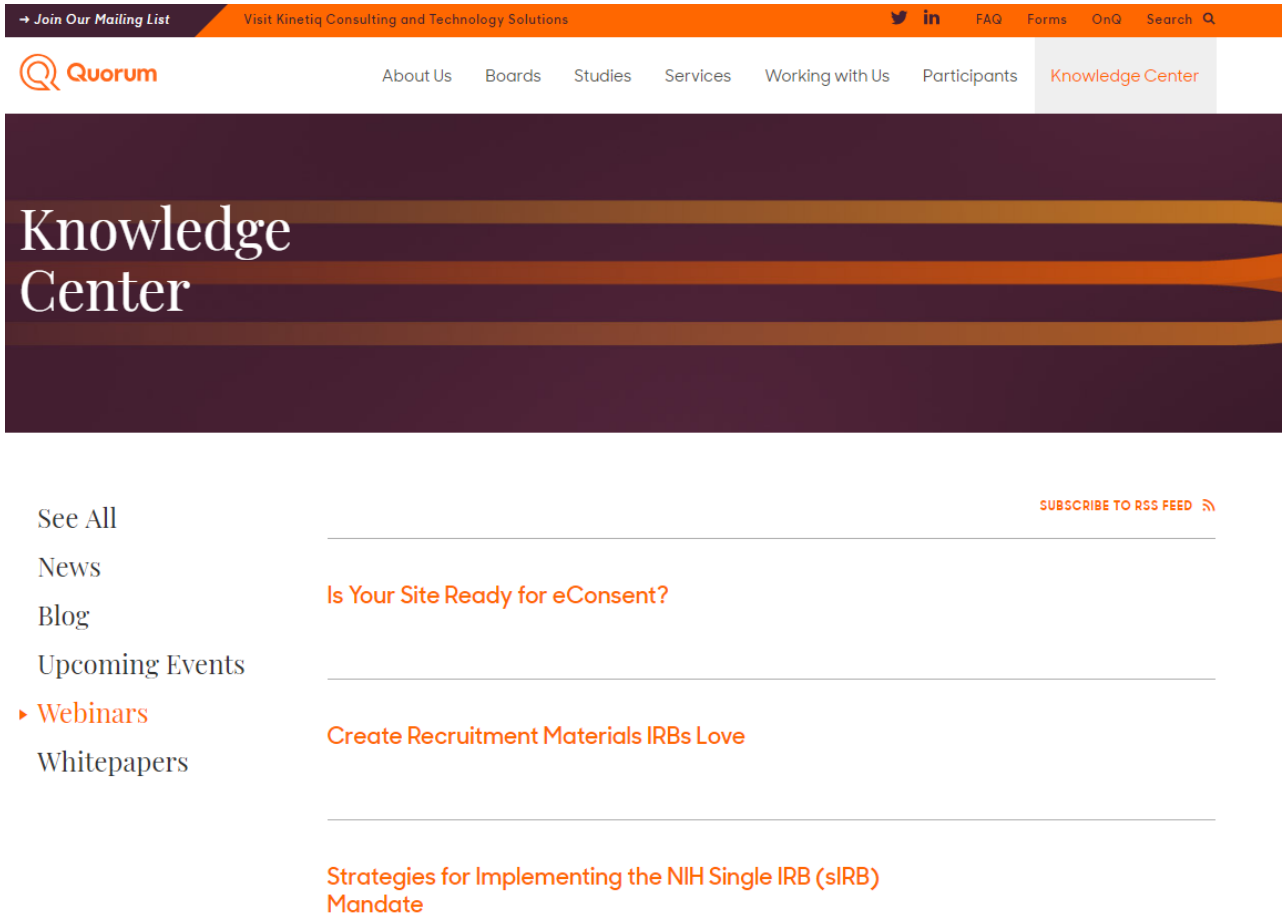
Create Recruitment Materials IRBs Love

Lizbeth Adams, PhD, CIP
Amanda Higley, PhD

May 2018

Quorum On-Demand Webinars

Quorum Review has a robust catalog of on-demand webinars that offer free CEU credit, to view the on-demand version of this webinar and others visit: http://bit.ly/QuorumWebinars



About Our Presenters

Lizbeth Adams, PhD, CIP

Executive Vice Chair

Quorum Review IRB

- Over 20 years experience in IRB operations and direction experience.
- Holds Certified IRB Professional (CIP) certification
- Former Director of Office of Research Integrity at Bastyr University
- Received PhD in Physiology and Biophysics from the University of Washington

About Our Presenters

Amanda Higley, PhD

Vice Chair, Scientific

Quorum Review IRB

- Adjunct Professor of Research Methods & Design at Point Loma Nazarene University
- Completed a predoctoral research fellowship at the National Institute on Drug Abuse and a postdoctoral fellowship at The Scripps Research Institute
- Received PhD in Psychology from Kansas State University
- Received Fellowship of Academic Research Award from the NIH in 2007 and the Young Alumni Medallion award from Jamestown College in 2010

Trial Start-Up

Challenges To Getting Participants In The Door:

- **11%** of sites selected are never activated because of their inability to enroll subjects[1]
- Poor site selection can increase costs by **20%**[2]
- **80%** of clinical trials fail to meet enrollment deadlines[3]

It is a poorly kept secret in the world of clinical trials that issues with patient recruitment and enrollment are the primary causes for missing clinical trial timelines.[4]

References: [1]Clinical Leader; From the Editor (May 30 2017), [2]Intralinks (https://www.intralinks.com/sites/default/files/file_attach/wp_faster_study_startup.pdf) , [3]Patient Recruitment and Retention; Forte Research Systems, [4]Industry Standards Research Reports (March 2014)

What Are Recruitment Materials?

Definition: Any subject matter that a research subject interacts with over the course of a trial

- Must be reviewed and approved by an IRB before use
- Intended to inform and encourage participation
- In many cases, the first point of contact an individual has with a study

Poll Question

How challenging do you find it to make recruitment materials both compliant and compelling?

A. *Very Challenging*
B. *Somewhat challenging*
C. *Not challenging at all*

How Are Recruitment Materials Used?

- **Pre-Consent:** Intended to broadly identify population of potential participants

  Limited information, slanted to encourage participation

- **Post-Consent:** Intended to collect study data, improve retention of participants, and inform ongoing activities

Today's Focus

Pre-Consent Materials Which Comprise the Following:

- Television and radio ads
- Social media posts
- Billboards or other public signage
- Targeted mailings
- Materials in physician office

Pre-Consent Example

Do you have depression?

If you struggle with Major Depressive Disorder, you may qualify for a clinical research study of an investigational medication. Qualified participants will receive all study-related care and investigational medication at no cost, and may be compensated for study-related time and travel. Health insurance is not required.

You may qualify to participate in a research study if you are between the ages of 18 and 65 and suffer from depression.

Call 555-555-5555

eXample℠

Quorum

Therapeutic Misconception

"…unless otherwise informed, research subjects will assume…that decisions about their care are being made solely with their benefit in mind"

Constitutes "…a critical handicap to the subject's ability to engage in an accurate assessment of benefits and risks"

- Appelbaum et al (1983)

Research NOT Treatment

Regulatory and Ethical Guidance

21 CFR and 45 CFR are not prescriptive about recruitment materials, except as defined under the regulations regarding informed consent

> *"…prospective subject {provided} the opportunity to consider whether… to participate {under circumstances} that minimize the possibility of coercion or undue influence."*

Regulatory and Ethical Guidance (cont.)

FDA

The IRB must ensure that materials are "not unduly coercive and not promise a certainty of cure beyond what is outlined in the consent and the protocol."

OFFICE OF EVALUATIONS & INSPECTIONS

- "Recruitment is a vital first step in the consent process {that must not} be coercive or misleading.
- "…Misleading information… may influence decisions about participating. This is viewed as eroding the value of the informed consent process."

Specific FDA Guidance on Approvable Language*

Recruitment Materials Should Not:

- ..claim that the {intervention} is safe or effective for the purposes under investigation, or that {} is known to be equivalent or superior to any other drug, biologic, or device.
- ..use terms such as “new treatment”, “new medication” or “new drug” without explaining that the test article is investigational. A phrase such as “receive new treatments” {mis}leads study subjects..
- …promise “free medical treatment” when the intent is only to say subjects will not be charged for taking part in the investigation

FDA Information Sheet, Recruiting Study Subjects (1998)”

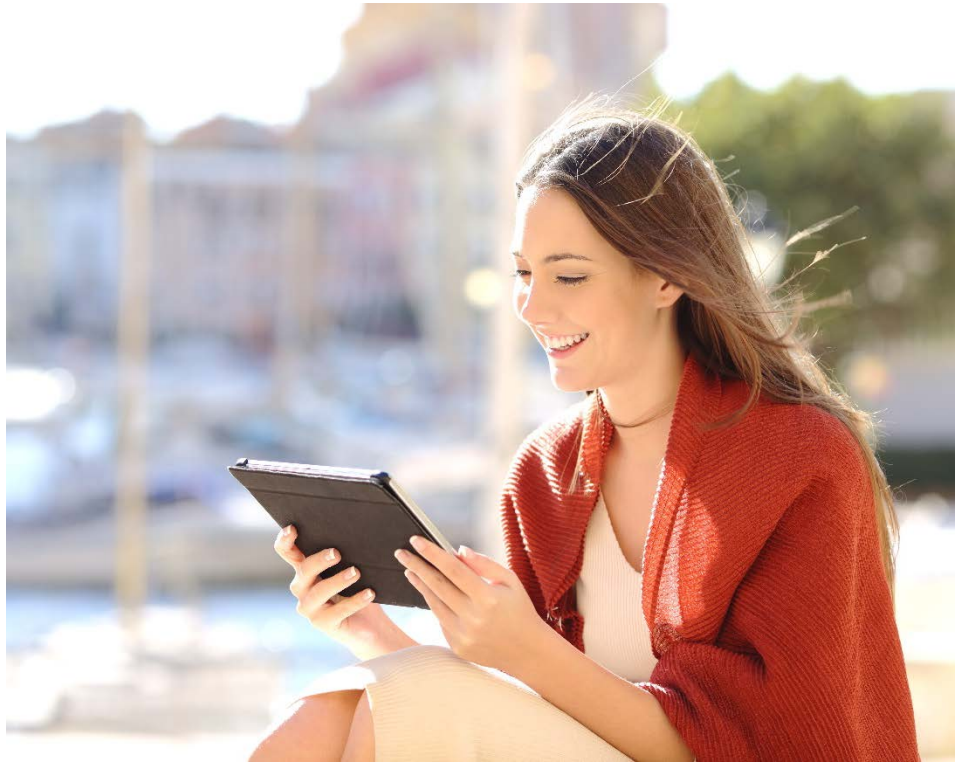
The Quorum Approach

Recruitment Materials Shouldn't Include Language That:

- May be unduly influencing
- Is overly reassuring
- Promotes therapeutic misconception
- Is coercive

Unduly Influencing Language

- Promising free treatment
- Emphasizing compensation
- Implying that a “cure” will be found
- Implying that the only or best hope for relief is to enroll in a clinical trial



Unduly Influencing Language Example

Quorum

Unduly Influencing Language Example – Considerations

Quorum

Unduly Influencing Language Example – Recommendation

Quorum

Overly Reassuring Language

- “…Is safe”
- “…Is painless”
- “…Involves a minor procedure”
- “…Approved by a regulatory body”

Overly Reassuring Language Example

Example Trials

Just Posted | Public

As a participant at Example Skin, you will have access to study doctors that ensure your safety, comfort, convenience and privacy. Procedures are quick and painless.

Participants Needed for Rosacea Study

exampleskintrials.com

Like Comment Share

Write a comment...

Quorum

Overly Reassuring Language Example – Considerations

Example Trials

Just Posted | Public

As a participant at Example Skin, you will have access to study doctors that ensure your safety, comfort, convenience and privacy. Procedures are quick and painless.

overly reassuring language

Participants Needed for Rosacea Study

exampleskintrials.com

Like Comment Share

Write a comment...

Quorum

Overly Reassuring Language Example – Recommendation

Example Trials

Just Posted | Public

As a participant at Example Skin, you will have access to study doctors that monitor your safety, comfort, convenience and privacy.

Participants Needed for Rosacea Study

exampleskintrials.com

Like Comment Share

Write a comment...

Quorum

Promoting Therapeutic Misconception

- “Treatment”
- “Doctor”
- “Medical”
- “Experts”

Therapeutic Misconception Example

eXample℠ 555-555-5555

The Next Time You Experience Symptoms of a Yeast Infection such as Vaginal Itching, Burning, Irritation

Don't

- ✓ Self Treat Yourself
- ✓ Get Your Medication at the Pharmacy or Grocery Store

Do

- ✓ Find out if you qualify for a clinical research study. There is no cost to you.

A clinical research study is currently underway testing a medication for women experiencing yeast infections.

Qualified participants must be:

- ✓ 18 years or older and not be pregnant
- ✓ Experiencing symptoms causing moderate to severe discomfort of a yeast infection- vaginal itching, burning, irritation

Qualified participants will receive a gynecological exam, medication and follow up visits. Compensation may be provided for time and travel.

Quorum

Therapeutic Misconception Example – Considerations

Therapeutic Misconception

"investigational"

"study-related"
"study"

Therapeutic Misconception Example – Recommendation

The Next Time You Experience Symptoms of a Yeast Infection such as Vaginal Itching, Burning, Irritation

eXample℠ 555-555-5555

Do

- ✓ Find out if you qualify for a clinical research study. There is no cost to you.

Find out if you qualify for a clinical research study. There is no cost to you.

A clinical research study is currently underway testing an investigational medication for women experiencing yeast infections.

Qualified participants must be:

- ✓ 18 years or older and not be pregnant
- ✓ Experiencing symptoms causing moderate to severe discomfort of a yeast infection- vaginal itching, burning, irritation

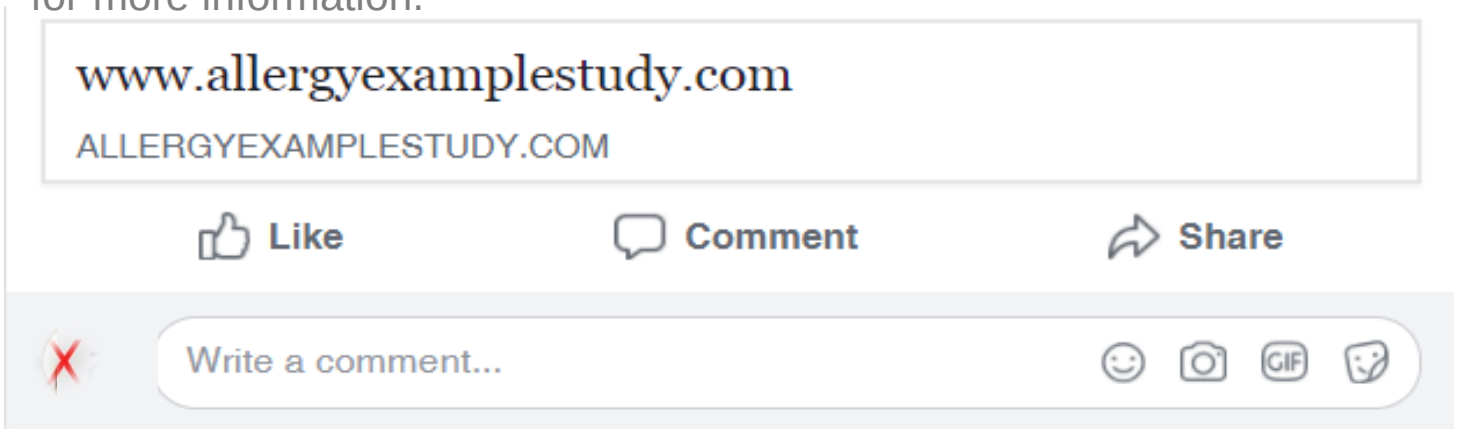
Qualified participants will receive a study-related gynecological exam, study-medication and follow up visits. Compensation may be provided for time and travel.

Quorum

Therapeutic Misconception Example

Example Trials
Just Posted | Public

Does Birch pollen stop you from enjoying the season? The Example Research Center is actively seeking participants to enroll in our Birch study to provide new treatments. Make an appointment today with one of our world-class doctors at 555-555-5555 or Visit www.allergyexamplestudy.com for more information.



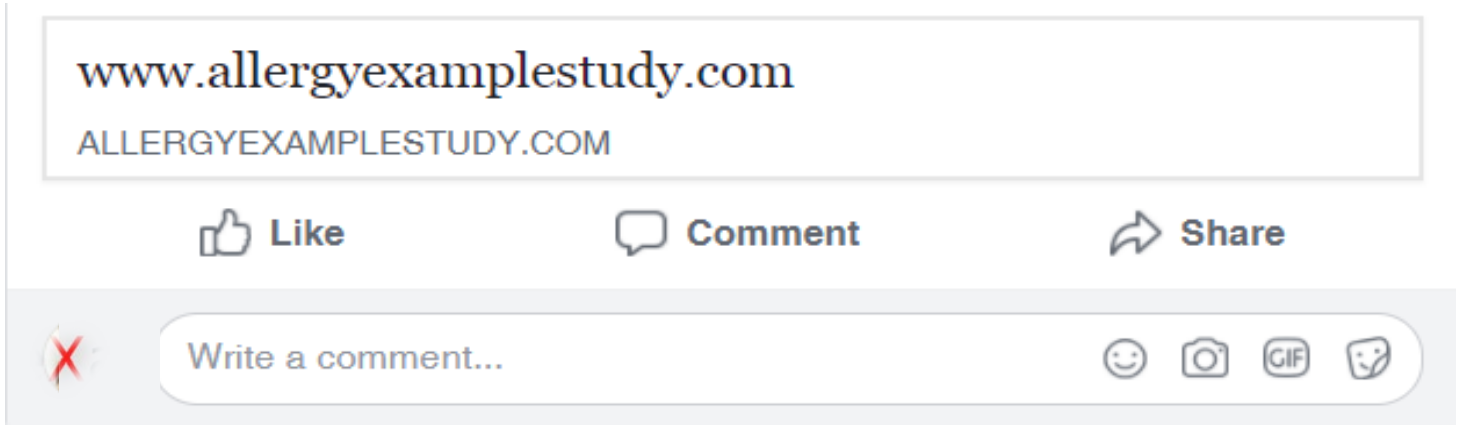
Therapeutic Misconception Example – Considerations

Example Trials
Just Posted | Public

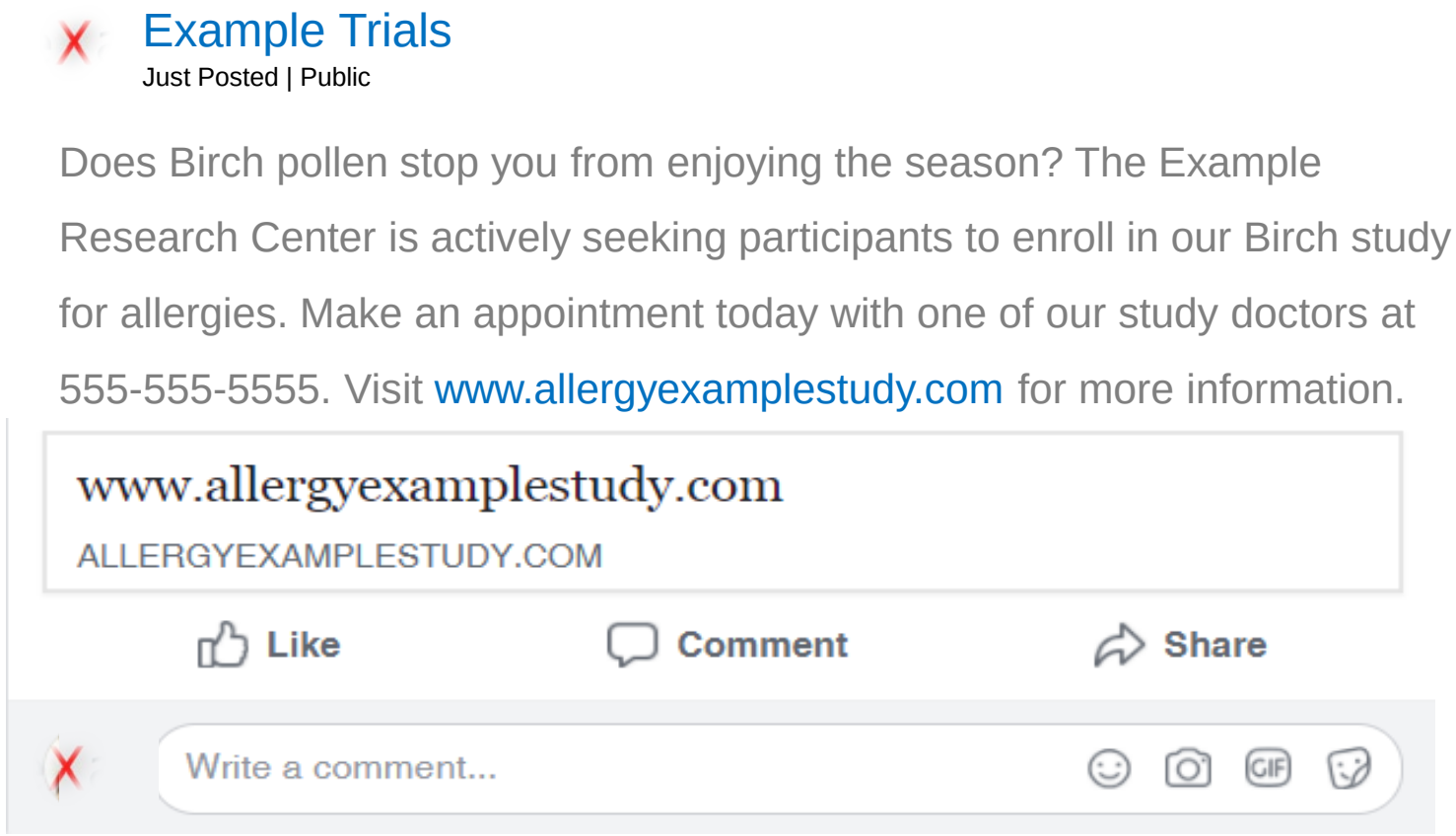
"for allergies"

"study doctors"

Does Birch pollen stop you from enjoying the season? The Example Research Center is actively seeking participants to enroll in our Birch study to provide new treatments. Make an appointment today with one of our world-class doctors at 555-555-5555 or Visit www.allergyexamplestudy.com for more information.



Therapeutic Misconception Example – Recommendation



Coercive Language

- Intended to encourage enrollment and/or to keep a participant enrolled
- Limits the “volunteer nature” of research studies

Coercive Language Example

Excerpt form Physician Letter:

“You may also choose to withdraw consent. This is obviously not the ideal situation. Withdrawing consent means you will no longer have any of the benefits of the study including free medical care and compensation for study visits. Withdrawing consent must be done in writing. Please understand that if you do not provide written notification that you want to withdraw consent from the study, our study team still has to contact you every 3 months.”

Coercive Language Example – Considerations

Excerpt form Physician Letter:

“You may also choose to withdraw consent. This is obviously not the ideal situation. Withdrawing consent means you will no longer have any of the benefits of the study including free medical care and compensation for study visits. Withdrawing consent must be done in writing. Please understand that is you do not provide written notification that you want to withdraw consent from the study, our study team still has to contact you every 3 months.”

Coercive Language Example – Recommendation

Excerpt form Physician Letter:

“You may also choose to withdraw consent. Withdrawing consent means you will no longer participate in study visits or have any information about you collected by the study doctor. Withdrawing consent is recommended to be done in writing. Please understand that if you do not provide written notification that you want to withdraw consent from the study, our study team still has to contact you every 3 months.

Additional Concerns: Sensitive Phone Screen Questions

- Questions about:
  - *Substance use/abuse*
  - *STDs*
  - *Mental health*
  - *Illegal activities*
- Once interaction has occurred, potential participants may develop a sense of obligation to complete the process

Phone Screen Example

Date Interviewed _____
Employee _____
Referred By _____

“Thank you for your interest in our clinical research study for an Investigation Medication. In order to determine if you meet the initial requirements for participation. I need to ask you a few personal health related questions. Before I begin I will give you a brief description of the clinical trial.

[Study Description]

With your permission, I’ll ask the questions needed to see if you meet the initial requirements. You don’t have to answer any questions if you feel uncomfortable in answering. If you end our interview, any information given to me to that point will be shredded. May I proceed?” **Yes___ No____**

Quorum

Phone Screen Example – Recommendation

Date Interviewed _____
Employee _____
Referred By _____

"Thank you for your interest in our clinical research study for an Investigation Medication. In order to determine if you meet the initial requirements for participation. I need to ask you a few personal health related questions. Before I begin I will give you a brief description of the clinical trial.

[Study Description]

With your permission, I'll ask the questions needed to see if you meet the initial requirements. **Some of these questions may be sensitive in nature, such as questions about HIV-AIDS, Hepatitis, drug/alcohol use or abuse, psychiatric illness, or incarceration. You do not have to answer any question that makes you uncomfortable and you may stop this call at anytime.** If you end our interview, any information given to me to that point will be shredded. May I proceed?"

Yes___ No____

Quorum

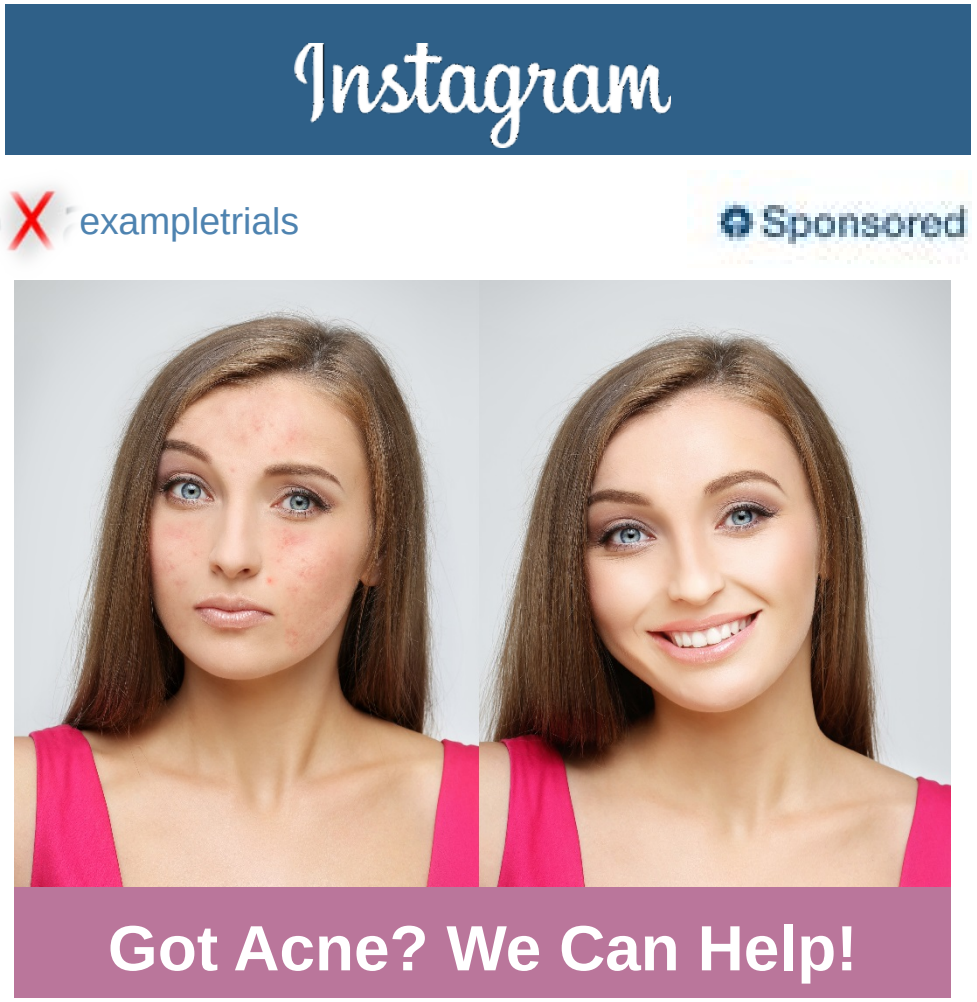
Additional Concerns: Vulnerable Populations

The IRB " should be particularly cognizant of …vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons."

" When some or all of the subjects are likely to be vulnerable to coercion or undue influence…additional safeguards{are} included to protect the rights and welfare of these subjects"

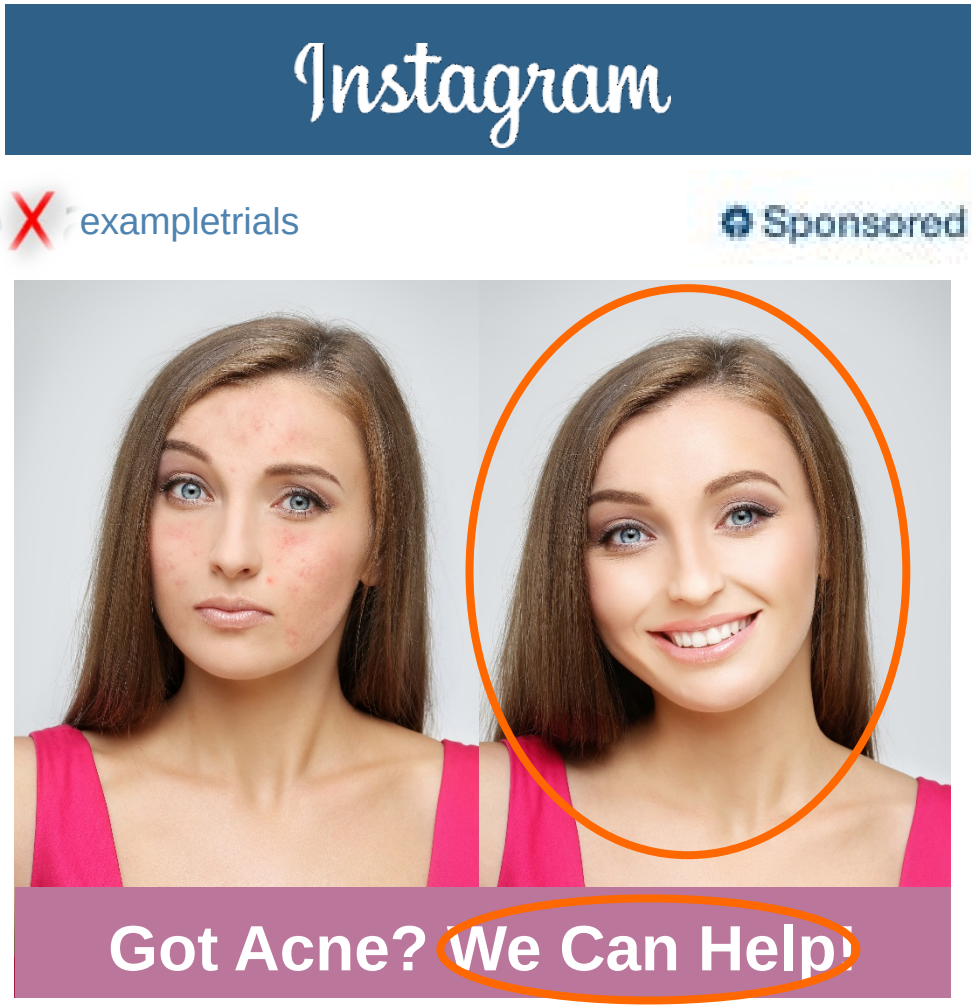
- Department of Health and Human Services

Vulnerable Populations Example



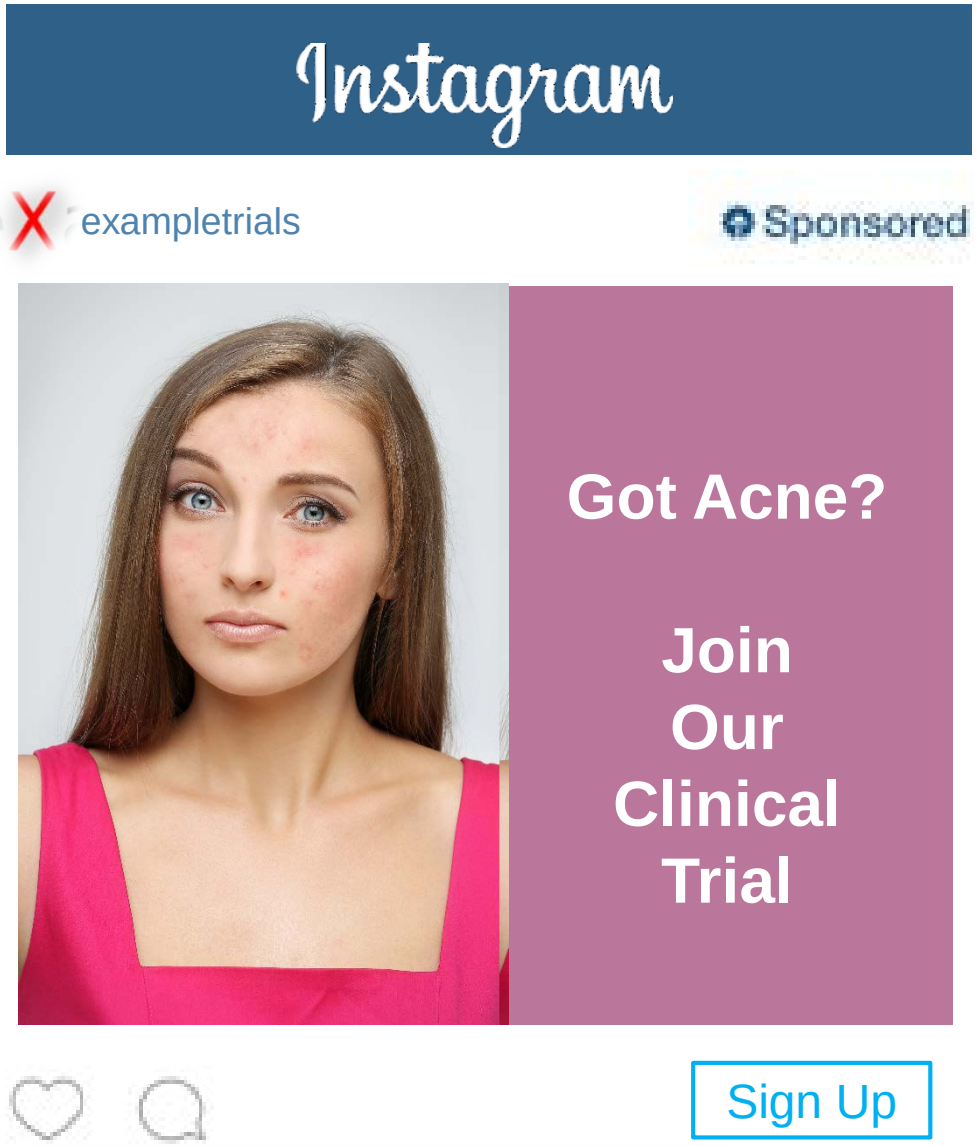
Quorum

Vulnerable Populations Example - Considerations



Quorum

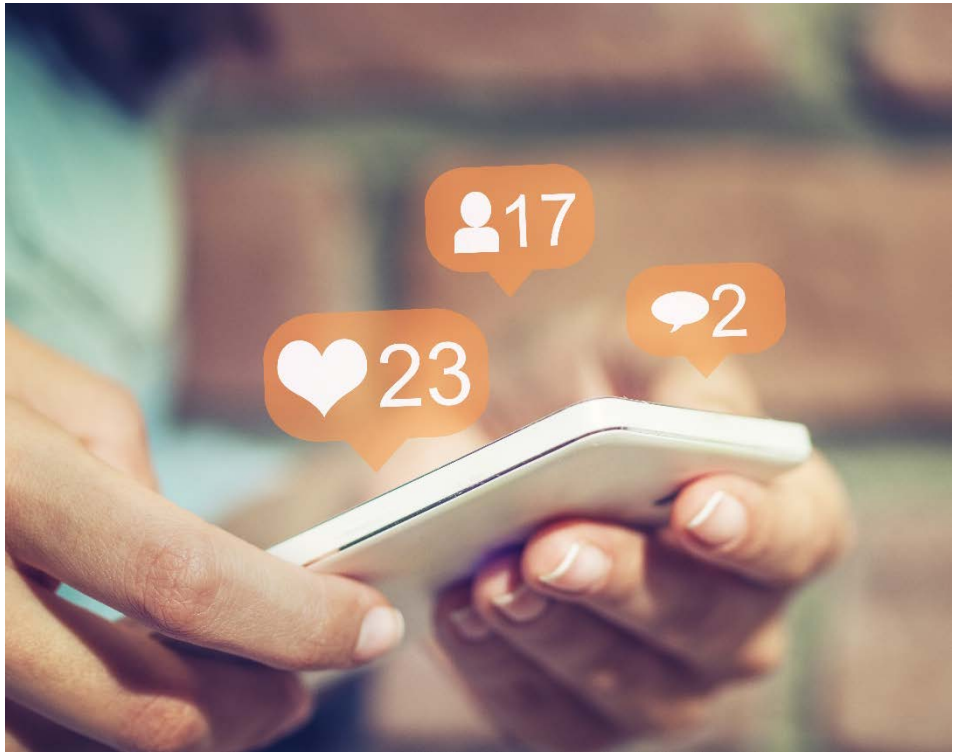
Vulnerable Populations Example – Recommendation



Quorum

Social Media as a Recruitment Tool

- Audience reach
- Security and privacy concerns
- Additional concerns related to post-enrollment



Social Media Concerns

- Breach of privacy
- Un-blinding of study groups
- Negative or misleading information
- Skewed reporting of benefits

Quorum

Creating a Protective Social Media Plan

- **Management and Monitoring:** How you will monitor user comments on a continuous basis and at what frequency?
- **Safety and Data Integrity:** How you will manage user comments related to safety, efficacy or that are potentially influencing in this investigational study?
- **Maintenance:** Describe your process in place for handling IT or technical issues. Is there a dedicated team for this?

Social Media Plan: Monitoring Example

- *“Social media platforms require consistent review, as the privacy policies and administrative limitations are always evolving. Careful monitoring of all social media campaigns, including real-time monitoring of comments, shares, and tags, is constantly being done. While we can closely monitor campaigns and hide negative comments, we cannot completely disable commenting.”*

- *“Comments across all channels will be reviewed twice per week day, and once per day during the weekend. These channels are constantly open on our digital marketer’s laptop, and a simple refresh is all that is needed to see the latest comments/tweets.”*

Social Media Plan: Potentially Influencing Example

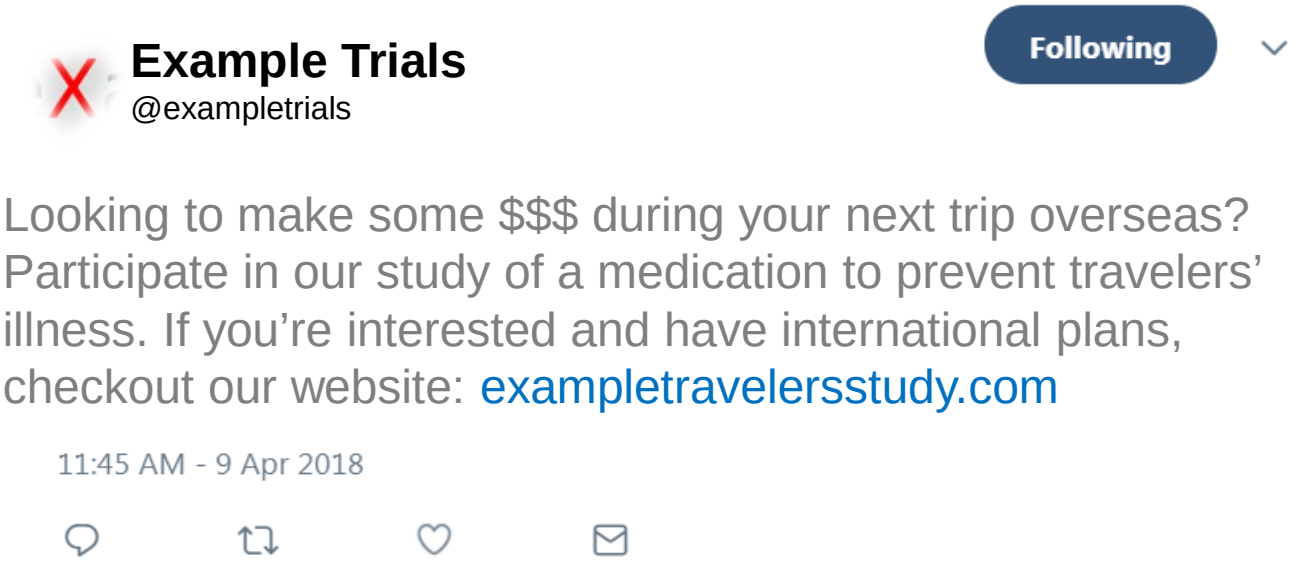
- *"If the user tries to spread false statements on our social media channels, their comments will be hidden/deleted. (Hiding their comments makes it to where they will not be seen by anyone viewing our business page, but the user will still see the comment. Hiding comments is usually the best practice as the user still believes it is public, but in reality only we can see it. If we delete the comment, the user will be notified of its deletion and may be more apt to continue commenting to make their point.) They will not be banned unless the behavior continues in an aggressive manner."*

- *"When users ask acceptable questions, post acceptable comments, or message the page directly, it will be responded to very generally by providing the study website and study hotline."*

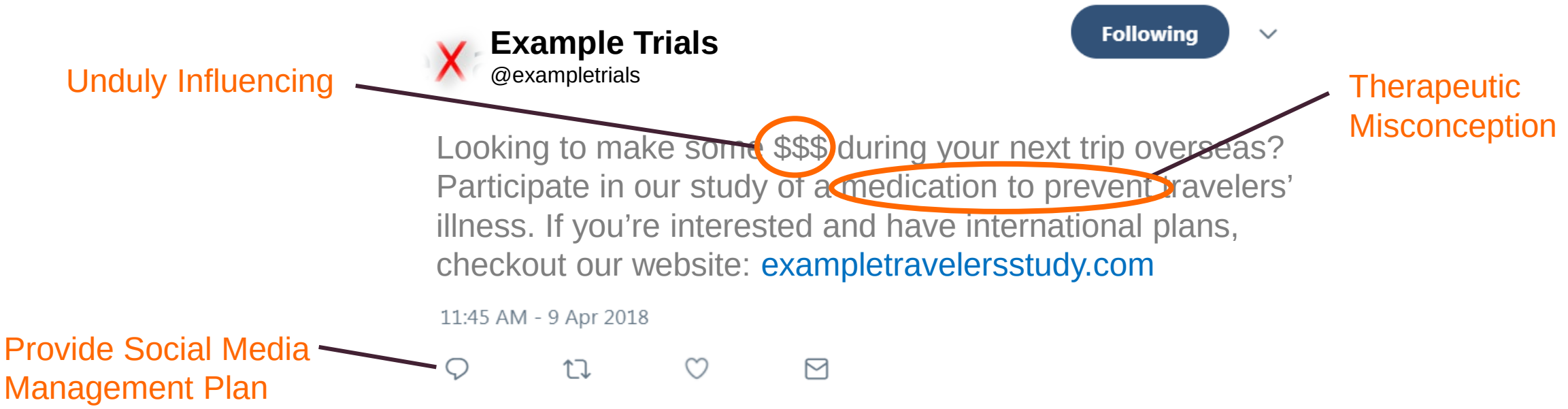
Social Media Plan: IT Maintenance Example

“Our Site employees an IT consultant who is available to address any issues that arise. Our process is that as soon as site is aware of a technical issue, our IT consultant is notified and addresses the issue as soon as possible.”

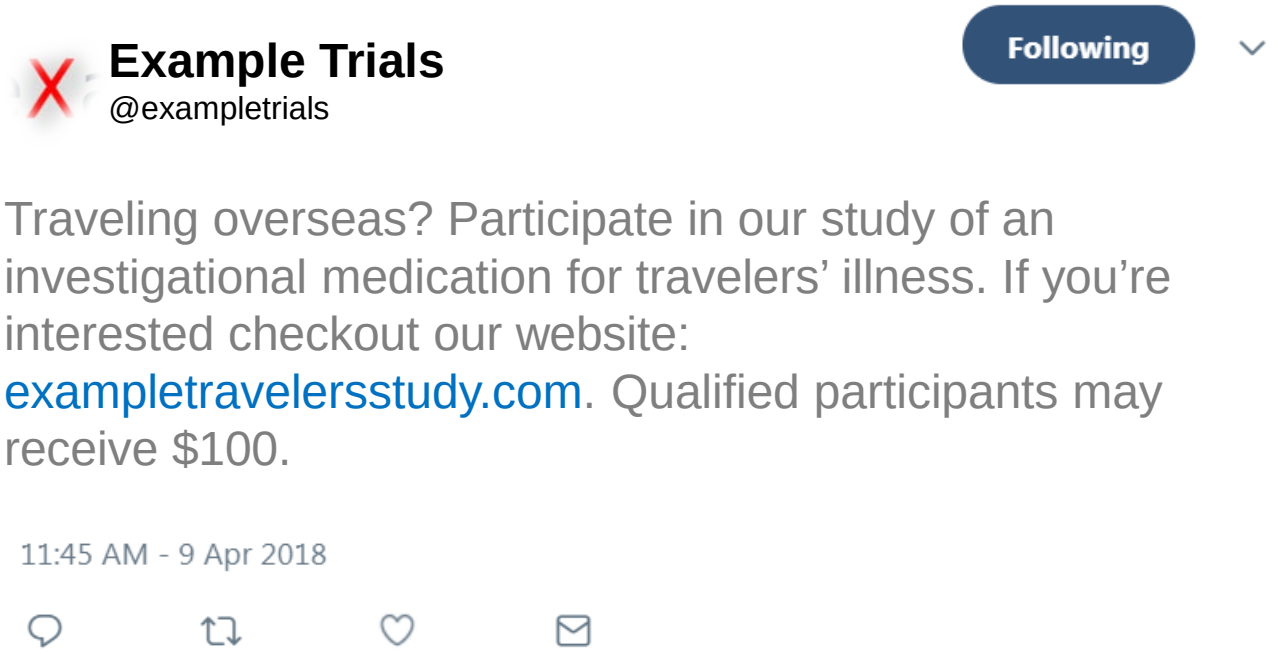
Now You Try



Now You Try – Considerations



Now You Try – Recommendation



Summary

- Balance between stimulating enrollment and protecting potential participants
- Accurate information at every stage improves retention and protects trust
- **Minor adjustments to language and images can make all the difference!**

Create Recruitment Materials IRBs Love

May 2018

Where Is Your Research Study?

One-Touch Collaboration™ makes Quorum the most preferred central IRB.

- One study contact
- One stream of clear, coordinated communications
- One streamlined study startup process

Start Your Study at QuorumReview.com

"I should have sent my study to Quorum."

Quorum

Q&A

Submitted a question during the webinar?

You will get an answer back from us in writing.

Quorum Mailing List

Sign up to receive updates about

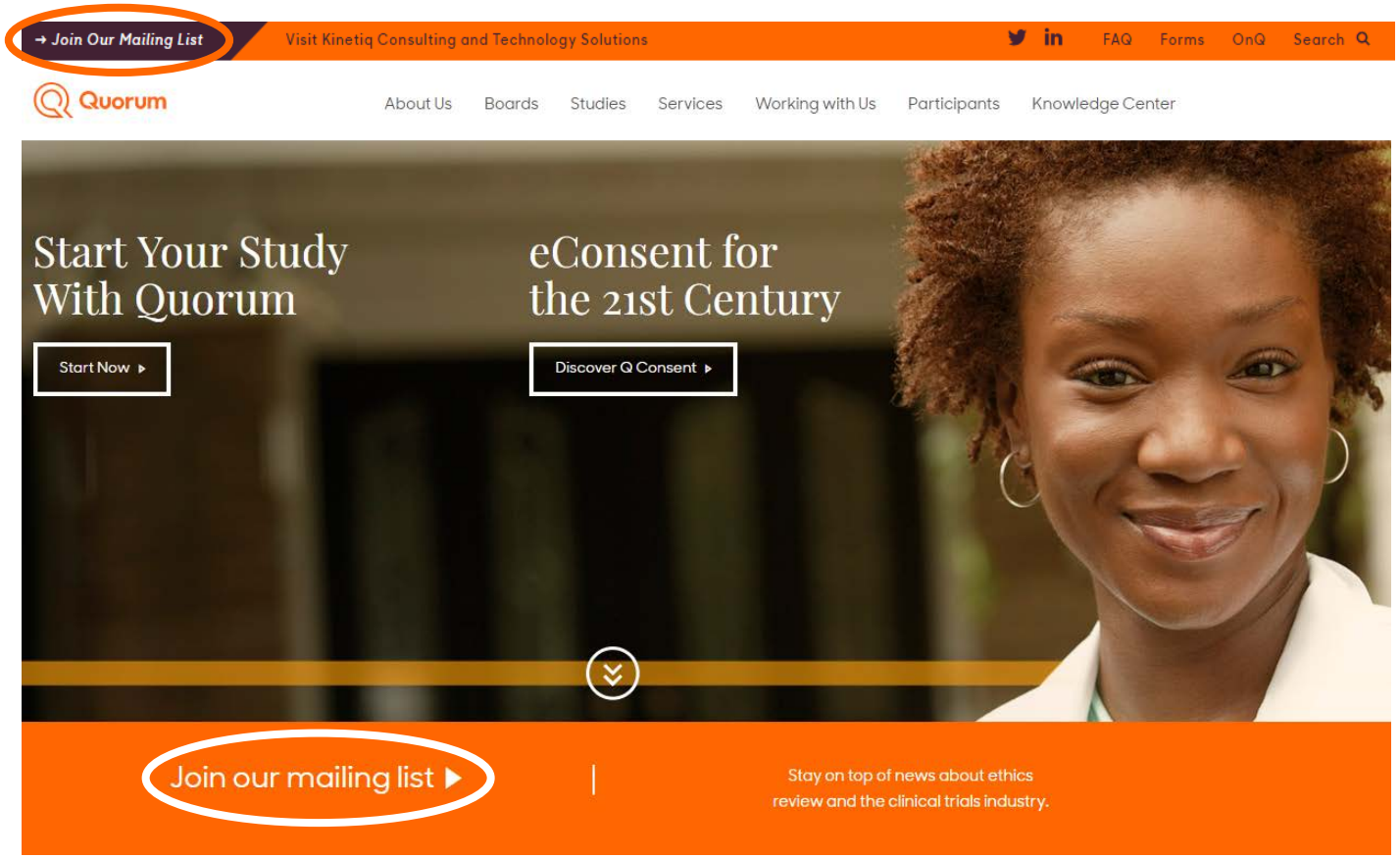
> Upcoming webinars

> Whitepapers

> Blog posts

> Events

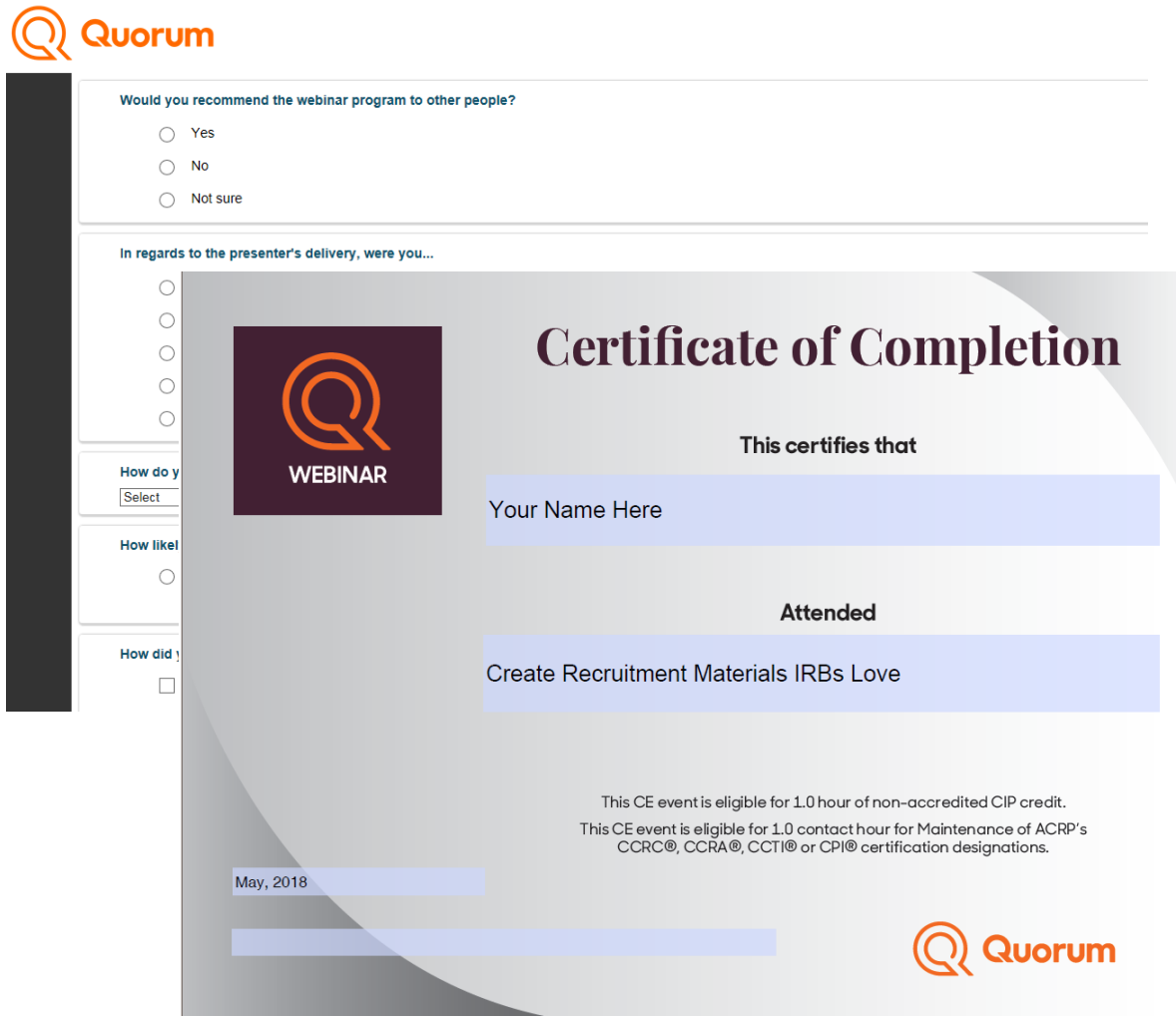
QuorumReview.com



Quorum

Certificates

- Remember: Complete the post-webinar survey in order to receive your certificate
- If you have any trouble obtaining your certificate, email us at clientrelations@quorumreview.com



Thank you!

CONNECT

Web QuorumReview.com

Email ClientRelations@QuorumReview.com

VISIT

QuorumReview.com/Knowledge-Center

SOCIAL MEDIA