

Advertising for Research

Advertising/Recruitment for research (general):

The IRB considers direct advertising for study subjects to be the start of the informed consent and subject selection process. The FDA and the OHRP require that an Institutional Review Board (IRB) review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109(a)]. An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. Recruitment for research should follow ethical guidelines.

Direct advertising includes, but is not necessarily limited to: **newspaper, radio, TV, bulletin boards, posters, and flyers** that are intended for prospective subjects.

Not included are: **(1)** communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for study subjects), **(2)** news stories and **(3)** publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

Advertising for research at BSD at UChicago:

Advertisements submitted to the University of Chicago BSD/UCMC Institutional Review Board should include:

- The purpose of the research
- Summary of eligibility criteria
- Estimated time commitment
- Name of the PI
- Location of the research
- Contact information
- Identification as advertisement for "research"

but

- NOT Promise free medical care or free medications
- NOT Emphasize payment or amount to be paid by such means as larger or bold type
- NOT Name study drugs not approved by the FDA by name
- NOT Contain therapeutic claims

Advertisements should ensure equitable selection of participants. This is especially important when considering "word of mouth" methods. The IRB recommends that students and employees should be recruited through general announcements, bulletin board postings or advertisements, rather than individual solicitations.

Advertising material for research displayed at UCMC sites should have a valid stamp at the header, documenting IRB approval (and expiration date, if applicable).

Ads displayed at UChicago/UCMC for studies taking place at UChicago: Ads and recruitment material to be stamped can be uploaded under **View 3.1** in AURA-IRB. There are times when recruitment material should be uploaded under Supporting materials - **View 8.1 question 2**:

- Ads submitted under AURA **View 3.1** should be specific to any recruitment that will be done at UChicago/UCMC.
- Study teams can also provide brochures or other information that they will utilize when recruiting or explaining the study at the UChicago site.
- Sponsor-issued flyers and social media ads can be provided under **View 3.1** for IRB review, generally with study team attestation (or documentation) that site-specific contact information will be provided. The Committee can decide to approve these or not, however, changes are generally not possible to these types of ads.
- Other sponsor-issued flyers, brochures, social media ads that are intended for display at any of the multiple sites on the sponsored study, and which direct potential subjects to the sponsor for more information, can be submitted under **View 8.1 question 2** in AURA.
- Submitted social media advertising images should also be accompanied by contents of the caption (or web text) underneath them.
- If a study team will include ads under **View 3.1**, a response script should also be provided (for when an interested party calls in or contacts the study team about the study).

Ads displayed at other locations for studies taking place at UChicago:

- For studies taking place at UChicago, when submitting recruitment material that will be posted at other private organizations, community centers, or clinics, study teams should also provide a letter of support from the external clinic or research center.
- For flyers at nearby/local coffee shops or public areas, such a letter would not be needed.

Ads displayed at the main UChicago undergraduate campus:

- These studies should ensure to include UChicago undergraduate students among their study population.

Ads for relying sites (sites for which UChicago is acting as the IRB of record):

- Recruitment material and advertisements for all relying sites should be submitted in AURA **View 3.1** and require review and approval by the UChicago IRB.

Resources:

Recruiting Study Subjects (FDA): <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recruiting-study-subjects>

BSD-IRB P&P Manual (March 2025): <https://dtdxsaqq5q4.cloudfront.net/sites/biologicalsciences/files/2025-04/P%20%26%20P%20March%202025.pdf>

IRB FAQ page: <https://biologicalsciences.uchicago.edu/irb/irb-faqs-and-guidance>

IRB Reliance – UChicago BSD: <https://biologicalsciences.uchicago.edu/irb/irb-reliance>

OHRP: <https://www.hhs.gov/ohrp/index.html>

-- AURA Snapshots and Examples (please see Appendix) --