Clinical Trials and Outreach Advertising Guidelines

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The U.S. Food and Drug Administration (FDA) requires that all ads seeking participants for enrollment in clinical trials must have Institutional Review Board (IRB) approval.

For questions regarding advertising for clinical trials, contact Noel Myers, senior analyst, Human Research Protections Program (HRPP), at 858-657-5156 or nmyers@health.ucsd.edu.
Non-Endorsement Standards

The U.S. Food and Drug Administration (FDA) requires that all ads seeking participants for enrollment in clinical trials must have Institutional Review Board (IRB) approval. Additionally, the FDA believes that any advertisement should be limited to the information that participants need to determine their eligibility and interest.

Clinical trial ads SHOULD include:

- Name and address of principal investigator (PI)
- Name and address of affiliated research facility
- Condition or disease under study
- Purpose of the research
- Criteria that will be used to determine eligibility for the study (e.g., gender, age range)
- Brief list of procedures required (e.g., X-rays, blood tests)
- Brief list of participation benefits, if any (e.g., a no-cost health examination)
- Compensation, if applicable, may be briefly mentioned, but not emphasized
- Mention of whether study participation may result in receiving a placebo instead of the actual study drug
- Time or other commitment required of the subjects (e.g., length of study, number of visits)
- Contact name and information for receiving further information (e.g., phone number, e-mail, URL)

Clinical trial ads should NOT include:

- Claims that a drug, biologic or device is safe or effective for the purposes under investigation or is equivalent to or superior to any other drug, biologic or device
- References to “new treatment,” “new drug” or “new medication” without explaining that it is investigational
- Claims that the subject will receive therapeutic benefit from participation in the study
- Inappropriate images
- Offers of compensation from a sponsor that would involve a coupon good for a discount on the purchase price of the product once it has been approved for marketing
Editorial and Design Style

The FDA also encourages that certain editorial and design styles be followed for clinical trial ads; HRPP policies and procedures also adhere to this. Deviation from the following editorial and design formats may delay your IRB approval.

The public recognizes the need for clinical trials in order to make new treatments and therapies available; however, the market for clinical trial participants is competitive. To capture someone’s attention, clinical trial ads must be effective. Effective ads can increase enrollment; effectiveness can be increased when attention is paid to tone, readability, layout, color, spacing and design.

Editorial Style

- Write copy at 6th grade reading level — unbiased, lay language
- Avoid acronyms or abbreviations unless these are well known to the public or your target audience
- Avoid coercive language
- Use the words “research study” instead of “treatment study” as they do not convey the same meaning
- Use the word “investigational” rather than “experimental”
- Use the term “healthy volunteers” instead of “normal volunteers”
- Use “participants” rather than “patients”
- Always put the person before the disease (ex: “a patient with cancer” not “a cancer patient” or “he has diabetes” not “a diabetic”)
- Use the words “at no cost” instead of “free,” if applicable
- No dollar amount should be listed; simply write “compensation provided”
- Use bullet point text — keep it simple
- Be precise with facts — how many, how often
- Verify contact information
- To view the entire UC San Diego Health Editorial Style Guide, visit pulse.ucsd.edu/styleguide.

Design

- Use appropriate images that represent your target audience (without evidence of disease)
- Do NOT use photos of patients (HIPAA violation)
- Use legitimate stock photography sources, such as Getty Images (gettyimages.com) or Shutterstock (shutterstock.com) for images — do not download images from other websites unless you have permission to do so
- Do not make references to compensation in the lead or highlight it in any way (ex: bold, enlarged type)
- Supply Chain’s Forms Management team has an in-house design resource available for layout and design. Once the content for your ad is approved, you can work directly with Forms Management to design your ad. You must provide an index number for the cost of design production. Contact forms@health.ucsd.edu for more information.
- After the ad is designed, it will still need IRB approval. Marketing and Communications is not involved in the design process of clinical trials ads.
Logo Usage

As stipulated by the IRB, all clinical trial ads should use the UC San Diego Health logo. No element of our brand identity plays a more critical role than our logo. Used properly, it will unify our various entities under a single brand and elevate our collective image. This guide provides detailed information on the correct positioning, size, color, clear space and other visual aspects for the logo.

Resources

You can request a logo package by contacting healthbrand@ucsd.edu. We recommend vector format for print ads (EPS). For more information on brand standards please refer to the UC San Diego brand guidelines at ucpa.ucsd.edu/brand.

Clear Space

The required amount of clear space ensures maximum visibility and legibility. It is determined by the height of the letter “U” in UC San Diego Health, and applies to all graphics using the logo, including department wordmarks.

Logo Positioning

The size and location of the UC San Diego Health logo is important for recognition, especially when seen across various materials. A consistent approach to logo placement helps create stronger brand recognition over time.

The primary position for the logo is in the upper left-hand corner of the page. The lower right-hand corner is the acceptable alternate position.

The logo should always be positioned at least a “U” height from both edges of the page.

Sizing

Logo minimum print size: 1.25” (31.75 mm) wide
Logo preferred print size: 2” (50.8 mm) wide

Logo Color

The primary logo color on all printed materials should be PANTONE® 2767 (navy) or its CMYK equivalent. Use the RGB or HEX breakdowns for web, video and display applications.

The primary accent color to accompany the logo is Pantone® 3015.

PMS 2767
CMYK: 100 86 42 42
RGB: 24 43 73
HEX #182B49

PMS 3015
CMYK: 100 35 3 21
RGB: 0 106 150
HEX #006A96

Corporate Typeface

Brix Sans is the corporate typeface for UC San Diego Health. This font is not available for general distribution and use but can be purchased at myfonts.com. Arial and Calibri are acceptable alternatives.

Brix Sans

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz
1234567890 (,.?!@#$%^&*-)

UC San Diego Health Clinical Trials and Outreach Advertising Guidelines
Proper Name Usage

UC San Diego Health

- Spell out “UC San Diego Health” for first reference
- Use “UC San Diego Health” not “the UC San Diego Health”
- “UC San Diego Health” cannot be translated into Spanish or any other language, as it is a brand name. When it is used within a publication written in Spanish or another language, it must still be referred to as it is in English.

For all editorial guidelines related to UC San Diego Health, visit pulse.ucsd.edu/styleguide-hs.
Sample Advertisements

Are you a prostate cancer patient?
Consider participating in the Men’s Healthy Eating and Living Study (MEAL) to help us find out if a healthy diet affects prostate cancer.
To learn more, please call 858-822-2895.

UC San Diego Health

Do You Have Gout?
The Center for Innovative Therapy, UC San Diego School of Medicine is currently seeking individuals to participate in a clinical research study for a medication that is used in the treatment of gout. If you have been diagnosed with gout, are a man 50 years old or older, or a woman 55 years old or older, you may qualify for this research study.
Qualified participants will receive study-related physical exams by a rheumatologist, laboratory tests and study medication at no cost. To learn more about this research study, please call Annette at 858-657-7040, or e-mail a5torres@ucsd.edu.
Types of Clinical Trial Advertising and Outreach

Any material with the purpose to inform and invite possible subjects to participate in a clinical trial is considered clinical trial advertising and requires IRB approval.

Examples include:
- Newspaper ads (ex: paid and free classified ads, formal display ads)
- Flyers and brochures
- Website and social media postings
- Newsletters
- Journal articles (if they contain recruitment information)
- Bulletin boards
- Posters
- PowerPoint presentations to general public with focus on subject recruitment
- Radio (paid and public service announcements — PSA)
- TV and cable (paid and PSA)
- Press releases
- Other media from sponsors

Dos and Don’ts
- Avoid creating a “therapeutic misconception,” where the benefits of participating in a study are overstated and risks are downplayed
- The word “research” should be included with “study” on first reference only
- Communications staff should consult the IRB on stories mentioning human study volunteers

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Human Research Protections Program

The Human Research Protections Program (HRPP) exists to promote high-quality, ethical research. HRPP does this by serving as the advocate for the rights and welfare of persons who participate in research programs conducted by UC San Diego Health faculty, staff and students, and its affiliates.

Though located within the School of Medicine, HRPP has responsibility for review of research involving human subjects conducted by all schools, centers and programs of UC San Diego Health. The HRPP office assists researchers in complying with federal, state and University policies regarding experimentation involving human subjects, and oversees the review and conduct of research. For more information, visit irb.ucsd.edu.

For additional information, visit:

Standard Operating Procedures and Policies (SOPP)
irb.ucsd.edu/SOPPs.shtml

Fact Sheet: Submitting Ads/Recruitment Materials Related to a Research Plan (Protocol)
irb.ucsd.edu/Ad_factsheet.pdf

Standard Operating Policies and Procedures, Advertisements and Recruiting Materials (Section 3.17)
irb.ucsd.edu/3.17.pdf