etiquet
 - feedback
 - film
 - fitness
 - flirt
 - food
 - frugal
 - gaming
 - nantien
 - gifts
 - haiku
 - health
 - help
 - history
 - housing
 - jobs
 - jokes
 - kink
 - litr
 - legal
 - linux
 - loc pol
 - m4m
 - money
 - motorcy
 - music
 - npo
 - open
 - outdoor
 - over 50
 - p.o.c
 - parent
 - nefn
 - philos
 - politic
 - psych
 - queer
 - recover
 - religion
 - rofl
 - science
 - shop
 - spirit
 - sports
 - tx
 - taxi
 - testing
 - transg
 - travel
 - vegan
 - w4w
 - wed
 - wine
 - women
 - words
 - writers
- personal**
 - strictly platonic
 - women seek women
 - women seeking men
 - men seeking woman
 - men seeking men
 - misc romance
 - casual encounters
 - missed connections
 - rants and raves

Right Sidebar:

- nearby cl**
 - allentown
 - annapolis
 - baltimore
 - central nj
 - delaware
 - eastern shore
 - frederick
 - harrisburg
 - jersey shore
 - lancaster
 - long island
 - new york
 - north jersey
 - philadelphia
 - reading
 - scranton
 - south jersey
 - southern md
 - washington
 - york
- us cities**
- us states**
- canada**
- cl worldwide**

Craigslist Continued

- No interactivity is allowed i.e. “It's NOT ok to contact this poster with services or other commercial interests” must be selected.
- Hyperlinks may be included that direct potential study subjects to the study center's landing page.
- Since Craigslist does not have a test environment, R&D Compliance must be notified as soon as the advertisement is posted and a confirmation review will be conducted.



Example of Requested Facebook Ad

- **Clinical Trials Research: Click Here**



- Adults 18-45 who don't use tobacco, see if you qualify for a Research Study in a city near you.
- May be compensated up to \$1,050 for time.

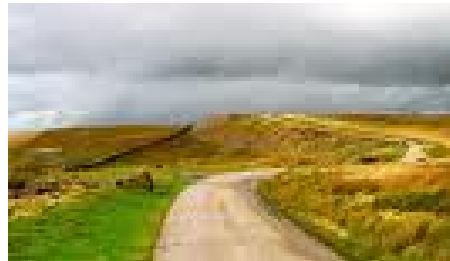
Should this ad be approved?

Recent News

- FDA's Bad Ad Program

- Run by DDMAC
- Urges doctors to report ads and sales pitches that violate FDA rules
- FDA will offer doctors training at medical conferences to help spot misleading ads

- What's next???



Conclusion

- Know the rules
- Is the ad promotional?
- Don't be:
 - Coercive,
 - Unduly influential
 - Overly reassuring
- Be cautious with study acronyms
- Develop social media policy and/or guidance
- Recall the landscape: weighing risk/benefit are key
- Keep abreast of guidance and regulations to come



