



During the COVID-19 emergency, the University of Rochester Medical Center has placed enrollment in clinical trials on hold and paused select research activities. For guidance on how this policy may affect your research study, please visit the University's webpage on [Guidance for Human Subject Research](#).

As many clinical research activities are currently paused, you may be able to dedicate time to reassessing your current recruitment and retention strategies, identifying possible shortcomings, and considering additional strategies that you can begin to implement now for when enrollment fully resumes.

Retaining your current participants

To ensure retention of your current participants for the duration of the hold, consider the following:

- **Communication Plan:** All active research participants need to be notified of the pause, and what it means for them. Let them know that the study will be continuing, any changes they can expect, and ensure that participants have the current contact information for the study team. You may want to convey what will happen with their collected data to date, and how the research will move forward in the future. We recommend that you contact each participant by phone, but you may also need to use ground mail and e-mail (if you have consent for email contact) under these circumstances. You do not need an IRB amendment for this notification.
 - Tip: Communicate in an easy to understand manner, taking into consideration [health literacy](#) best practices.
 - Tip: If you need assistance with language, you can refer to the script offered on the University's webpage on [Guidance for Human Subject Research](#) under "What should I tell study subjects?" This script may be adapted to fit your particular study.
 - Tip: You should document what you have communicated to your study subjects, and when you communicated it.
- **Fostering Relationships:** Increased communication helps with retention by minimizing the risk of dropouts. Keep in touch with participants throughout the length of the enrollment hold. Plan methods to keep participants updated on the current study status, check in on how they are doing during this time, and answer any study questions they have.

- Tip: Consider sharing information and resources with participants that they may find helpful. For example, you could share the resources available on the [URMC Coronavirs \(COVID-19\)](#) webpage.
- Tip: Some of your study's research activities may be able to continue if conducted remotely, or you may be able to continue activities with modifications, like moving to remote data collection by video chat. If the study is continuing in some way, remember you can still consider retention and fostering a relationship with participants during such visits.

Planning for future recruitment

During the enrollment pause, you may be able to dedicate more time to recruitment planning and developing of recruitment materials for your ongoing study (or a future study not yet open to enrollment). You may want to create an action plan that includes some or all of the following:

- **Assess the current state of your study enrollment:** Consider any updated timelines from the study funders and changes to enrollment goals. Can you estimate how many volunteers you may need to screen – and by what time points - in order to ensure you meet your sufficient enrollment numbers?
- **Explore additional recruitment channels:** The CTSI Recruitment Unit can support you in using a variety of recruitment channels, such as:
 - Post your research study on the [UR Health Research Website](#)
 - Promote your study with nearly 6,000 local volunteers in the URM Research Participant Registry that have agreed to be contacted about research opportunities.
 - Promote your study with [ResearchMatch.org](#), a national registry of nearly 150,000 willing research participants.
 - Tap into the Greater Rochester Practice-Based Research Network (PBRN), a vast network of local primary care practices to collaborate and recruit participants for clinical studies.
 - Develop a social media advertising campaign
 - **Set up a no-cost consultation** to review your current strategies and to discuss in detail any of the above recruitment channels. You can schedule a consultation through the CTSI [Research Request Dashboard](#).
- **Review your current recruitment materials:** This includes flyers, brochures, recruitment letters, advertisements, etc. How could you update your materials with small changes to make them better? Do you need a complete campaign/material refresh? Do you need to

develop new materials based on any additional strategies you are planning to implement?

- **Update your protocol with the IRB:** All recruitment material revisions, new materials, and updates to your recruitment plan must be submitted to the IRB as a protocol amendment.
- **eConsent:** Electronic informed consent (eConsent) is media that can be used to provide information contained in a consent document to a potential subject or legally authorized representative and can be used to obtain documentation of consent through a REDCap form. Subjects can “sign” their consent electronically by typing their name at the bottom of the form or REDCap also has a Signature field type, which uses a stylus, mouse, or finger to “write” a signature on the form.

If you would like to implement eConsent for your study, please read in full the [Guideline for Using REDCap for Electronic Informed Consent \(eConsent\)](#).

For existing, approved research studies, a modification must be submitted to the IRB and approved to update the consent process to include eConsent with REDCap. The consent process in the protocol should be updated consistent with the information in the guideline, and the modification must be approved before contacting Academic IT for help with installation of eConsent.

- **Assess the needs of future studies:** Does your team have future studies in the pipeline for which you could develop a recruitment plan and materials now?

The UR CTSI is here to help you improve your recruitment and retention plans. Researchers can schedule a free consultation through the [Research Request Dashboard](#) to address concerns and challenges they have about recruiting and retaining participants for their research studies. While consultations are free of charge, some solutions we identify may have a cost.