



Create Recruitment Materials IRBs Love

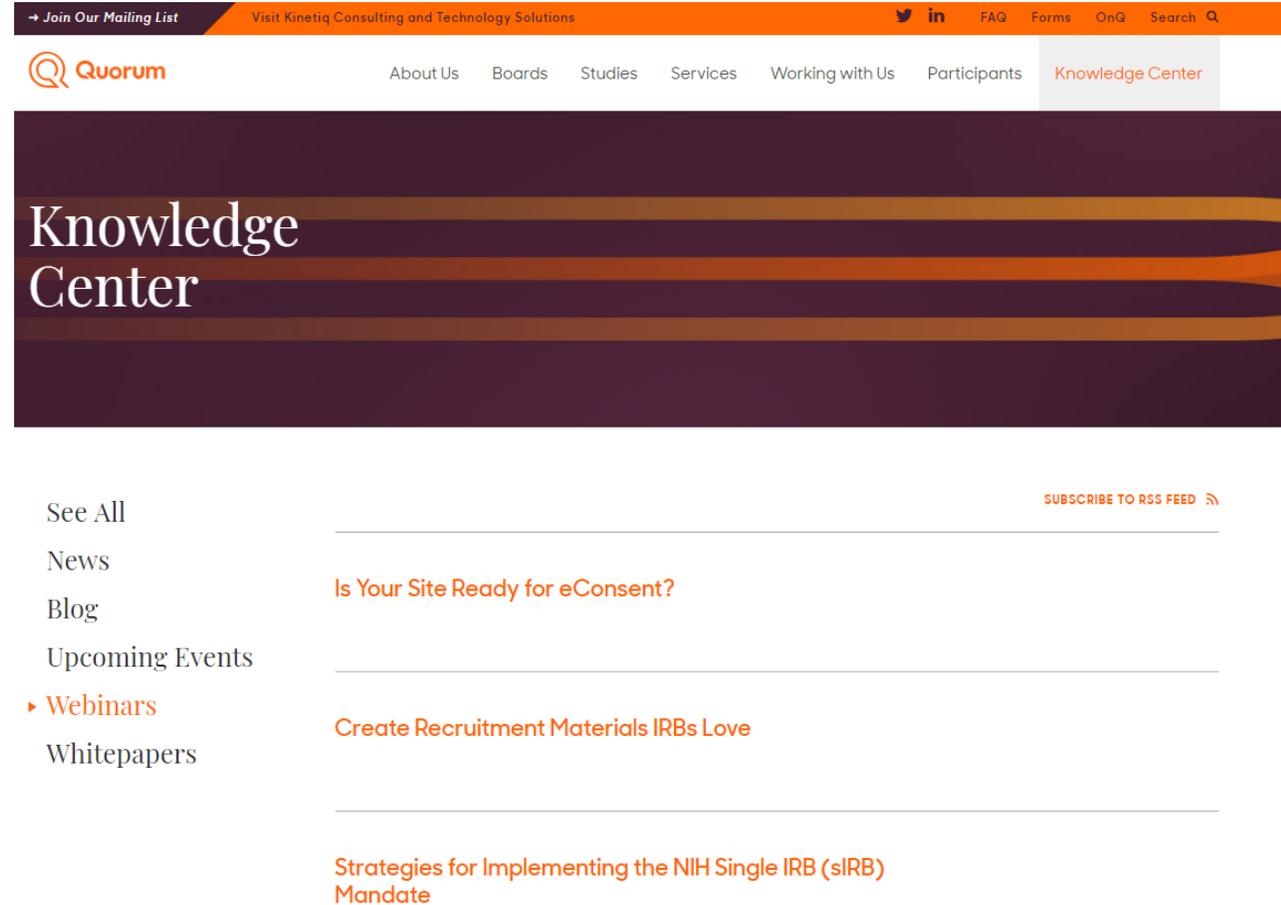
Lizbeth Adams, PhD, CIP
Amanda Higley, PhD

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:

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The screenshot shows the Quorum Knowledge Center website. The top navigation bar includes links for "Join Our Mailing List", "Visit Kinetiq Consulting and Technology Solutions", social media icons for Twitter and LinkedIn, and links for "FAQ", "Forms", "OnQ", and "Search". The main navigation menu includes "About Us", "Boards", "Studies", "Services", "Working with Us", "Participants", and "Knowledge Center". The "Knowledge Center" section is highlighted. Below the navigation, there is a large banner with the text "Knowledge Center". To the left of the main content area, there is a sidebar with a list of categories: "See All", "News", "Blog", "Upcoming Events", "Webinars" (highlighted with a red arrow), and "Whitepapers". To the right of the sidebar, there is a "SUBSCRIBE TO RSS FEED" link. The main content area displays three articles: "Is Your Site Ready for eConsent?", "Create Recruitment Materials IRBs Love", and "Strategies for Implementing the NIH Single IRB (sIRB) Mandate".

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 subjects¹
- > Poor site selection can increase costs by **20%**²
- > **80%** of clinical trials fail to meet enrollment deadlines³

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

exampleSM



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

STOMACH PAIN AFTER EATING FATTY FOODS?



Do experience pain under the right side of the rib cage? Pain that radiates to the back or right shoulder? If you said yes, and are between the age of 40 to 75 you could qualify for our study!

Call now to see if you qualify!

555-555-BURN

HEARTBURNSTUDY@EXAMPLE.COM

COMPENSATION UP TO \$500.00!!!

1111 5th St
Example, USA

eXample™

example.com

Unduly Influencing Language Example – Considerations

STOMACH PAIN AFTER EATING FATTY FOODS?



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Unduly Influencing Language Example – Recommendation

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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...



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...



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...



Promoting Therapeutic Misconception

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

Therapeutic Misconception Example



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



eXample™ 555-555-5555

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.

Therapeutic Misconception Example – Considerations

Therapeutic Misconception

Don't

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

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“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

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

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.

www.allergyexamplestudy.com

ALLERGYEXAMPLESTUDY.COM



Like



Comment



Share



Write a comment...



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.

www.allergyexamplestudy.com

ALLERGYEXAMPLESTUDY.COM

 Like

 Comment

 Share



Write a comment...



Therapeutic Misconception Example – Recommendation

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 for allergies. Make an appointment today with one of our study doctors at 555-555-5555. Visit www.allergyexamplestudy.com for more information.

www.allergyexamplestudy.com

ALLERGYEXAMPLESTUDY.COM



Like



Comment



Share



Write a comment...



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**_____

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_____

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

Instagram

exampletrials Sponsored

Got Acne? We Can Help!

Sign Up

exampletrials Acne ruining your social life? Our study offers hope and participants may receive up to \$1500!!!

Vulnerable Populations

Example - Considerations

Instagram

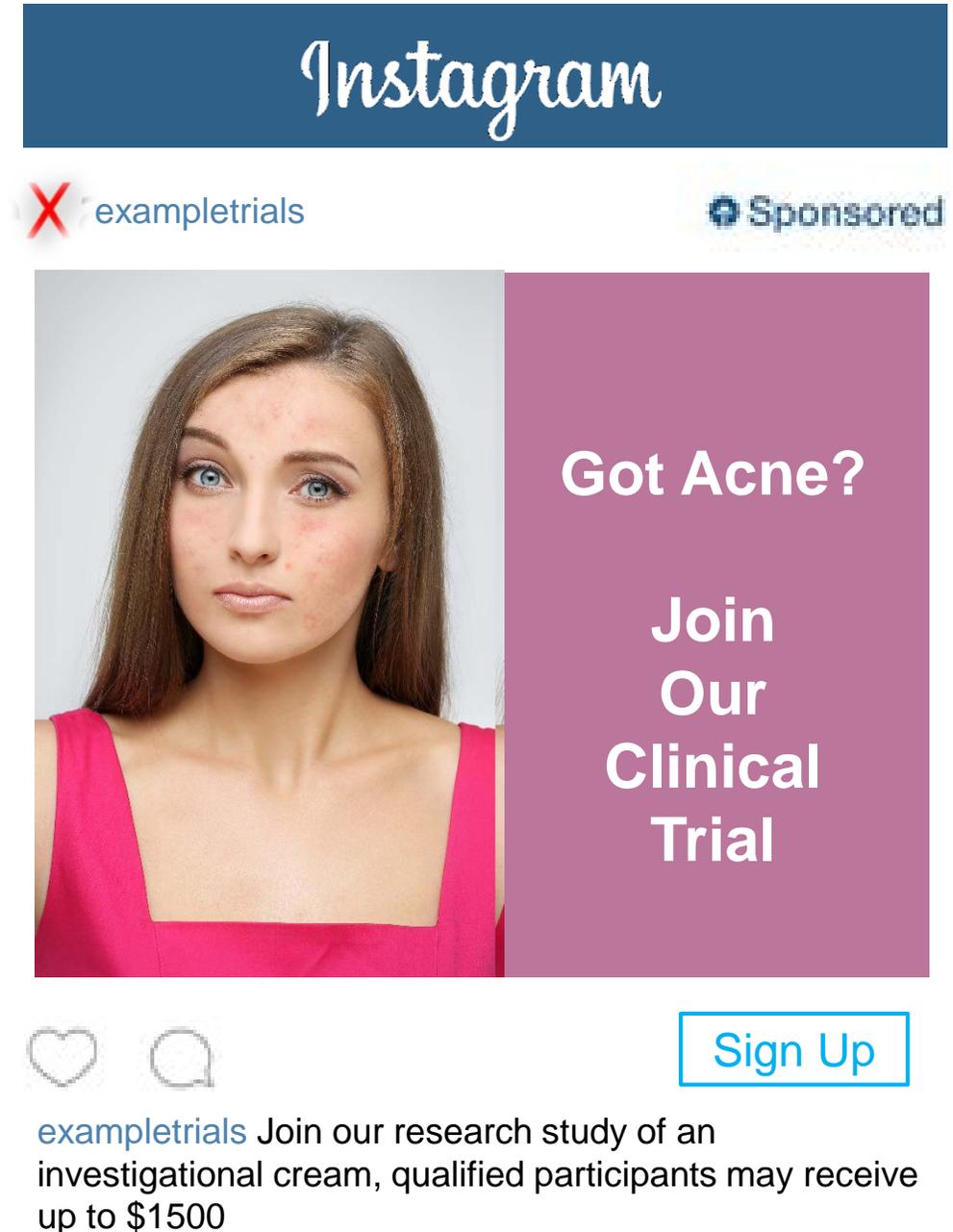
exampletrials Sponsored

Got Acne? We Can Help!

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Vulnerable Populations Example – Recommendation



The image shows a screenshot of an Instagram post. At the top, the Instagram logo is displayed in white on a dark blue background. Below the logo, the username 'exampletrials' is shown with a red 'X' icon next to it, and a 'Sponsored' badge is visible in the top right corner. The main content of the post is a square image. On the left side of this image is a portrait of a young woman with long brown hair and blue eyes, wearing a bright pink top. She has visible acne on her face. On the right side of the image is a purple-to-pink gradient background with white text that reads 'Got Acne?' at the top, followed by 'Join Our Clinical Trial' in a larger font. Below the image, there are icons for a heart and a comment bubble. To the right of these icons is a blue-outlined button with the text 'Sign Up'. Below the image and icons, the caption reads: 'exampletrials Join our research study of an investigational cream, qualified participants may receive up to \$1500'.

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



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



Example Trials

@exampletrials

Following



Looking to make some \$\$\$ during your next trip overseas? Participate in our study of a medication to prevent travelers' illness. If you're interested and have international plans, checkout our website: exampletravelersstudy.com

11:45 AM - 9 Apr 2018



Now You Try – Considerations

Unduly Influencing



Example Trials

@exampletrials

Following



Looking to make some \$\$\$ during your next trip overseas?
Participate in our study of a medication to prevent travelers' illness. If you're interested and have international plans, checkout our website: exampletravelersstudy.com

Therapeutic Misconception

Provide Social Media Management Plan



Now You Try – Recommendation



Example Trials

@exampletrials

Following



Traveling overseas? Participate in our study of an investigational medication for travelers' illness. If you're interested checkout our website: exampletravelersstudy.com. Qualified participants may receive \$100.

11:45 AM - 9 Apr 2018



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](https://www.QuorumReview.com)



"I should have sent my study to Quorum."

Q&A

Submitted a question during the webinar?

You will get an answer back from us in writing.

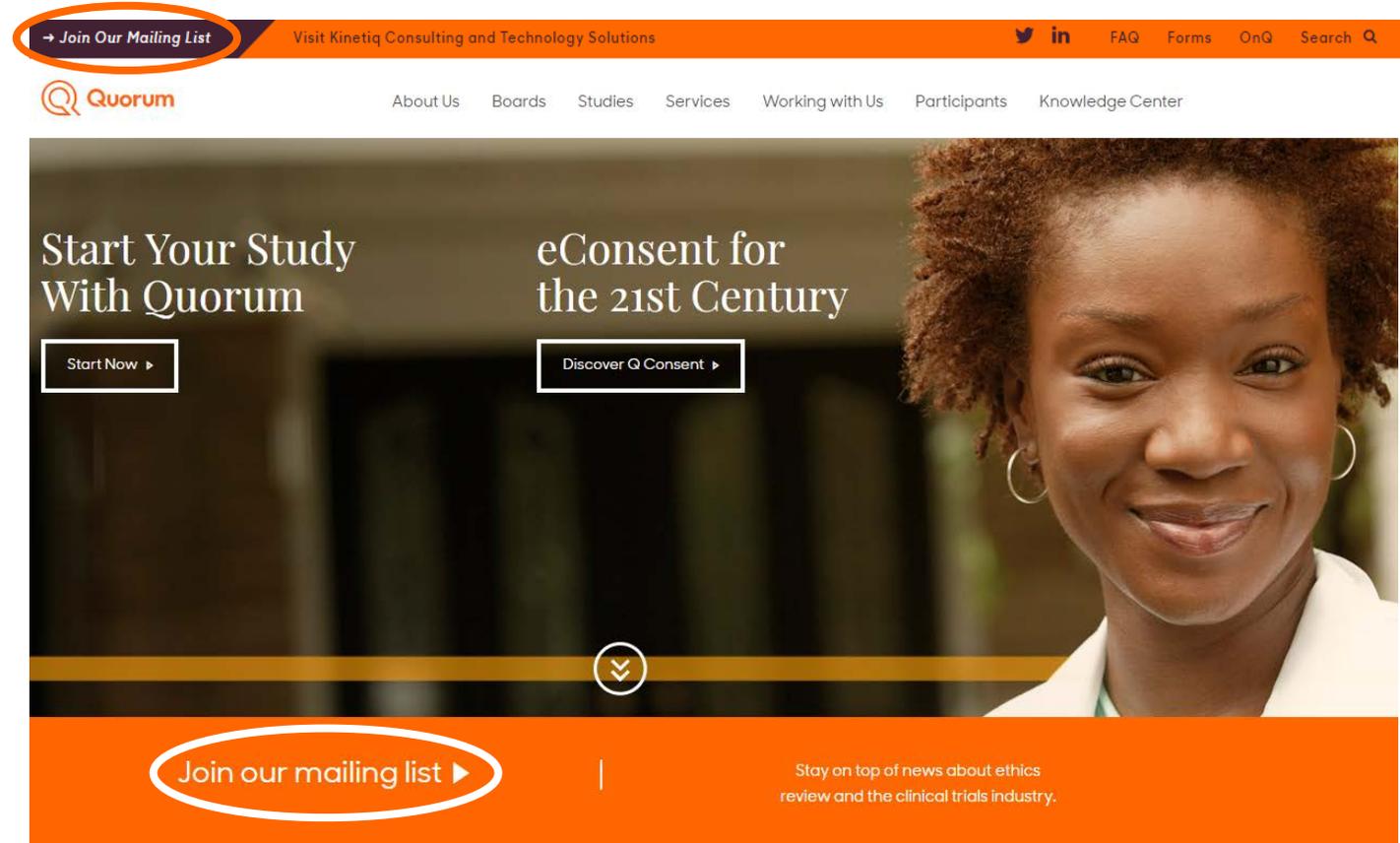


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Certificates

- > 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

The image shows a screenshot of a Quorum webinar completion survey and certificate. The survey is titled "Would you recommend the webinar program to other people?" and has three radio button options: "Yes", "No", and "Not sure". Below this is a section titled "In regards to the presenter's delivery, were you..." with five radio button options. The survey is partially completed, with "How do you" set to "Select", "How likely" set to "1", and "How did" set to "1".

The certificate is titled "Certificate of Completion" and features the Quorum logo and the word "WEBINAR". It certifies that "Your Name Here" attended the webinar "Create Recruitment Materials IRBs Love" in May, 2018. The certificate also includes a note about CE credit: "This CE event is eligible for 1.0 hour of non-accredited CIP credit. This CE event is eligible for 1.0 contact hour for Maintenance of ACRP's CCRC®, CCRA®, CCTI® or CPI® certification designations." The Quorum logo is visible in the bottom right corner of the certificate.

Thank you!

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SOCIAL MEDIA

