About Schulman Associates IRB

- Established in 1983
- US and Canadian boards fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP)
- Superior audit history with FDA—five consecutive audits with no findings
- 21 CFR Part 11 compliant electronic systems
- Compliant with FDA, OHRP and Health Canada requirements
About Schulman Associates IRB

- Full board meetings **five days a week**
- Dedicated **daily expedited review** of qualifying minimal risk protocols
- **Phase I Board** with streamlined processes tailored to Phase I timelines
- **Oncology Review Board** for all phases of oncology research
- Customized services for **institutions and AMCs**
- Experienced primary points of contact for sponsors, CROs, institutions and sites
About Schulman Associates IRB

- Clinical Quality Assurance (CQA) and Human Research Protection (HRP) consulting services provided by Provision Research Compliance Services

Provision is a joint venture between Schulman Associates IRB and Falcon Consulting Group

www.provisionrcs.com
About Today’s Presenter

Kim Looney, RN, JD
IRB Vice Chair

- Nursing Diploma, St. Mary’s Nursing School
- BA in English, University of Tennessee
- Juris Doctor, University of Cincinnati
- US Air Force Nurse Corps, Veteran
- Extensive experience as RN, Clinical Risk Manager and Attorney with healthcare systems
- Experience as IRB Member in both institutional and commercial settings
- Joined Schulman in 2003, having served as IRB Member, Assistant Counsel, Counsel and presently serves as IRB Vice Chair
About Today’s Presenter

Ashley Dixon, Th.B.
IRB Member

- Bachelor’s Degree in Theology from Apostolic Bible Institute
- With Schulman since 2007
- IRB Member since 2009
- Project lead for Canadian Ethics Board development and implementation
Presentation Objectives

- Review the regulations governing IRB review of subject recruitment materials.
- Describe content guidelines for development of appropriate recruitment materials.
- Examine recruitment material case studies.
- Identify strategies for submitting recruitment materials for IRB review.
FDA requires that an IRB review and have authority to approve, require modifications in, or disapprove all research activities covered by federal regulations governing human subjects research.

- 21 CFR 56.109(a) and 45 CFR 46.109(a)

In fulfilling these responsibilities, an IRB reviews the methods and material that investigators propose to use to recruit subjects.

FDA considers direct advertising for study subjects to be the start of the informed consent and subject selection process.

Code of Federal Regulations

- FDA considers claims of safety or efficacy of an investigational product, drug or device to be unlawful promotion of investigational products.

21 CFR 312.7(a), 21 CFR 812.7(d)

FDA Information Sheets

[Links to relevant information sheets]
Regulations and Recruitment

Per the FDA’s Federal Guidance on Recruiting Study Subjects, the IRB should ensure that advertising:

• Does not coerce or unduly influence potential subjects to participate.
• Does not state or imply a favorable outcome or other benefits beyond that outlined in the consent document and protocol.
• Makes no claims, explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation or that the test article is equivalent or superior to any other drug, biologic or device.
Partial Waivers of Authorization

- **General Rule:**
  - Except as otherwise permitted by the HIPAA Privacy Rule, a covered entity must obtain a valid HIPAA Authorization for its use or disclosure of protected health information (PHI).  
    - 45 CFR 164.508(a)(1)

- **Exception:**
  - The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by an IRB or Privacy Board.  
    - 45 CFR 164.512(i)(2)

- Covered Entities must obtain a partial waiver of authorization to use and/or disclose individually identifiable health information (i.e., PHI) for recruitment purposes.

- Each organization is responsible for determining whether it is a [Covered Entity](#).
Content Guidelines

- Generally, recruitment material should be limited to the following information:
  - A statement that the study involves research
  - The condition being studied and/or the purpose of the research, e.g., “an investigational drug to determine if it may improve (condition)”
  - A summary of eligibility (inclusion/exclusion) criteria
  - A list of potential benefits, if any
  - Location of the research site and the contact information
Tips for using lay language:

- Use “investigational” or “experimental” wherever appropriate.
- Use “research study” instead of “clinical trial.”
- When describing study purpose (e.g., “…a research study of an investigational drug…”), include “to determine if it helps…,” “to determine if it improves…,” or “to see if it….”
Avoid language that could create **therapeutic misconception**

- Occurs “when a research subject fails to appreciate the distinction between the imperative of clinical research and of ordinary treatment and therefore inaccurately attributes therapeutic intent to research procedures.”

Avoid **exculpatory language**.

- OHRP and FDA consider exculpatory language to be language which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt.

*Clinical Trials and Medical Care: Defining the Therapeutic Misconception*

“Suffering with poor health? Feeling trapped or unable to do anything about it due to lack of insurance? Consider volunteering for clinical research. Your condition may meet the requirements of an on-going study. If so, no medical insurance will be required, and medication and treatments will be provided at no cost to you.”
“Suffering with poor health? Feeling trapped or unable to do anything about it due to lack of insurance? Consider volunteering for clinical research. Your condition may meet the requirements of an on-going study. If so, no medical insurance will be required, and medication and treatments will be provided at no cost to you.”

- Therapeutic misconception
- Reference to treatment
- Inaccurate portrayal of drug regulatory status
“Suffering with poor health? Feeling trapped or unable to do anything about it due to lack of insurance? Consider volunteering for a clinical research study. Your condition may meet the requirements of an on-going study. If so, no medical insurance will be required, and investigational medication and treatments—study-related care will be provided at no cost to you.”
Unacceptable Content for Recruitment Materials

- Emphasis on subject compensation
- Misleading mottos or logos — “Tomorrow’s Drugs Today!”
- Excessive repetition of words such as “free” or “at no cost”
- Dollar compensation amounts for studies involving children
- Referral fees (finders’ fees) offered to referring physicians or subjects based on enrollment and/or retention
What Do We Mean by “Recruitment Materials”?

- Newspaper ads
- Radio and TV ads
- Subject/patient letters
- Online ads, study websites, Craigslist postings
- Social media
- Screening scripts
- Newsletters
- Generic pre-screening informed consent documents
- Health workshops, screenings and health fairs for recruitment purposes

...Basically anything a potential study subject will encounter that informs them about the specific study.
Got Acne?

Sign up for our acne research study & be eligible for up to $450 in compensation for your time and travel!

Gotham City Research is conducting a research study to evaluate the safety and effectiveness of an investigational topical gel medication used in the treatment of moderate to severe facial acne.

You may qualify if you:
- Are over the age of 13
- Have mild to severe facial acne
- Can commit to 8 visits over a 16 week period at our Gotham City office

To see if you qualify, contact 555-555-5555
Content Case Studies: Print Ad

Sign up for our acne research study & be eligible for up to $450 in compensation for your time and travel!

Gotham City Research is conducting a research study to evaluate the safety and effectiveness of an investigational topical gel medication used in the treatment of moderate to severe facial acne.

You may qualify if you:
• Are over the age of 13
• Have mild to severe facial acne
• Can commit to 8 visits over a 16 week period at our Gotham City office

To see if you qualify, contact 555-555-5555

- Compensation prominently displayed
- Therapeutic misconception
- Dollar amounts listed in a pediatric study
Sign up for our acne research study & be eligible for up to $450 in compensation for your time and travel!

Gotham City Research is conducting a research study to evaluate the safety and effectiveness of an investigational topical gel medication used in the treatment of moderate to severe facial acne.

You may qualify if you:
• Are over the age of 13
• Have mild to severe facial acne
• Can commit to 8 visits over a 16 week period at our Gotham City office

To see if you qualify, contact 555-123-4567 or your child.
A generic pre-screening informed consent contains the following list of procedures with descriptions:

a. Limited medical history
b. Blood draws
c. Pulmonary function test/spirometry
d. Temporarily stopping one or more current medications
e. Vital signs and/or physical examination
A generic pre-screening informed consent contains the following list of procedures with descriptions:

- Limited medical history
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- Temporarily stopping one or more current medications
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Temporarily stopping one or more current medications
FSA Information Sheet titled “Screening Tests prior to Study Enrollment” states:
“For some studies, the use of screening tests to assess whether prospective subjects are appropriate candidates for inclusion in studies is an appropriate pre-entry activity. While an investigator may discuss availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research, including withdrawal from medication (wash-out). When wash-out is done in anticipation of or in preparation for the research, it is part of the research.”

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm
Types of Recruitment: Video and Audio Recording

- Recommend submitting video and audio scripts and storyboards for review prior to production.
  - The completed video or audio recording must also be submitted for review prior to use.
  - Keep this additional review in mind when considering timelines.

- By submitting the script/storyboard prior to production, the IRB can review and, if necessary, request changes to the content before time and resources are spent in recording.
FDA guidance recommends that IRBs consider certain questions pertaining to the use of the information obtained during a telephone screen:

- What happens to personal information if the caller ends the interview or hangs up?
- Does a marketing company gather the data? If so, are the names, etc. sold to others?
- Are the names of non-eligible callers maintained in case they may qualify for another study?
- Are paper copies of phone screen documents shredded or readable copies put in the trash?
A phone screening document contains the following questions:

a. Are you currently pregnant or breast feeding?
b. What are your current birth control methods?
c. Are you currently suicidal?
d. Have you participated in a clinical trial in the past 90 days or more than 2 trials in the past year?
A phone screening document contains the following questions:

a. Are you currently pregnant or breast feeding?
b. What are your current birth control methods?
c. Are you currently suicidal?
d. Have you participated in a clinical trial in the past 90 days or more than 2 trials in the past year?
IRB’s notation:
“In light of the potentially serious legal ramifications if appropriate action is not taken for callers at serious risk of self-harm, please remove the question or enhance the procedure to be followed if an affirmative response is received (i.e. keep the caller on the line and call 911).”
Types of Recruitment: Online Recruitment

- Online recruitment is a tricky issue—little regulatory guidance is available on this specific topic.
- Although websites use a different medium than traditional print or broadcast advertisements, the requirements are the same.
  - Consider online recruitment the same way you would a print ad or poster.

If you’re using the content to recruit subjects to a specific study, it probably needs IRB approval.
Types of Recruitment: Social Media

- Consider how potential subjects can interact with social media platform.
- May be beneficial to turn off comments or closely moderate all interactions on social media platform.
  - These interactions may affect subject privacy, potential disclosure of PHI, and misconceptions regarding the investigational product’s effectiveness.
Submitting Recruitment Materials for IRB Review

- Be familiar with IRB & federal guidelines for review of recruitment materials.
- When in doubt, be conservative.
- If possible, submit recruitment materials at the time of initial protocol submission.
- Provide similar previously approved recruitment materials to the IRB.
- Find out if IRB has guidance documents to assist you in creating and submitting recruitment materials.
- Be aware of the timetable for review of recruitment materials and allow time for revision if necessary.
Submitting Recruitment Materials for IRB Review

- Do not send materials with statements that cannot be modified.
- Do not print several hundred recruitment brochures prior to IRB review.
- Do not record audio/video before IRB approves the script.
- Be responsive to IRB requests for revisions to recruitment materials.
- Contact the IRB if you do not understand its rationale for requesting revisions.
Conclusion

- Always note at least once in the material – “Research Study.”
- Always note the regulatory status of the study product.
  - e.g., “investigational drug” or “investigational use of a marketed drug”
- Avoid therapeutic misconception.
  - Research is not medical treatment.
- When in doubt, compare advertisement content to the informed consent document to ensure accuracy.
- If you’re not sure about something, speak with your IRB.
IRB Review of Recruitment Materials
Engaging Subjects Responsibly & Ethically
December 10, 2014

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