RIC COVID-19 RECRUITMENT + RETENTION TOOLKIT

Resources and community informed advice for clinical trial recruitment during the pandemic

Version 2: July 2021

r!c RECRUITMENT INNOVATION CENTER

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RECRUITMENT CHALLENGES DURING COVID-19

The COVID-19 pandemic has significantly disrupted clinical trial recruitment and implementation nationwide. Researchers recruiting for trials have been forced to confront an array of recruitment challenges, including:

- Closure and re-opening of study sites, now with strict requirements on occupancy, physical distancing, and use of personal protective equipment (PPE).
- Shifting responsibilities of study staff – either working remotely or proceeding with caution for on-site work.
- Continued implementation of existing studies while also conducting urgent trials for COVID-19 diagnosis, prevention, and treatment.
- Time-sensitive windows for recruiting into COVID-19 trials -- enrolling the "right participants at the right time."
- Competition with fellow researchers to recruit a sufficient volume of participants to conduct a statistically sound trial.

Participants, too, have faced hard decisions within this altered clinical trial arena. Even as study sites reopen, the danger of becoming infected with COVID-19 when visiting a hospital or clinic, or while traveling to the site, has given potential participants pause.

Moreover, COVID-19 is having a disproportionate impact on disadvantaged populations, including racial and ethnic minorities and individuals with limited English-language proficiency. This toolkit contains strategies throughout its pages that the Recruitment Innovation Center (RIC) has developed to increase representation of underrepresented populations in COVID-19 research. (See page 28 for a summary of strategies)

The RIC has been heavily involved in multisite COVID-19 trial design and implementation, having consulted on 29 COVID-19 related studies as of this writing. While striving to maintain our values of community engagement, participant-informed methods, and scalable design, we have developed new tools and strategies that work in this transformed clinical trial space.

To learn more about the RIC and the resources we offer, visit the
Trial Innovation Network website,
or contact us at info@trialinnovationnetwork.org

TRIAL **INNOVATION** NETWORK

RIC COVID-19 RECRUITMENT & RETENTION TOOLKIT

The purpose of this toolkit is to share the community input we received, and the resources we have developed, that can help study teams conduct trials in a manner that is safe, trustworthy, and respectful of all participants. [1]

Organized by the continuum of recruitment activities needed to complete a trial (Figure 1), we present here the ideas, concepts, and materials that the RIC has successfully implemented to support recruitment and retention for COVID-19 trials, as well as for non-COVID trials taking place during the pandemic. Note that this toolkit is not comprehensive – only those areas in which the RIC has gained experience are shared here. We encourage study teams to use this toolkit to fit their study-specific recruitment needs.

Disclaimer: All tools, methods, and materials need IRB approval for the individual study prior to implementation.

CONTINUUM OF CLINICAL TRIAL RECRUITMENT ACTIVITIES

AWARENESS & OPPORTUNITY

SCREENING

INVITATION TO PARTICIPATE

CONSENT & ENROLLMENT

ENGAGEMENT & RETENTION

RETURN OF RESULTS AND RETURN OF VALUE
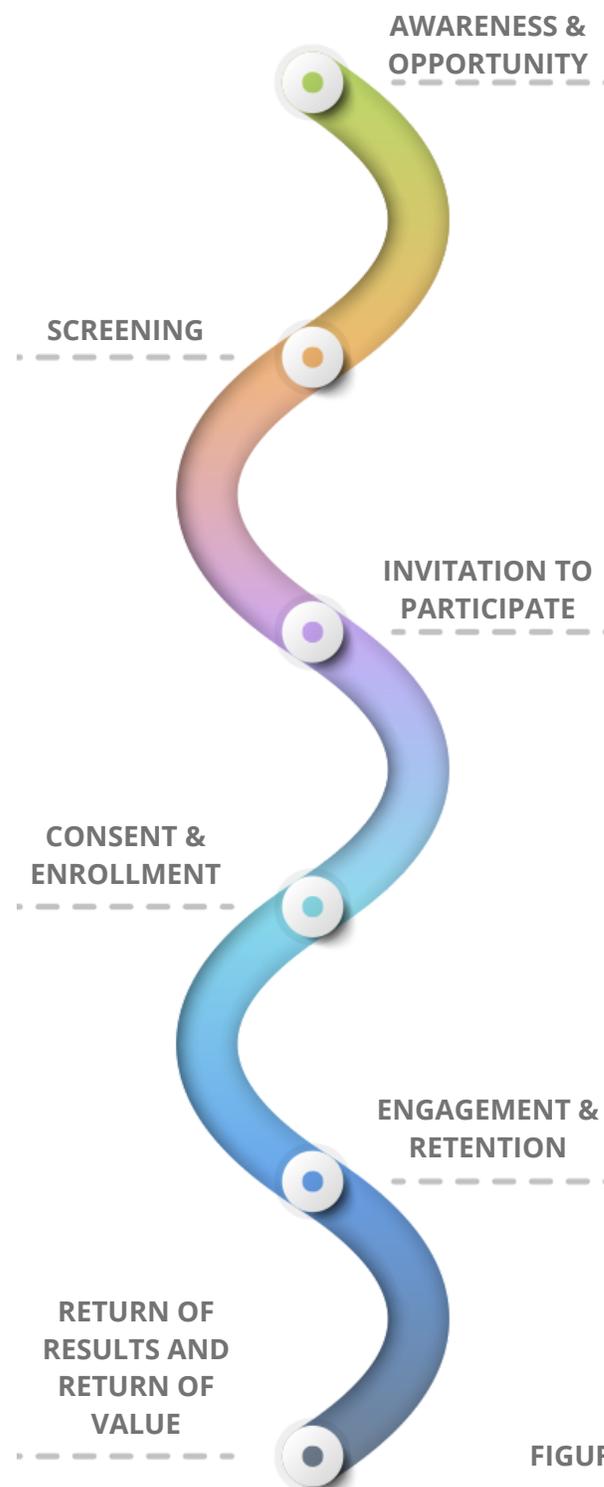
FIGURE 1

COMMUNITY ENGAGEMENT

A growing body of evidence emphasizes the importance of participant and community engagement in all phases of research to increase both the relevance and the overall success of clinical trials.

A Community Engagement Studio[2] is a consultative method that engages diverse groups of research participants and community stakeholders in the planning and implementation of research. Individuals participating in community engagement studios are experts in the topic being studied through their lived experiences. Studios can solicit guidance on identifying and addressing barriers to participation, developing and refining recruitment messages and materials, conducting the study, and disseminating results.

This toolkit contains counsel and recommendations from a diverse group of patient and community stakeholders who participated in Community Engagement Studios conducted for multi-site COVID clinical trials.

These stakeholders included:
- Healthcare and Essential workers
- Individuals living in COVID hotspot cities who were at a higher risk of being hospitalized for COVID due to age, race, ethnicity, or chronic health diagnosis

Guidance was also gathered through other means, including from:
- COVID-19 study teams
- Feedback at presentations on COVID-19 research to community organizations
- Conversations with extended families disproportionately affected by COVID-19
- RIC Community Advisory Board

Community Engagement Studio held virtually during the pandemic

In forming an engaged, inclusive, and equitable participant base for COVID-19 research that reflects the true diversity of this country's population, the unique perspectives of individuals from subpopulations and communities traditionally underrepresented in biomedical research are essential. Consequently, the resources and tools contained in this toolkit have been meaningfully informed, by thought leaders and research participants from those underrepresented communities.
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AWARENESS & OPPORTUNITY

Awareness of available clinical trials is the first step in recruitment. The opportunity to enroll can be expanded by reducing or eliminating barriers that impede participation, and by designing materials, messaging, and recruitment strategies that are participant- and community-informed.

Lessons Learned

Problem: *Fears regarding immigration status exposure* – Potential participants are hesitant to join a study that might reveal their immigration status to enforcement agencies.

Solution: Apply for a Social Security Waiver to avoid having to report social security numbers when compensating participants for study participation. Remind participants that their information is confidential and will not be shared with outside agencies.

ADVICE FROM COMMUNITY EXPERTS

INCREASING AWARENESS AND OPPORTUNITY TO PARTICIPATE

General recommendations:
- Collaborate with local and state government and heath agency leaders to highlight study launch in their own press announcements.
- Distribute recruitment materials to community and faith-based organizations, established coalitions, and other networks in order to reach traditionally underrepresented groups, including lower socioeconomic status (SES), BIPOC (Black, Indigenous, and People Of Color), and rural participants.

Healthcare Workers + Essential Workers:
- Utilize institutional leadership buy-in by pushing out promotional messaging at each individual clinical trial site.
- Partner with local group organizations (e.g., unions, childcare centers, restaurant industry, etc.) to expand study promotional reach.
- Consider recruiting participants via email and phone. Make sure you are available to answer questions and address concerns.

African American/Black Community Experts:
- Include primary care and specialist providers in the process to enroll chronic care patients to address patient concerns.
- Distribute information via testing sites, local clinics, and other community-based sites to reach highest potential patient population.
- Collaborate with BIPOC community to develop and co-brand materials and promote study via trusted thought leaders and established organizations that serve the community.
- Approach patients for enrollment upon hospital admission or early in the process to ensure ample time for decision-making.

ADVICE FROM COMMUNITY EXPERTS

INCREASING AWARENESS AND OPPORTUNITY TO PARTICIPATE

Hispanic/Latinx
- Hire competent, bilingual staff who can effectively communicate about the study and translate for providers to help them inform potential participants about the study.
- Collaborate with primary care providers and community-based clinics that serve Spanish- speaking patients to assist with enrollment as they have established trust.
- Distribute study promotional material through traditional and trusted community outlets (e.g., Hispanic churches, fiestas, bodegas, community-based organizations and clinics).
- Implement a multi-tiered communication and outreach approach that utilizes traditional approaches and social media platforms that are customized based on current demographic reach (e.g., WhatsApp is used widely by immigrant and refugee populations).
- Adopt and apply lessons learned from the HIV community who has years of experience in rolling out national trials.

Older Adults – Age 65+:
- Engage collaborating hospitals that serve a patient population reflective of the communities that are disproportionately impacted.
- Highlight study on all existing clinical trial platforms including ResearchMatch.
- Implement a national virtual town hall series promoted via existing collaborations at study sites, health advocacy groups and other community-based organizations (CBOs) when implementing large scale studies.

ResearchMatch

ResearchMatch[3] is a free online platform that connects researchers at participating US institutions with volunteers who are interested in learning more about research opportunities.

ResearchMatch allows researchers to use filtering criteria to search for de-identified volunteers who have registered themselves as being interested in participating in research. Next, the researcher sends their IRB-approved contact message via email to volunteers via ResearchMatch. Contacted volunteers can then express interest in learning more and provide permission to be directly contacted by the study team for study enrollment. ResearchMatch is also available in Spanish.[4]

This platform is especially useful for 'no-touch' recruitment that allows researchers to connect with and recruit eligible volunteers for both COVID and non-COVID related research studies. To date, ResearchMatch has been used to match over 70,000 volunteers with 110 COVID-19 related studies.

To learn more about using ResearchMatch or registering your institution, please access the ResearchMatch Toolkit in the TIN Toolbox.

SCREENING

Screening for participant eligibility can be a challenge during the pandemic, as changing inclusion and exclusion criteria, as well as the time-sensitive nature of many COVID-19 trials, add new elements of complexity. Wide promotion of studies can also attract more ineligible individuals than usual.

REDCap (Research Electronic Data Capture)[5,6] can automate many screening tasks, with these potential benefits:

- Facilitating a no-touch approach to pre-screening potential participants
- Enabling conversion of inclusion and exclusion criteria into a participant-facing survey
- Creating automated messages based on responses to make screening 'instantaneous' for participants and research teams

Lessons Learned

Problem: *Participant unfamiliarity with medical center* – A Spanish speaker called the medical center's trial registration hotline. He had finished his COVID-19 treatment and wanted a note clearing him to go back to work, but did not have his provider's number.

Solution: Study teams should have contact information handy for reaching other departments within the system, including the medical records department, charity care, billing, and social workers.

COVID-19 Research Data Mart

The COVID Research Data Mart was developed at VUMC to support screening and recruitment for COVID-19 studies. Given the nature of the pandemic and the need to expedite research, many studies are targeting the same patient population at the same time. The Data Mart was created to help facilitate rapid recruitment by identifying the 'right patient for the right study and the right time.' The Data Mart workflow also requires study teams to track enrollment statuses, thus increasing transparency across studies and helping to minimize participant fatigue.

The Data Mart consists of a database of patients who have tested positive for COVID and have agreed to be contacted directly for research. This Data Mart:

- Is supported by a combination of data feeds from our Epic electronic health record (EHR) system, including Fast Healthcare Interoperability Resources (FHIR) endpoints:
  - Census data (inpatient vs. outpatient)
  - COVID test date and time
  - COVID positive test result date and time
  - Medications
  - Allergies
  - Problem list
  - Labs
  - Appointments
- Aggregates this clinical information with patient information (demographics, consent-to-contact)
- Leverages REDCap to implement custom logic driven by study-specific inclusion and exclusion criteria to identify potential participants
- Maintains a dashboard, updated hourly, displaying the pool of potential participants (positive COVID test and consent-to-contact for research) and indicating the studies for which they have been identified as a potential match
- Generates an Excel file of potential participants which is shared with the respective study team on a pre-determined schedule (e.g., daily, once a week)

The study team then performs additional screening and contacts the eligible participants as detailed in the study's approved IRB application or protocol. While the Data Mart is proprietary to Vanderbilt, other institutions can use REDCap to pattern their own efforts after ours.

INVITATION TO PARTICIPATE

The invitation to participate in a clinical trial may be delivered through clinicians and directly to potential participants through a range of multimedia channels and platforms. The RIC has produced multiple printed materials, study apps, and videos to promote COVID-19 trials, incorporating community feedback and input.

Clinician-facing Materials

Clinician Study Information Sheet

Clinician referrals can be an important source of connection with potential participants, yet clinicians sometimes fail to refer those who are eligible, especially potential participants from underrepresented groups.   A Clinician Study Information Sheet is a one-page overview of a study aimed at referring physicians that simplifies the referral process by placing key study information at the clinician's fingertips. It includes:

- a study description
- explanation of the importance of the research
- study visit expectations
- participant eligibility criteria
- participant compensation
- study coordinator contact information for referring a potential participant to the study
- encouragement to include all potentially eligible participants in the referral process

The RIC offers a [template](#) to simplify the process of designing a Clinician Study Information Sheet.

Lessons Learned

Problem: *Competing priorities* – If life needs are not being met, participants understandably may have less interest in learning about a research study.

Solution: Maintain a list of resources about employment, schools, etc., or have contact information for a social worker, community health worker, or other navigator who can assist those potential participants who are experiencing difficulties that might present a barrier to participation.

Problem: *Lack of information* – Study teams encountered varying knowledge about COVID-19 among potential participants, due to a lack of available information and materials.

Solution: Provide factual resources on COVID-19 to help ease concerns and reduce participation hesitancy.


Clinician Study App (CSA)

A Clinician Study App (CSA) is a website designed for use on mobile devices and is intended to provide clinicians with simplified access to study-specific information such as inclusion and exclusion criteria. It serves as a handy 'mobile version' of the Clinician Study Information Sheet described above.

The advantages of using a CSA over a printed information sheet is that it:
- reduces the need for distributing print materials
- allows clinicians to share information directly with potential participants
- facilitates 'one-click' contact with local study coordinators by phone or email
- enables links to other steps in the referral process
- allows embedding of videos

Example CSA:
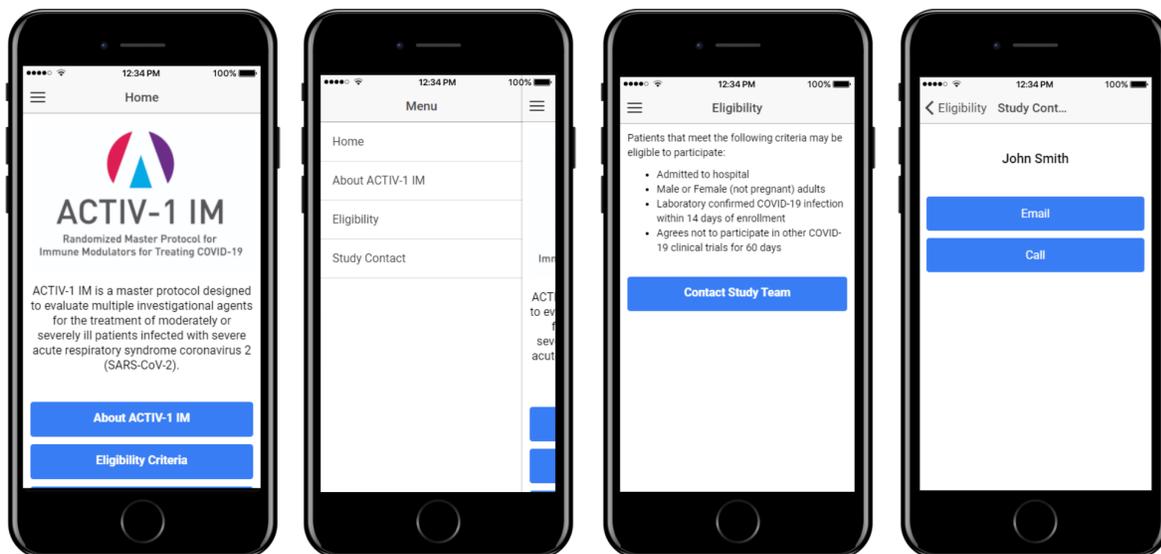
| Personalized with study graphics | Custom menu navigation | Organized study information | Site specific contact with one-click access to email or call |

RIC-developed CSAs are offered as part of a Trial Innovation Network proposal submission. Alternatively, study teams can develop their own applications using programs such as Ionic.

Participant Facing Materials

Participant materials can include but are not limited to, brochures, flyers, posters, social media posts, and study websites. Materials can be shared as both print and digital versions. Input from community members can help research teams design materials that are:

- culturally relevant and sensitive to the community
- written at an appropriate literacy level
- address potential participant concerns about privacy and trust

ADVICE FROM COMMUNITY EXPERTS

IMPROVING PARTICIPANT-FACING MATERIALS

General recommendations:
- Utilize study names that are clear and easy for participants to understand the study's purpose without needing additional context.

Healthcare Workers + Essential Workers:
- Outline the approximate length of time for clinical trial participation (i.e., time to attend appointments, survey length, oral swabs, etc.).
- Ensure the text is concise and at an appropriate literacy level for the community.
- Highlight the benefits and potential side-effects as well as compensation levels.
- Clarify who qualifies for the study and how testing occurs (i.e., what qualifies as a household; whether age will influence testing)
- Emphasize how the results of this study could impact the study of COVID/flu.
- Use photos that show the diversity and representation of healthcare worker positions, such as hourly workers (e.g., housekeeping, labs, food services).
- Create a simple web page that gives study overview and FAQ.

INVITATION TO PARTICIPATE

Lessons Learned

Problem: *Lack of access to medical care* – Some individuals testing positive for COVID-19 have no medical provider and have received no instruction on how to care for themselves at home if they have mild symptoms.

Solution: Provide educational materials that detail home treatment, translated into other languages that reflect those in the local population. Have a list of potential medical providers.

QR Codes

A Quick Response (QR) Code can be added to print materials that when scanned will direct participants to a website for more information about the study and how to join. A QR Code is a two-dimensional barcode consisting of a black and white pixel pattern which allows it to encode up to a few hundred characters, such as a URL for a website.

QR Codes were originally envisioned as a strategy to more easily recruit individuals with sensitive conditions, who may be averse to picking up a brochure that could jeopardize their privacy. Now, in the presence of COVID-19, a QR Code on a poster offers a 'no-touch' solution to the issue of handling possibly contaminated printed materials.

ADVICE FROM COMMUNITY EXPERTS

IMPROVING PARTICIPANT-FACING MATERIALS

African American/Black Community Experts:
- Use diverse images on study materials that represent a wide range of people and families, including single individuals, multi-generational, and a variety of class-depictions that reflect hourly-workers, as well as professionals.
- Create materials that incorporate a family decision-making model to assist with sharing information.

Hispanic/Latinx
- Use diverse images on study materials that represent a wide range of people and families, including single individuals, multi-generational, and a variety of class-depictions that reflect hourly-workers, as well as professionals.
- Create materials that incorporate a family decision-making model to assist with sharing information.
- Translate materials but be mindful of regional and cultural dialects and differences.
- Clearly communicate that study information is not shared with immigration officials to address fear of U.S. Immigration and Customs Enforcement (ICE) and other governmental entities.

Older Adults – Age 65+:
- Develop materials inclusive of multiple backgrounds, ages, cultures, etc. as this disease has a wide-ranging affect and people need to see themselves and their family members represented.
- Create flyers to distribute via testing sites and for trusted community and national organizations to share with their clients.
- Be mindful of not using stigmatizing language when referring to individuals who have high risk of contracting COVID-19.

**PARTICIPANT-FACING MATERIALS
RIC EXAMPLES**

FLYERS/POSTERS

COVID CSSC-001 Research Study — Logo Placeholder

Have You Been Exposed to COVID-19, But Do Not Have Symptoms?

Join us in our fight against COVID-19

This study will test whether an infusion of plasma containing antibodies from persons who have recovered from COVID-19 can prevent others from getting it.

Can I join? If you are 18 or older and at high risk of exposure to COVID-19 you may be able to join. You are at high risk if you work in a hospital (clinical staff, dining services, etc.) or you are caring for someone with COVID-19.

What's Involved?
- One Plasma infusion
- Up to 8 study visits*
- Medical history
- Physical exam
- Blood tests

*You may earn $50 for each study visit.

Learn More — Scan here with smartphone camera

Contact Us 📞 +1 450 568-8793 ✉ covid19research@jhu.edu

Volunteer for a Local COVID-19 Study

Are you or your loved one a patient in the hospital being treated for COVID-19?

Researchers are studying different investigational drugs to treat COVID-19.

Together, we can find answers to treat COVID-19.

Learn More about ACTIV-1 IM
www.website.com

Contact:
Email: name@organization.com
Hotline: 000-000-0000

SAMPLE
Scan with smartphone for survey

ACTIV-1 IM
Randomized Master Protocol for Immune Modulators for Treating COVID-19

ABOUT CLINICAL TRIALS In clinical trials, researchers test new ways to prevent, detect, or treat disease. Clinical trials are the best way to see if a treatment works. In the United States, people of color are four to five times more likely to be hospitalized with COVID-19 than are white people (CDC, August 15, 2020). Having members of Black, Hispanic/Latino, & Native American communities in COVID-19 research is important in order to make sure treatments are safe, effective, and work for everyone.

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INVITATION TO PARTICIPATE

**PARTICIPANT-FACING
MATERIALS
RIC EXAMPLES**

FLYERS/POSTERS

Join the fight against the COVID-19 pandemic.

Become a part of the VUMC Research Registry.

- Our world-renowned researchers are focusing on finding ways to prevent, diagnose and treat COVID-19. **We can't do it without you!**

- People who have tested positive or think they've had COVID-19 can help us answer the most important research questions as quickly as possible.

- Essential workers are at higher risk for getting COVID-19. This is because the critical role they serve in keeping our communities up and running.

- **Register now** if you would like to be contacted about COVID-19 research studies at Vanderbilt University Medical Center (VUMC).

To Register:
Complete a short online survey so VUMC researchers may contact you about COVID-19 research studies that could be right for you.

Contact:
Email: research.support.services@vumc.org
Hotline: 615-322-7343

Scan with smartphone for survey

VANDERBILT UNIVERSITY
MEDICAL CENTER

If you join the VUMC COVID-19 research registry, you are not obligated to take part in a research study. You will not be enrolled in any studies without your consent. Becoming a part of this registry does not guarantee that you will be able to join a study. Taking part in this research registry will not affect any future care for you at Vanderbilt University Medical Center.

Your blood could **save lives.**

JOIN THE FIGHT AGAINST COVID-19

Have you tested positive for COVID-19 and recovered?

You may be able to join our research study to test if antibodies in your blood could help others recover faster.

Contact us today to see if you can join. Together we can make a difference.
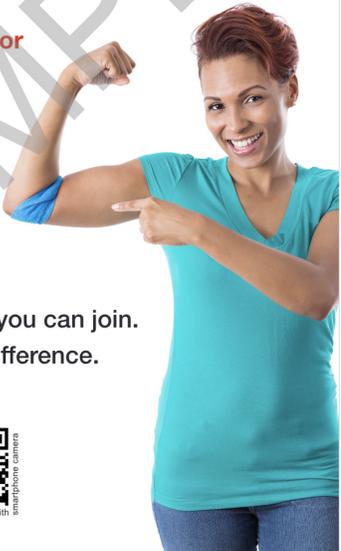
**Study Contact Name
Study Contact Phone
Study Contact Email**

Scan here with smartphone camera

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PARTICIPANT-FACING MATERIALS
RIC EXAMPLES

WHAT TO EXPECT/STUDY GUIDE

ACTIV-1 IM
Randomized Master Protocol for
Immune Modulators for Treating COVID-19

Scan here with
smartphone camera

Thank you for your interest in the ACTIV-1 IM research study. Together, we can find answers to treat COVID-19.

In clinical trials, researchers test new ways to prevent, diagnose, or treat disease. Clinical trials are the best way to see if a treatment works.

This study is for people in the hospital with COVID-19. The purpose is to learn if different investigational drugs can help treat COVID-19.

Taking part in the ACTIV-1 IM study is voluntary and will not affect the care you receive now. You can withdraw from the study at any time. If you have questions, please contact your research team – we're always here to help!

What does the Study Involve?

1 First Visit

Occurs 1-2 days after enrolling in the study. Includes the following:
- Confirm a positive COVID-19 test
- Complete a medical history and blood tests
- [Females] Confirm not pregnant or breastfeeding or trying to become pregnant

2 Treatment Period

This is the time the study drug or a placebo is taken. A placebo looks exactly like the study drug but contains no active product. Includes the following:
- Take study drug — Study drug will be given either by mouth (28 days) or by vein (1 day).
- Daily health checks while in the hospital and occasional health checks after discharge.
- Up to 8 blood tests — some will be done in the hospital, some may be done after discharge.

3 Follow-Up Visit

This is the time following hospital discharge or after the study ends:
- Study team will follow you closely for 29 days and check in with you at 60 days. Study participants may be asked to come back to the research site for blood tests if possible.

4 Study Costs

- Participants will not be charged for study drugs or procedures.

Study Findings

We value the contributions of all study participants. Once the study has ended and results are confirmed, the overall results will be shared.

LEARN MORE

Contact Name | contactname@email.com | 888.888.1122

www.activ-1.org

Study Information Sheet
University of Utah

Hydroxychloroquine (HCQ) for Outpatients with Confirmed COVID-19 (HCQ Trial)

We are doing a research study on COVID-19 in the state of Utah. If you have tested positive for COVID-19, you would be able to participate.

This research study is designed to test possible treatments for COVID-19 and should help us better understand the virus and if HCQ might be a good treatment. If you test positive, a staff member from University of Utah hospital will contact you. Then a research coordinator will contact you to ask if you are interested in joining the study. This project will help us gain important information about how to better treat COVID-19.

What To Expect with the HCQ Trial

Are there any costs?

No. Taking part in this study will not cost you money.

Study Procedures

You can complete study procedures from your home. These include:

Phone call: Our team will contact you by phone on day 1 to explain the study in more detail.

Study pills: You will be asked to take either study drug or a placebo, our team will deliver the pills to your house.

Study supplies: Our team will deliver all study supplies (mouth swabs and instructions) to your house.

Questionnaires: You will be asked to answer questions (via an online survey) - every day for 14 days, once after 28 days, and once after 6 months.

14 Your Study Samples

You will be asked to provide samples so we can measure COVID-19.

1) **Mouth swabs:** You will be given a mouth swab kit that can be used at home. You will be asked to swab your mouth daily for 14 days. All supplies will be delivered to your door. Once you collect samples, you will place them in a box outside of your home to be picked up.

2) **Blood samples:** You might be asked to come to a clinic for a blood sample.

Household Samples

If you agree to join the study, we may ask your household members to take part in providing samples. We are interested in how the virus spreads between people living together in a home. We may ask members of your household to collect daily mouth swabs. We may collect very basic information about your household members including gender and age.

QUESTIONS: If you have any questions, you may contact the project manager [Insert Site Contact] at [Insert site contact phone number] or email [Insert contact email address].

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PARTICIPANT-FACING MATERIALS
RIC EXAMPLES

PASS IT ON

WEBSITE

SOCIAL MEDIA
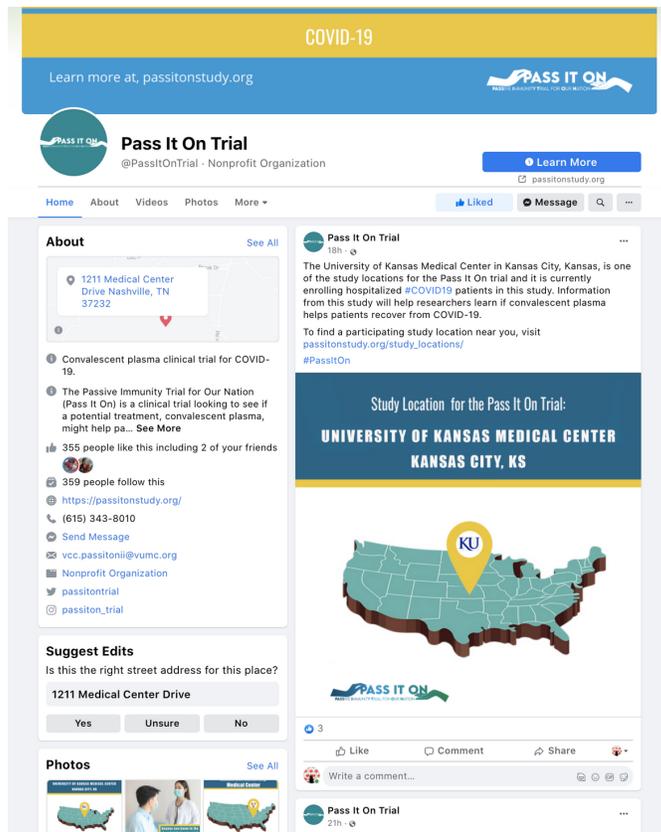
BEST PRACTICES: MESSAGING + DESIGN

The following lists of best practices have been developed and refined by the RIC over several years and scores of consultations. Extensive community feedback has been obtained to formulate these guidelines.

Content + Messaging

| **Font** | Text size, style and spacing are especially important with studies seeking middle-aged or older adults, those with possible vision impairment, or participants with low literacy skills. |

- Size - Text should be at least 12-point font size, with titles at least 13-point or larger.
- Style - Use font styles that are simple and easy to read (e.g., Arial, Calibri, Verdana, Helvetica). Avoid using scripts and more decorative typestyles.
- Line spacing is the distance between lines of text. For your materials, use a line spacing that is somewhere between 1.2 and 1.4. that of the font size. (For reference, single spacing is 1.0 and double spacing is 2.0.)
- Use bold face type when emphasis is needed – keep italics at a minimum.

| **Messaging** | Messaging should be clear, concise, lay-friendly and accessible to those who may have not participated in research before. Plain language resources are available here. |

- Text should be written at approximately a 6th grade reading level.
  - Microsoft Word has a readability and grade level assessment tool you can utilize for determining grade reading level and reading ease.
- Avoid using medical/research jargon. For guidance on replacing jargon with everyday words, click here. (Click here to access additional CDC resources on health literacy and plain language tools).
- Any medical terms should be simplified or clarified (e.g., replace "hypertension" with "high blood pressure"). Click here to access the CDC plain language thesaurus for medical terms.
  - Avoid medical acronyms unless commonly used by the general public or specific population the material is designed to help recruit (e.g., "MS" is a term commonly used by the general public for "multiple sclerosis", whereas "TBI" is not a term used commonly by the public for "traumatic brain injury").
  - Rather than spelling out the words of the study acronym, consider including a brief statement about the purpose of the study.
  - Use terms "research study" or "study" rather than "trial".
  - Use terms such as "able to join" rather than "eligible".
- The title of each recruitment piece should be phrased as a 'call to action' to potential research participants that indicates the study's goal or potential benefit of the study (e.g., "Join us in the fight to…", "Together we can help prevent…").

BEST PRACTICES: MESSAGING + DESIGN

Design

Logos	Incorporate study and institutional logos, as well as the logo for the study sponsor (funding agency/pharmaceutical company) for transparency in who is conducting the study and how it is funded
Colors	Whenever possible, incorporate disease/condition awareness colors in recruitment materials (e.g. red for heart disease, pink for breast cancer).
Photos	- Photo on front should reflect the primary population you are trying to recruit. This is especially important for populations historically underrepresented in biomedical research (e.g., racial, ethnic and gender minorities; populations of lower income and/or educational attainment; physically and/or mentally disabled; rural populations). - Photos should be inviting, colorful, and show people who look approachable. - Utilize photographs of people who appear to fit the: - demographic diversity of the disease/condition incidence in the population - inclusion/exclusion criteria - Consider including a photo of a potential participant having positive interaction with a doctor (avoid white lab-coat pictures whenever possible). - Brochures - For disease/conditions that have a genetic component or for older adult studies, be sure to include an inter-generational photo/photo with loved ones, preferably in the "why should I participate" section.

DESIGNING MATERIALS

Canva is a free, easy-to-use drag-and-drop design program with a library of pre-designed templates. If you don't have a Canva account, you can sign up here!

WHERE TO FIND PHOTOS

FREE PHOTOS

Always comply with copyright restrictions.

- CDC - Public Health Image Library
- National Cancer Institute Visuals on Line
- The Noun Project
- Unsplash
- Pexels
- Pixabay

PAID PHOTOS

- iStock
- Adobe Stock
- Shutterstock

VIDEOS Study teams are increasingly including videos on their websites to provide explanations or instructions to participants..

ADVICE FROM COMMUNITY EXPERTS

IMPROVING RECRUITMENT VIDEOS

General recommendations:
- Develop a series of video-shorts to promote and highlight the value of the study, risks, inclusion criteria, and why it is important to participate.

Healthcare Workers + Essential Workers:
- Develop video testimonials of staff from diverse roles (e.g., nurses, transportation, housekeeping, etc.) who have joined the registry and participated in trials.
- Produce videos that are personal (i.e., showing people with their families, co-workers).
- Ensure videos are no longer than 2-3 minutes.
- Develop a strong call to action emphasizing the urgency and importance of the study.
- Create a montage of diverse, influential, and well-known community leaders using the same language to emphasize the importance of trial registries.

Examples of recruitment videos:

The RIC assisted with the development of several videos to promote The Passive Immunity Trial for Our Nation (Pass It On), a randomized controlled trial evaluating the use of convalescent plasma in hospitalized COVID-19 patients.

These videos include:
- Clinicians explaining the trial in layperson terms, with English, Spanish, Chinese, and Arabic language versions
- An explanation of convalescent plasma and blood products
- Participant testimonials

The RIC also designed an instructional video, in English and Spanish, for teaching participants how to perform a throat swab for a COVID-19 trial on hydroxycholoroquine.
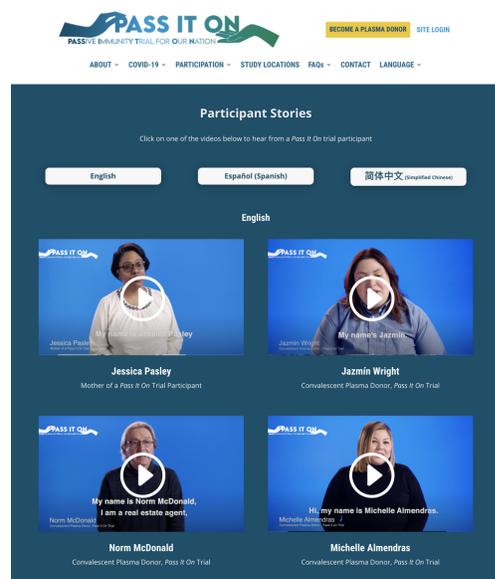
BEST PRACTICES: VIDEO DESIGN AND PRODUCTION

General Guidelines and Best Practices

- **Seek input / feedback from the community** who will ultimately be viewing your video through the process.
  - This can be accomplished through a group consultative feedback session like a Community Engagement Studio or a focus group.
  - Alternatively, research teams may seek feedback from individual community members through cognitive interviews or more informal conversations. The goal is to get feedback directly from the target audience (for example, if the project is focused on sickle cell disease, the team should seek input from sickle cell patients).
- **Consider Length**: in general, research teams should be hesitant to exceed 5 minutes for an educational video. There are exceptions for more complicated topics, but be mindful that it can be challenging to keep your audience's attention for an extended period of time. While average video lengths are increasing, this seems to be largely due to an increase in content like documentaries, commentaries, and tutorials.
- **Interviews**
  - For projects involving interviews, ensure that you have a conversation in advance with the interviewee. Try to avoid scripting responses, but it is a good idea to map out the conversation and discuss key talking points.
  - When interviewing, the interviewee should repeat the first part of the question asked. For example, if the question is "What was your experience being a part of this study?" the interviewee should start the answer with "My experience being a part of this study was…" as opposed to "I had a great experience".
  - Additional tips available here.
- **Accessibility**
  - Scripts intended for the public should be written at a 5-6th grade reading level. Reading level is easily assessed using online tools (example here).
  - Ensure your video is captioned. This is easy to accomplish on YouTube. Additionally, be aware that not all individuals will be able to see or read text on the screen, so consider utilizing narration to provide additional information. Additional information available here.

Pre-production (Preparation & Scripting)

The pre-production period is a time to prepare for the filming (or 'production') of your video by developing any materials you will need to have on hand when filming. This could include a script, an interview guide, a list of materials - what you need to prepare entirely depends on the type of video you are planning to make.

On Screen	Text Read Allowed	Text on Screen
	In this video, we will go through how to collect a throat swab	Text: How to Collect a Throat Swab
	also called an oropharyngeal swab. Please watch through the entire video before collecting your specimen.	Text: Throat Swab / Oropharyngeal Swab
Shots of swab, specimen bag, and collection tube	To collect your sample, you will need: your sealed swab, a specimen bag, a collection tube called a transport vial, good lighting and a mirror.	Text: Swab / Transport Vial / Specimen Bag Text: You will also need: good lighting / mirror
Participant places collection tube in a cup	You may also need: something to hold the tube upright - a cup or mug works well.	

Example 1: Scripting / Outlining Video

Scripting could be as simple as a chart detailing what the individuals on screen are doing, what is read and what text appears on screen (see Example 1).

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BEST PRACTICES: VIDEO DESIGN AND PRODUCTION

Production (Filming)

It is not necessary to be a professional to create an engaging video - it does help to keep key rules of filmmaking in mind as you film.

- Resources & Guidance
  - Smartphones can be used to make simple, yet high-quality videos. To learn more about creating videos with a smartphone, click here and here). Equipment (tripod, lighting) is helpful to have, but not required. Rather than filming hand-held, you can easily make a tripod out of household items (instructions here).
  - It is possible to record portions of a presentation using PowerPoint's built-in screen recorder. Research teams should ensure that all material is appropriate for a lay audience.
  - If possible, bring a second device to record sound. This could be a secondary phone placed closer to the subject or a microphone if you have the budget (examples here, here, and here *last example typically used for interviews).
  - Bring a backup battery or charger for the device you plan to film with. Notoriously, batteries tend to run out just when you need them most.
  - Always film everything twice. Even if everything seemed perfect, it is always a good idea to have a second option.

Post-Production (Editing & Distribution)

- Resources
  - Wikipedia Commons / Creative Commons for free-use images
  - Flat Icon for creative commons use icons
  - For royalty-free / free-use music, a fairly comprehensive list can be found here.
  - Editing software can be costly, however, several options are free or of limited cost. These include iMovie (Mac), Video (Windows PC), Adobe Premiere (can be purchased month to month for limited cost), and Adobe Spark (free for short videos created on mobile). Additionally, PowerPoint can be used for screen capture/animation (more details available here).
- Guidance
  - For distribution, consider if you want your video to be publicly searchable or private - visibility can be edited upon upload to YouTube or Vimeo. Many projects choose to have videos 'unlisted' which allows anyone with the link to access.
  - Typically for submitting to an IRB, provide both a script/transcript and the link to the live video. Some projects choose to submit a script for approval prior to filming.

Examples

- What is it like to get an MRI?
  - **What this does well:** clearly describes the procedure, utilizes narration to explain process, and is short in length to maintain audience interest
- The Importance of Research
  - **What this does well:** includes both participant and researcher perspective
- All of Us Participant Testimony
  - **What this does well:** engaging testimony from participant, not limited to classic "interview" video style
- Risk Bites - What is Nanotechnology
  - **What this does well**: uses simple imagery/whiteboard animation to explain complex concepts

CONSENT & ENROLLMENT

eConsent

In situations where in-person access may be limited or in cases where not all consenting parties are in the same location, electronic consenting (eConsent) is especially useful as the platform allows for consenting to occur entirely remotely.

The REDCap eConsent framework[7] was informed by nearly 5 years of discussion with researchers, Vanderbilt IRB analysts and legal counsel, developers, and prospective participant users, in addition to conversations with stakeholders across the Clinical and Translational Science Award (CTSA) Network and the Trial Innovation Network (TIN).[8]

Key Features of REDCap-based eConsent:
- Web-based consent allows for review and signature of consent documents via tablet, smartphone, or desktop either in-clinic or fully remotely.
- Leverages standard REDCap survey features including multi-lingual language capacity for information rendering and capture; video, audio and/or image rendering; 'read it to me' accessibility options; skip logic to support comprehension questions or trigger 'help needed' events; 'wet' signatures; document upload; and camera integration for photos and images.
- Maintains record of all interactions with eConsents and key information (including documented changes, consent type, status, and version). Copies of consents are also stored in separate secure document system.
- Potential for Part 21 CFR Part validation.

Throughout the COVID-19 pandemic, use of eConsent has allowed studies to continue recruiting and consenting utilizing 'no-contact consenting', where potential participants are sent a unique link to review the consent either entirely remotely or on a tablet/mobile device in a hospital setting. For example, the ORCHID study, a blinded, multicenter, placebo-controlled randomized clinical trial of Hydroxychloroquine vs placebo to treat hospitalized COVID-19+ patients, consented using tablets, which were delivered to patient rooms to allow potential participants to consent while maintaining strict measures to reduce risk of transmission.

eConsent Workflow Considerations

1. Objective of the eConsent:
   a. What are the requirements and limitations for consenting at your site?
   b. How are you thinking about operationalizing the eConsent? (i.e., content planning, development, obtaining stakeholder feedback from study team and/or prospective participants, integrating eConsent with study/participant workflow, monitoring, storing data, closeout (filing, device collection, and more)).
2. Timeline – when do you want eConsenting to be available?
3. What percentage of the participants do you anticipate will be using the eConsent?
4. Where will you use the econsent?
   a. Clinic
   b. Self-initiated (i.e., participants engage using their own electronic devices via brochures, posters, etc. which contain web-links or QR codes)
   c. Call Center
   d. Email participants and consent remotely
5. How will you confirm participant identity (i.e., ask participant to add DOB to form, study-specific PIN number, etc)?
6. Will this be used for just consent or also for screening participants?
7. Devices
   a. What type of devices will you be using to collect the data? (e.g., home computer, clinic-provided tablet, participant's portable electronic device)
   b. How many devices do you need per site (e.g., if using tablets in clinic – consider workflow for maintaining charge of device, ensuring device is not taken/stolen, paper backups if wi-fi fails)
   c. Who is providing the devices?
   d. Will the sites need Wi-Fi access and does the site have the bandwidth to support eConsenting?
   e. Do the sites need institutional approvals? (firewall, etc)
   f. Do sites need to access a printer? (participant copy)
8. How will you obtain the participant's consent signature? (ex. typed signature, PIN number, "wet electronic signature" via stylus or finger);
9. Features – what features do you envision in the eConsent? Options include:
   a. multimedia,
   b. audio,
   c. consent in sections,
   d. knowledge review,
   e. participant attestation,
   f. e-signature (and how participants sign),
   g. audit requirements,
   h. regulatory requirements,
   i. any specific considerations based on anticipated participants age, comfort with technology, other,
   j. a dictionary or glossary
10. Database – where do you envision the database will reside – who will build/manage the database? Does the study require FDA – Part-11 compliance?
11. Workflow – how do you envision the workflow from eConsent to enrollment (i.e., who needs to sign the consent following the participant? Will all signatories be in the same location? LAR, translator?)
12. Site requirements – do we know the site-specific requirements around eConsenting and eSignatures?
13. Language – do you need a language other than English?

eConsent Customizations

One of the primary benefits of eConsent is the ability to customize the platform based on the needs of particular communities. For example, the multi-site PREVENTABLE study, which focused on recruiting older adults (> 75 years old), utilized features within eConsent to increase the standard text size as well as text-to-speech functionality to allow potential participants to elect to have the consent read to them. The eConsent also included additional instructions (e.g., how to sign the document) to guide users who may have lower technological literacy through the eConsent interface.

Additional eConsent customizations include:
- In-Line Descriptive Popups: allows end users to hover over or click key words/phrases in a survey to get pronunciations, images, or definitions without linking out to another site.
- Avatars: customized to reflect a broad range of cultural identities, can be enabled to walk a participant through a consent document with voiceover instruction, clarification, or additional information.
- Multi-Lingual Module: allows multiple languages to appear on a single consent document as well as alter the language of interface elements (e.g., next page, submit).
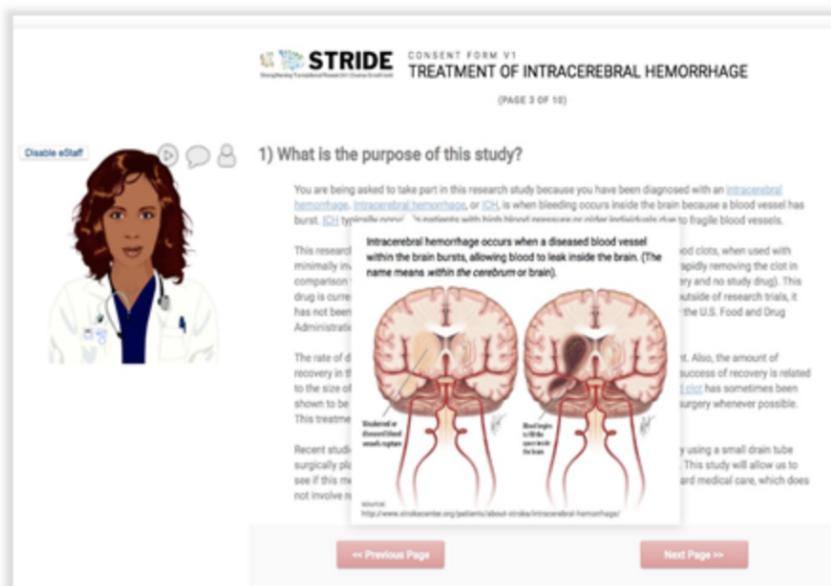
eConsent Additional Training Resources:
- [eConsent Part 11 documentation and educational videos](#)
- [Trial Innovation Network Webinar: eConsent Framework/Part-11 Compliance](#)
- [Trial Innovation Network: eConsent Customization Features](#)
- [Using REDCap to Consent Research Participant (University of Washington CTSA)](#)

ENGAGEMENT & RETENTION

Participant engagement and retention is an important part of meeting clinical trial enrollment goals. Community stakeholders consistently emphasize the importance of effective and regular communication, study value, and fair compensation as ways to promote retention. Continued interaction of researchers with the community even after study completion will promote future study engagement.

CONDUCTING STUDIES VIRTUALLY

The COVID-19 pandemic has introduced the 'remote space' as the new locale for conducting clinical research. This shift has accelerated technology and study design innovations that are likely to continue post-COVID-19. Now that new methods have been devised to keep participants and study team members safe or at home, the same safeguards and conveniences are likely to be expected far into the future.

During a pandemic such as COVID-19, it can be easier to recruit participants for studies that are conducted partially or fully online. In some cases, for research that investigators originally presumed would require in-person visits, workarounds have been devised that have allowed study visits to take place via remote appointments and with materials provided on-line. Examples of these tailored methodologies include the following:

- shipping a study drug directly to the homes of participants and using telehealth technology for study visits (C-DIFF Study; COVID-19 Treatment Study)
- conducting synchronous group behavioral treatments via web-based video conferencing (Opioid Misuse Study)
- providing online group presentations by the study Principal Investigator to present study information and answer participant questions to reduce time needed for in-person consent (or making it easier to replace in-person consent with eConsent) (Weight Loss Study).

These methods are enabling already-funded studies to move ahead more rapidly, and may pave the way for permanent changes that increase flexibility and convenience for participants, potentially leading to recruitment that is simpler, faster, and more diverse in terms of race, ethnicity, socioeconomic status, and geographic location of study participants.

Lessons Learned

Problem: *Cultural insensitivity –* Study team members showed up in Hispanic neighborhoods to conduct COVID-19 testing, wearing full PPE gear. This was perceived by participants as a major violation of cultural norms and privacy.

Solution: Conduct testing somewhere private and secure, such as in a drive-through environment, with the protocol explained to participants beforehand.

ADVICE FROM COMMUNITY EXPERTS

IMPROVING RETENTION

Healthcare Workers + Essential Workers:
- Provide participants with regular updates, study progress and researcher observations, and study trends via email, letter, or other form of communication.
- Provide adequate, fair, and phased compensation.
- Communicate regularly with participants and send regular reminders to ensure participants are following study expectations.
- Emphasize the value of the study. Ensure participants understand the purpose and goal of the study to encourage continued participation.

RETURN OF RESULTS AND RETURN OF VALUE

Returning study results to participants is increasingly recognized as an issue of importance to those who have given of their time and of themselves to participate in a study. This can be seen as a matter of justice.[9] Research shows that study participants want findings returned to[10] them. Researcher willingness to share results demonstrates transparency and builds trust, which can potentially increase willingness to participate in future studies.

Extensive instructions for returning results to participants can be found here:
https://victr.vumc.org/dissemination-of-research-results/

ADVICE FROM COMMUNITY EXPERTS

RETURNING VALUE TO PARTICIPANTS

General recommendations:
- Return aggregate trial results to participants in a timely manner to reinforce transparency and establishe trust.
- Return individual study findings (such as vital signs, genetic data, etc.) where feasible.
- Provide updates on how participants' research data are being used.
- Consider using established templates and examples to ensure that the right information is being communicated to research participants (https://victr.vumc.org/disseminating-results-to-study-participants/) and to the general public (www.victr.vumc.org/disseminating-results-to-the-public/).
- Communicate results using a variety of mechanisms including study web sites, newsletters and social media to reach participants and community.
- Build collaborations with health advocacy groups, patient support networks, and other community-based organizations to accelerate the dissemination of study findings and reach a diverse audience.
- Use resources like plainlanguage.gov and AHRQ Health Literacy Universal Precautions Toolkit, 2nd edition to assess the readability and literacy levels of dissemination materials.
- Incorporate easy to read graphics to communicate study data including clear and concise explanations where needed.
- Avoid the use of medical jargon, acronyms, and other terms that might be difficult for the average patient to understand.
- When possible, partner with patient participants and/or community investigators to co-develop patient-facing dissemination materials, co-publish publications, and co-present at any community meetings or professional conferences.

DISSEMINATION OF STUDY RESULTS TO PARTICIPANTS RIC EXAMPLE

RETURN OF VALUE STUDY

STUDY RESULTS:
What do research participants value receiving?

What the research team wanted to know
Sometimes people who participate in research want to get results from the study. A team of researchers at Vanderbilt University Medical Center wanted to find out what results people would value getting back. Some types of results are lab tests, blood pressure readings, and genetic testing. But there are other kinds of information that might be valuable to participants too.

Who was in the study
A total of 2500 adults from 49 states participated. They came from different ages, incomes, and backgrounds.

What the research study did
The research team created a survey that asked what research results and information people cared most about receiving. They sent the survey to volunteers in online platforms including ResearchMatch.

What the research team learned
More than three out of four people said they would like to get results back from a study they took part in. Many people also said that getting results would help them trust researchers more.

People valued genetic information the most. They wanted to know how their bodies might respond to a medicine and how likely they were to get a disease.

People also thought it would be valuable to learn about nearby clinical trials and get updates on how researchers were using their data.

HOW VALUABLE RESULTS WOULD BE

	NOT VALUABLE (1)	VERY VALUABLE (7)
HOW I MIGHT RESPOND TO MEDICATIONS BASED ON MY GENETICS		6.3
HOW GENETICS MIGHT AFFECT MY RISK OF GETTING A MEDICAL CONDITION		6.3
HOW MY LIFESTYLE AFFECTS MY RISK OF GETTING A MEDICAL CONDITION		6.0
INFORMATION ABOUT CLINICAL TRIALS NEAR ME		5.8
INFORMATION ABOUT HOW RESEARCHERS ARE USING MY DATA		5.8
MY ANCESTRY		5.7
MONETARY COMPENSATION FOR PARTICIPATING IN THE STUDY		5.6

Why this matters
People taking part in a research study often don't get any results back from it. Sometimes researchers worry that people might not understand the results. They wonder if the results would be useful to participants or would cause them to feel stress. Also, it can cost a lot of money and work to send out results. This study shows that participants care about getting different kinds of results back. They also care about getting other types of information. These findings will help researchers plan for sharing results and other information.

Thank you!
A special 'thank you' to all the participants in the Return of Value study. You are making a difference!

To view the full scientific article about the Return of Value study, please click on this link:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706772/#S22

Returning results is just part of returning value to participants. Even when returning results is not possible, there are other ways to provide participants with information they may find of value. The graphic below shows the relative value to participants of receiving certain types of information or compensation from study participation, from the Return of Value Study noted on the previous pages..
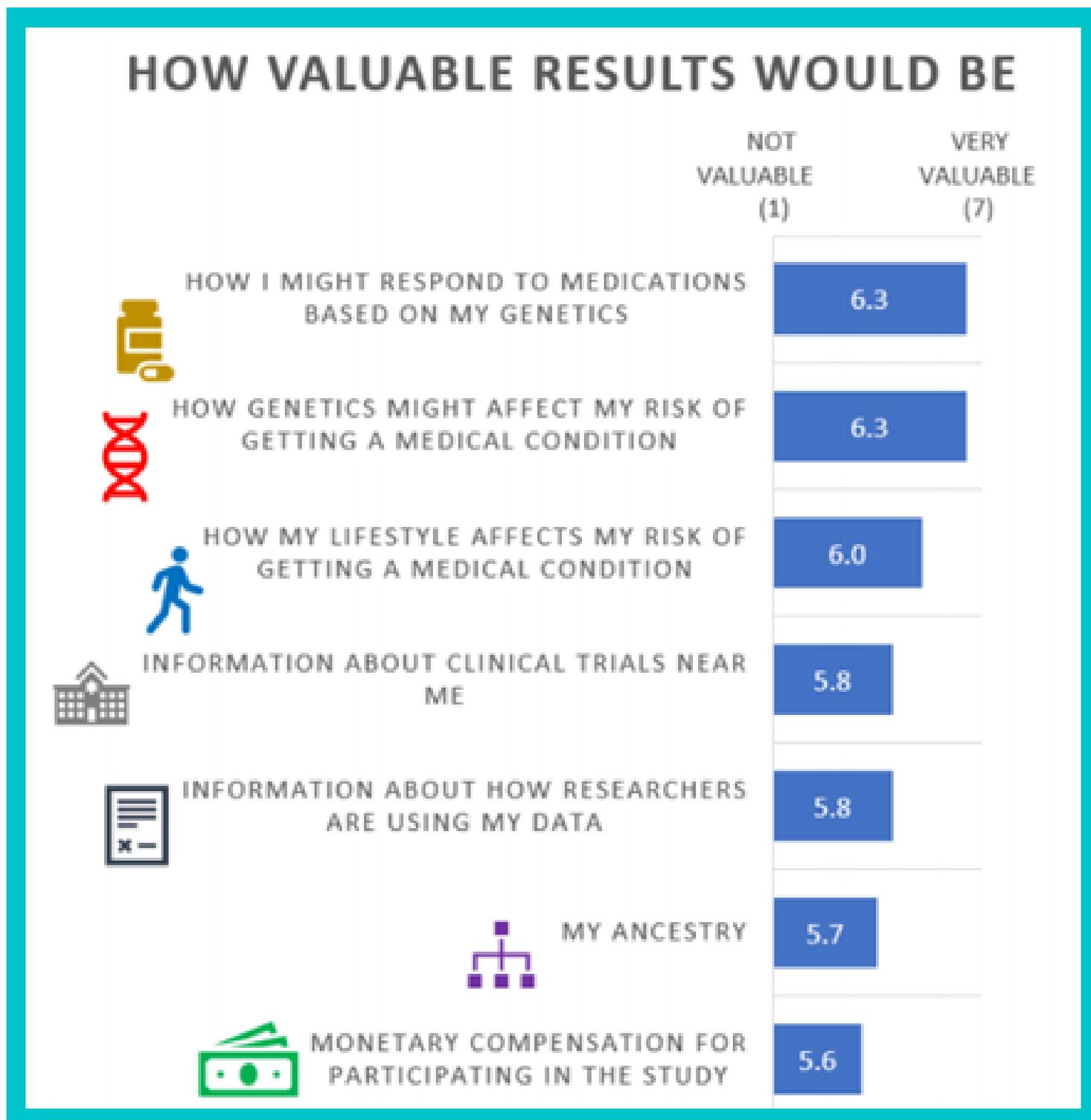
HOW VALUABLE RESULTS WOULD BE

	NOT VALUABLE (1)	VERY VALUABLE (7)
HOW I MIGHT RESPOND TO MEDICATIONS BASED ON MY GENETICS	6.3	
HOW GENETICS MIGHT AFFECT MY RISK OF GETTING A MEDICAL CONDITION	6.3	
HOW MY LIFESTYLE AFFECTS MY RISK OF GETTING A MEDICAL CONDITION	6.0	
INFORMATION ABOUT CLINICAL TRIALS NEAR ME	5.8	
INFORMATION ABOUT HOW RESEARCHERS ARE USING MY DATA	5.8	
MY ANCESTRY	5.7	
MONETARY COMPENSATION FOR PARTICIPATING IN THE STUDY	5.6	

SUMMARY OF STRATEGIES TO INCREASE INCLUSIVITY OF UNDERREPRESENTED POPULATIONS IN CLINICAL RESEARCH

A critical element of COVID-19 clinical trial design is developing and implementing methods to increase the diversity and inclusion of individuals from communities disproportionately impacted by the disease. To represent these individuals more fully in research, the RIC has formulated extensive strategies that are woven throughout the toolkit. This list summarizes these methods.

OBTAIN COMMUNITY FEEDBACK.

- **Use Community Engagement Studios** to solicit input from underrepresented groups on all phases of the proposed research.
- **Listen to concerns and obtain advice on recruitment methods from informal sources**, including current participants, extended families, and community organization leaders.

COMMUNICATE VALUE OF STUDIES.

- Take advantage of opportunities to **increase awareness of the value of COVID-19 research** and the importance of minority participation.
- Find ways to **return value and study findings** to participants.

REMOVE BARRIERS TO PARTICIPATION.

- Carefully **vet inclusion and exclusion criteria** that might restrict eligibility among minority groups.
- **Examine compensation** for the study and increase as needed to minimize financial barriers that disproportionately impact enrollment of underrepresented groups.
- **Consider virtual conduct of trials** where possible to minimize travel barriers to enrollment for these groups. (Note: Additional resources, training, and support for underrepresented participants may be needed.)

GET INVOLVED IN THE COMMUNITY, AND GET THE COMMUNITY INVOLVED IN THE STUDY.

- **Enlist the aid of local community organizations** to champion the study.
- Encourage researchers to **include members of the non-academic community on the research team**. If impractical to include community members themselves, consider including community health workers and community partners as a 'bridge alternative' or liaison with the community.

INCREASE CLINICIAN INVOLVEMENT.

- Use clinician-facing materials such as printed information sheets and Clinician Study Apps to **encourage clinicians to offer study information to all potentially eligible participants**, regardless of race, ethnicity, age, primary language, or literacy level.

SUMMARY OF STRATEGIES TO INCREASE INCLUSIVITY OF UNDER-REPRESENTED POPULATIONS IN CLINICAL RESEARCH (CONT'D)

MAKE STUDY INFORMATION MORE ACCESSIBLE.

- **Print participant-facing brochures and posters in additional languages** commonly spoken or present in the community being studied. Translate participant-facing videos into these languages as well.
- **Revise the text on all participant-facing materials to a 6th- or 7th-grade reading level** to be more inclusive of those with limited English proficiency.

MAKE STUDY INFORMATION MORE APPROPRIATE.

- ·**Ensure cultural appropriateness and diverse imagery** in participant-facing recruitment materials, websites, and videos.
- On recruitment materials and websites, **include participant testimonials** that feature individuals from diverse backgrounds.

IINCREASE INCLUSIVITY VIA eCONSENT.

- **Implement eConsent options that increase inclusivity,** such as:
  - multi-lingual language capacity
  - text-to-speech ('read it to me') accessibility
  - increased text size for older adults and those with visual impairment
  - hover-over' pop-ups for definitions and images to increase comprehension
  - enhanced instructions for those with low technology literacy
  - avatars that reflect a wider range of racial, ethnic, and cultural backgrounds

CONSIDER THE VIEWPOINT OF PARTICIPANTS.

- Have members of the research team **consider all research strategies through the lens of diversity** (e.g., racial, ethnic, and gender minorities; populations of lower income and/or educational attainment; physically and/or mentally disabled; rural populations).
- ·Have study team members **take the Faster Together course** to learn ways to increase research participation by diverse groups (https://www.coursera.org/learn/recruitment-minorities-clinical-trials).
- **Be mindful of the mistrust in research** resulting from historical research atrocities. Communities are still experiencing health disparities and they need trustworthy researchers.

PROTECT PRIVACY.

- **Use discretion** when performing COVID-19 testing in neighborhoods.
- **Apply for a waiver to eliminate the need to collect Social Security numbers.**

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