

UB/CTSI Recruitment Services: Boilerplate Protocol Language

The following sample language can be used in section 11 of IRB's Protocol Template (HRP-503, Ver. 1/23/19). Please remove the green text below and add study specific details to customize this boilerplate language for your study.

Remember that recruitment must be addressed throughout your protocol and not just in section 11. A few other protocol sections that must address recruitment include: 11.1-11.3, 12.4, 18.2, and 20.1-20.5.

Sample Language and Resources

CTSI Recruitment Assistance The [PI/Research Coordinator/Research Nurse] will oversee all study recruitment and enrollment activities. Participants will be recruited by [insert methods of recruitment. These should be tailored to your target population and study topic. Include when, where, how, and by whom participants will be recruited. For example, "Flyers placed by the Research Coordinator at X locations (with permission from the establishment)", descriptions of internal databases/registries/contact lists used, explanation of current/potential community partners, names of clinics or clinicians who will refer patients to you, details about use of ResearchMatch, EHR-based methods like i2b2/TriNetX, etc.]. The study team will utilize the University at Buffalo's Clinical and Translational Science Institute (CTSI) for recruitment assistance and consultation. The CTSI's Recruitment Team provides resources, guidance on appropriate recruitment strategies, and assistance in linking our study team with partners to effectively reach recruitment goals and target populations.

Community Engagement Team: General We will be working with the Clinical and Translational Science Institute (CTSI) Community Engagement Team (CET) to create awareness of the study through their professional and community contacts. The tools they have available may include the Buffalo Research Registry (BRR, IRB Approved STUDY00000806), the Patient Voices Network (PVN), the Conventus CTSI/PVN and Evergreen Research Tables, and conducting outreach at various community events. These tools are methods by which the CET distributes IRB-approved recruitment information to community members.

Community Engagement Team: Specific Tools (BRR, Conventus, Outreach) We will also utilize the services of The CTSI Community Engagement Team (CET) to assist in participant recruitment.

BUFFALO RESEARCH REGISTRY
The Clinical and Translational Science Institute's (CTSI) Community Engagement Team (CET) hosts the Buffalo Research Registry (BRR, IRB Approved STUDY00000806), a resource that connects researchers looking to recruit participants and community members looking to get involved with research. To participate in the registry, volunteers complete a voluntary intake form.

Volunteers have agreed to be contacted about potential research opportunities based on their self-reported information.

As described in the BRR's IRB Approved Protocol (STUDY00000806), key personnel from the CTSI will serve as the conduit between our research team and the registry volunteers. Key personnel will verify our IRB study approval, review inclusion and exclusion criteria and will sort the registry data accordingly.

In terms of recruiting for our study, key personnel will pull volunteer reports using the inclusion and exclusion criteria. Key personnel will centrally invite volunteers to participate in the study and provide a warm hand off to our team.

There are two ways we may share our study. These include:

1. Electronically- Using the volunteer report from REDCap, key personnel from the CTSI will send initial e-mail invites to introduce our study to registry volunteers.
2. Post Mail- Key personnel from the CTSI will provide our team with contact information (i.e. first name, last name, post mail address) to prepare a mailing. This information will be shared in a password protected excel spread sheet. The password to the spreadsheet will be sent in a separate follow-up e-mail.

We will only use the list for this protocol and we agree to destroy the list once recruitment for the study has closed. We also plan on conducting follow-up by phone/email after initial contact. This contact information will be provided in a password protected excel spread sheet. The password to the spreadsheet will be sent in a separate follow-up e-mail. We will only use the list for this protocol and we agree to destroy the list once recruitment for the study has closed. We will have no access to the health information provided in the registry.

The CET hosts the Buffalo Research Registry (BRR, IRB Approved STUDY00000806), a voluntary registry which can connect us to community members who have completed a health profile and are interested in participating in research. These community members have agreed to be contacted about potential research opportunities based on their self-reported information.

COMMUNITY OUTREACH AND TABLING

The CET also tables at many events in the community throughout the year and may display the IRB approved flyer for this project at their table at community events. Examples of events the CET attends include Good for the Neighborhood hosted by Independent Health Foundation, UB on the Green, Juneteenth, Elmwood Arts Festival and many others.

The CET also hosts standing tables at the Conventus Building on the 4th floor of UBMD and at Evergreen where the IRB approved flyer can be made available to community members and patients. This will occur only after agreement between the CET and UBMD Conventus and/or Evergreen partners that the study is appropriate for the venue.

Digital Display Boards We will be posting a digital flyer on digital display boards located at the UB Jacobs School of Medicine and Biomedical Sciences, Clinical and Translational Research Center and UBMD. Displays are used upon approval from the administration at each building.

Please note: templates for digital display boards are available by contacting CTSI's recruitment team, Briana Getman: bmd7@buffalo.edu

Flyers Please visit the [CTSI Recruitment Toolkit website](#) for recruitment flyer templates. UB branded versions of the templates are available with and without tear-off tabs. They are in MS Word .doc format, making them easy to customize for your study. For guidance on creating advertisements to aid in recruitment, refer to IRB's Worksheet for Advertisements, [HRP-315](#).

If you would like customized advertising materials or assistance with what information to include on your flyer, please contact CTSI's Recruitment Team bmd7@buffalo.edu.

I2b2 & TriNetX See UBMD policies/SOP and approved template language.

Important Note: When completing your Protocol Template (HRP-503), it must state that the data is stored on a "secured, encrypted server" in section 18.1, otherwise IHI will not approve the release of the data. You must also submit a HRP- 611 Partial HIPAA Waiver for access to the identifiable data.

ResearchMatch See RM handout for template language (available on [CTSI's Recruitment Toolkit website](#))