UNC | SCHOOL OF MEDICINE
North Carolina Translational and Clinical Sciences Institute

Participant Recruitment Refresher

Emily Olsson, CCRP | Manager, Research Recruitment and Retention

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Participant Recruitment Resource Center:
go.unc.edu/prrc

Want to Talk it Through?
go.unc.edu/recruitment-intake

What is considered recruitment?

Anything intended to engage a potential participant in a specific study prior to signing the informed consent document

Flyers	Social Media	Print Advertisements	TV/Radio Advertisements
Digital Advertisements	Letters	Info Sheets & Consent Aids	Research for Me @UNC or other websites
Phone Scripts	Face to Face Conversations	MyChart Recruitment	Physician Referral

Reminders

- UNC IRB SOPs: Recruitment guidance is found on pages 21-25
- UNC Health Privacy Policy
- Answers to patient FAQs (UNC)
- Recruitment Etiquette (UNC)
- FDA Information Sheet: Recruitment
- FDA Information Sheet: Compensation
- Office of Research Support and Compliance (UNC)

Participation is voluntary.

Recruitment is the first step in the informed consent process.

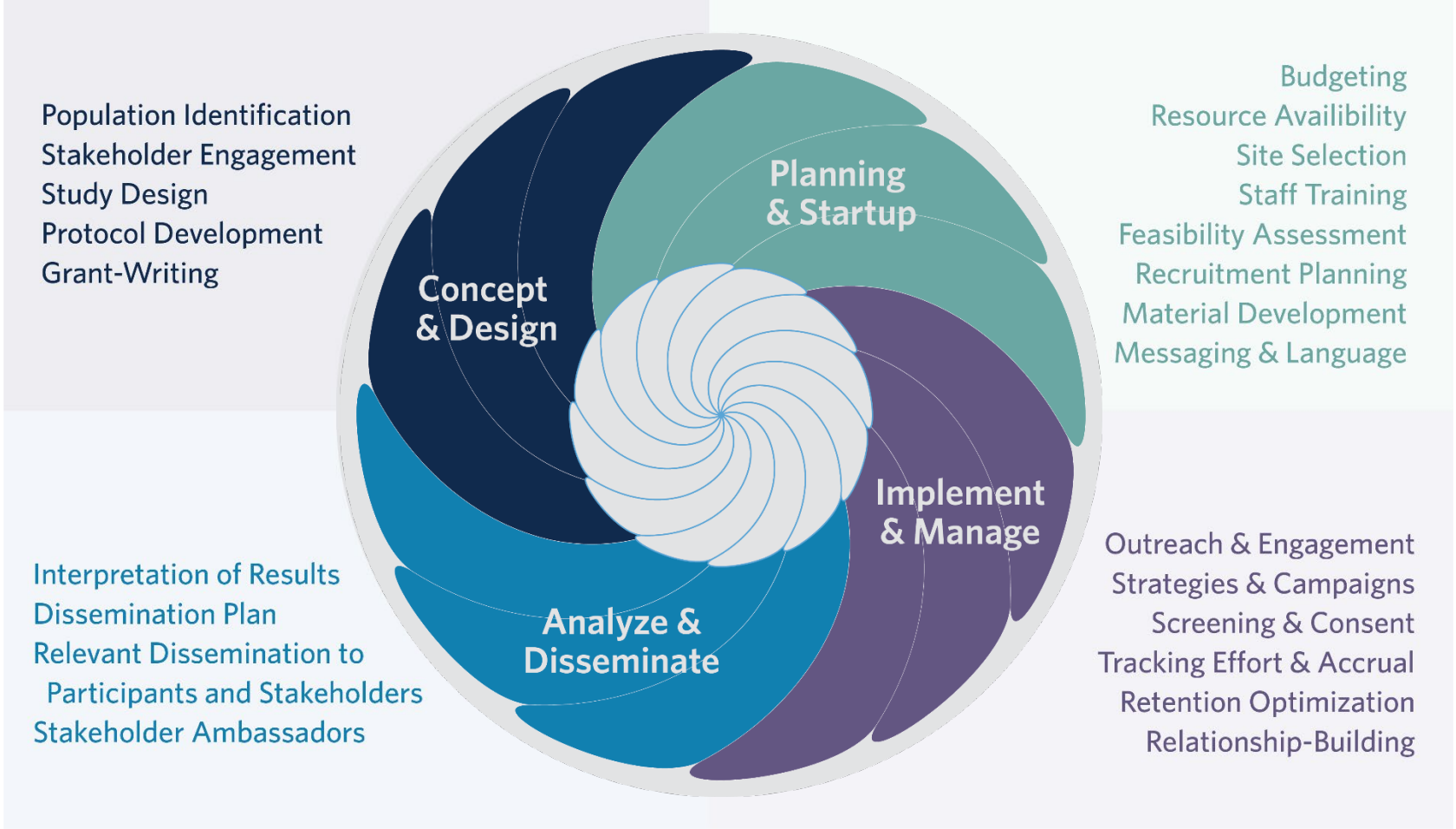
All recruitment strategies and materials need to be reviewed by the IRB. Changes need to be re-reviewed.

Not sure about something? Just ask!

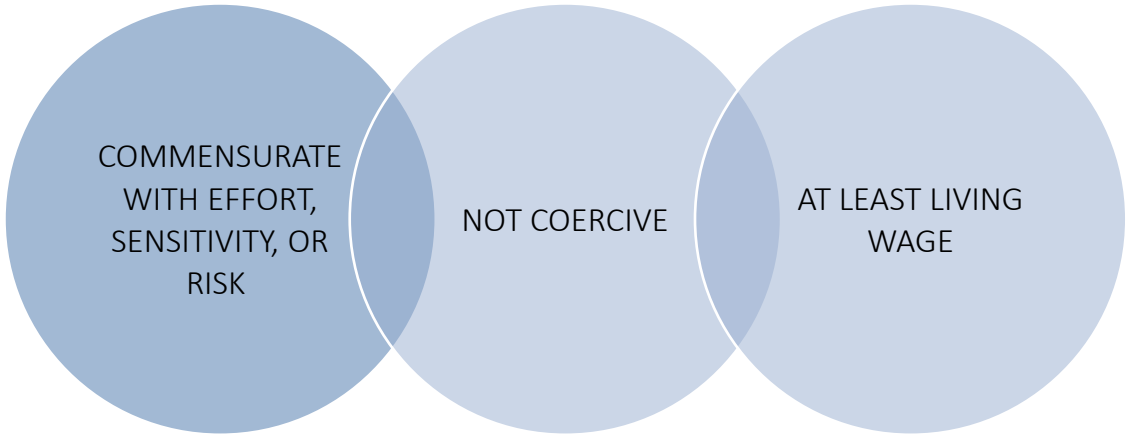
Recruitment and Retention in the Study Lifecycle

The choices you make matter

When should you think about recruitment?



Compensation



- Payment schedule and method
- Alternatives to individual compensation
- Compensation does not have to be monetary!

"We pay for what we value in America. If everyone in the room is making $50-100/hr and I'm getting just a sandwich? That's disrespectful."
– NC TraCS Community Stakeholder, 2022

I'm an expert on me, my family, my community. Pay me for my expertise.
- NC TraCS Community Stakeholder, 2022

Take steps throughout to:

- Identify and engage a representative and well-rounded group of participants who are diverse in their Demographic, Experiential, and Cognitive characteristics
- Set up infrastructure and be intentional in acknowledging biases as to ensure equal opportunity for participation in research for all
- Create a study, strategy, and environment that considers the context of all potential participants by removing barriers, expanding to diverse audiences, and meeting each individual where they are with what they need

Recruitment Planning

Guiding participants from interest to investment

Recruitment Planning

Where will you recruit?

How will you recruit?

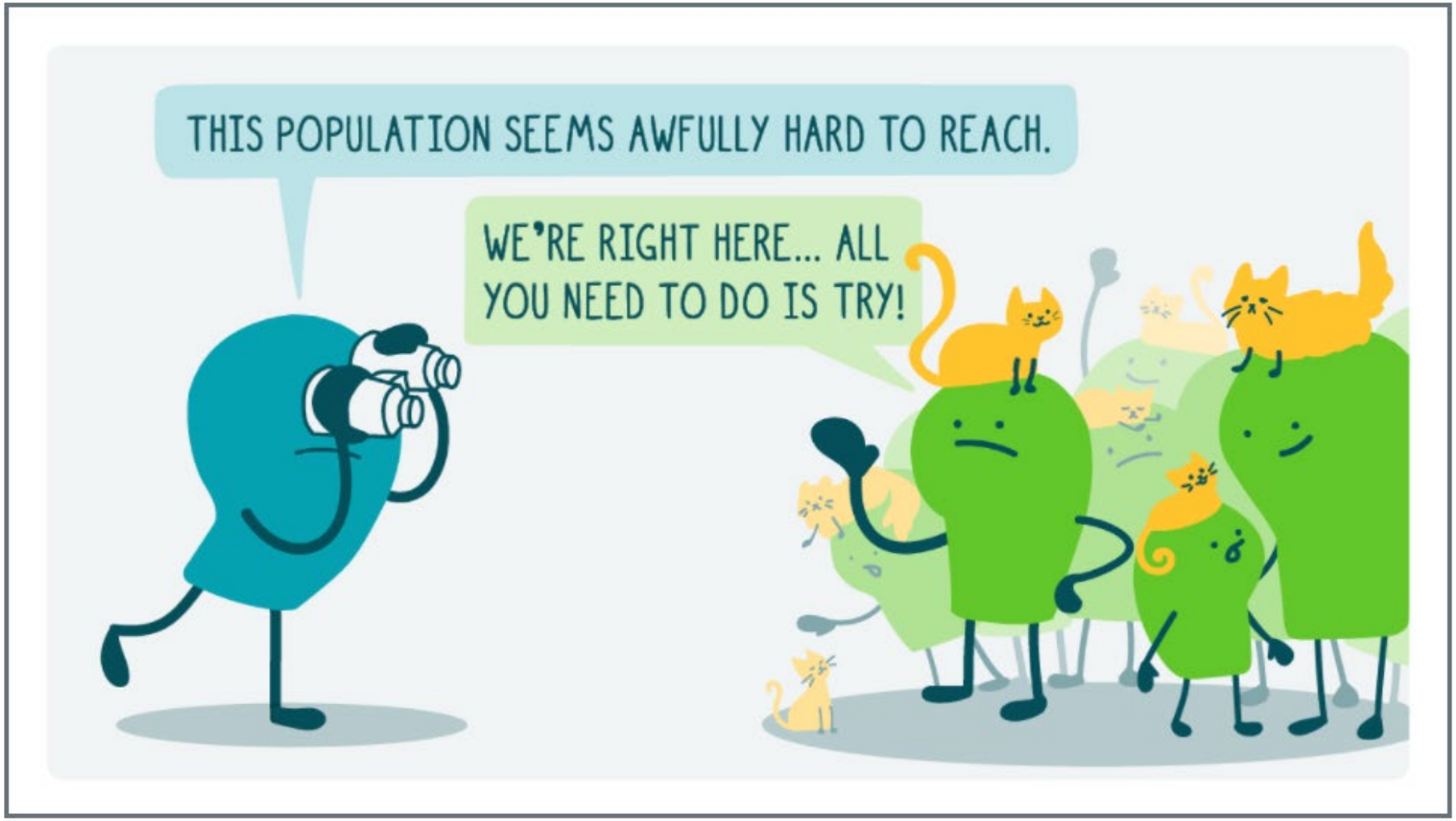
How will you describe the study?

How will potential participants contact you?

What resources do you have available?

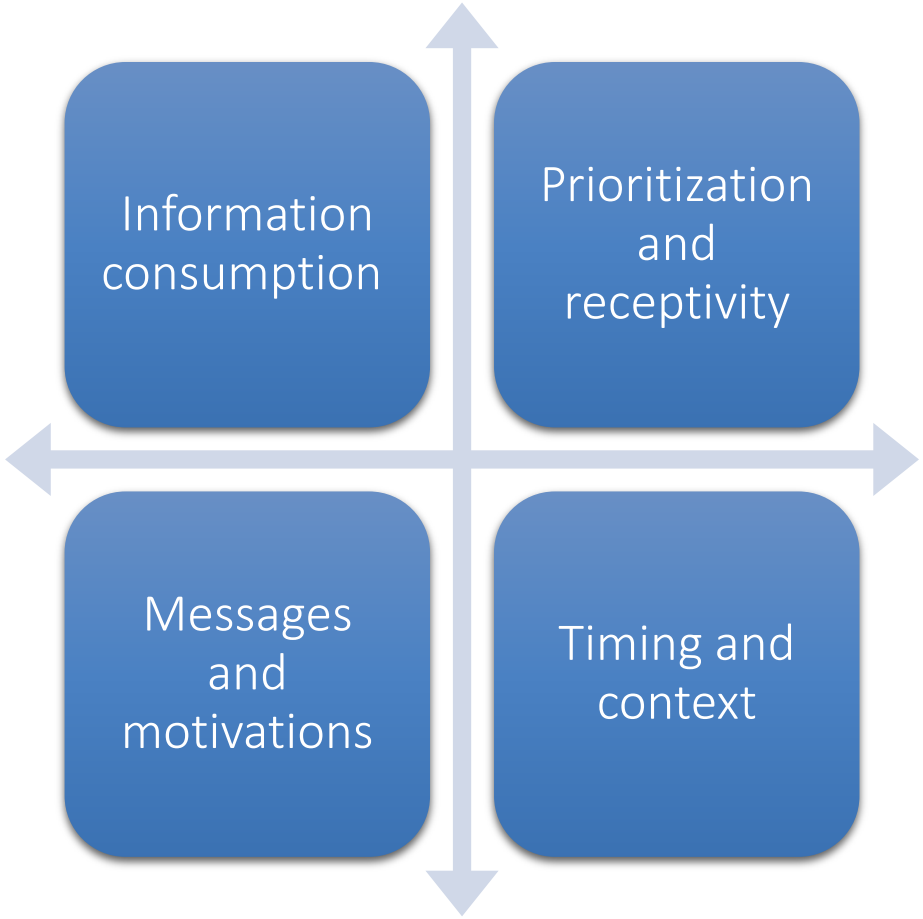
What tools will you use to keep participants invested and on track?

How will you monitor accrual and pivot?



From Communicate Health, August 2021

Your audience is made up of individuals



Tailor your recruitment strategies and materials to the participants you need to reach! Try more than one thing. Get creative and be intentional with delivery, message, and format.

- Where do you consume information?
- When are you most responsive to or dismissive of advertisements or solicitations?
- What makes something trustworthy? Or not?
- What makes something interesting/appealing? Or not?
- Do you typically take action right away?

Approaches

Customize your approach to the study, audience, and your capabilities

- **Active Recruitment**
  - You identify and pursue individual potential participants
  - Ex. - EHR screening; CDW lists, physician referral, targeted community events
- **Passive Recruitment**
  - You rely on potential participants to contact you and express interest
  - Ex. - Flyers, social media, digital study listings, listservs, advertising
- **Word of Mouth and Participant Networks**
  - Encourage participant ambassadors; create peer to peer networks, create registries, create advisory boards
- **Effort Tracking to inform future studies**

Recruitment Outreach Tools and Methods

Research for Me @UNC Recruitment Listing

Carolina Data Warehouse for Health

UNC Mass Email

ResearchMatch.org

My*UNC*Chart

Partner with colleagues to conduct sub-study

- Direct contact via phone, letter, secure email
- In-person/in-clinic recruitment
- Chart review or registries
- Flyers, pamphlets, info cards
- Social Media Campaigns
- Advertising (print, TV, radio, buses)
- Websites and Screening Tools
- Physician referral
- Lunch 'n' Learns
- Attend staff meetings or in-services
- Listservs
- Consult with patient advisory boards
- Plug into existing networks
- Community events and outreach

Define Your Message(s)

One size does not fit all

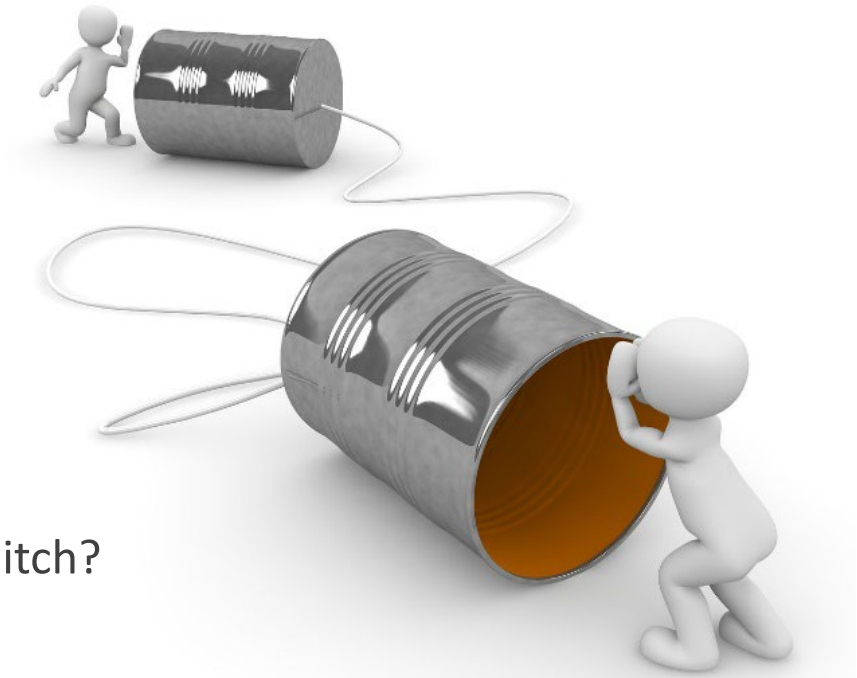
Messaging in Recruitment

Common Questions

1) Will people understand my study?
2) Will it get me the response rate I want?
3) Is it too much information?
4) Is it inclusive and relatable?

Important Questions

1) How will people feel about my study? Do they care?
2) Does it anticipate *their* questions?
3) What is their frame for this conversation?
4) Do they need other information before they can consider my pitch?
5) Is it coercive? Offensive? Affected by positionality?
6) What are they getting out of this?
7) Am I offering information in a logical, digestible way?

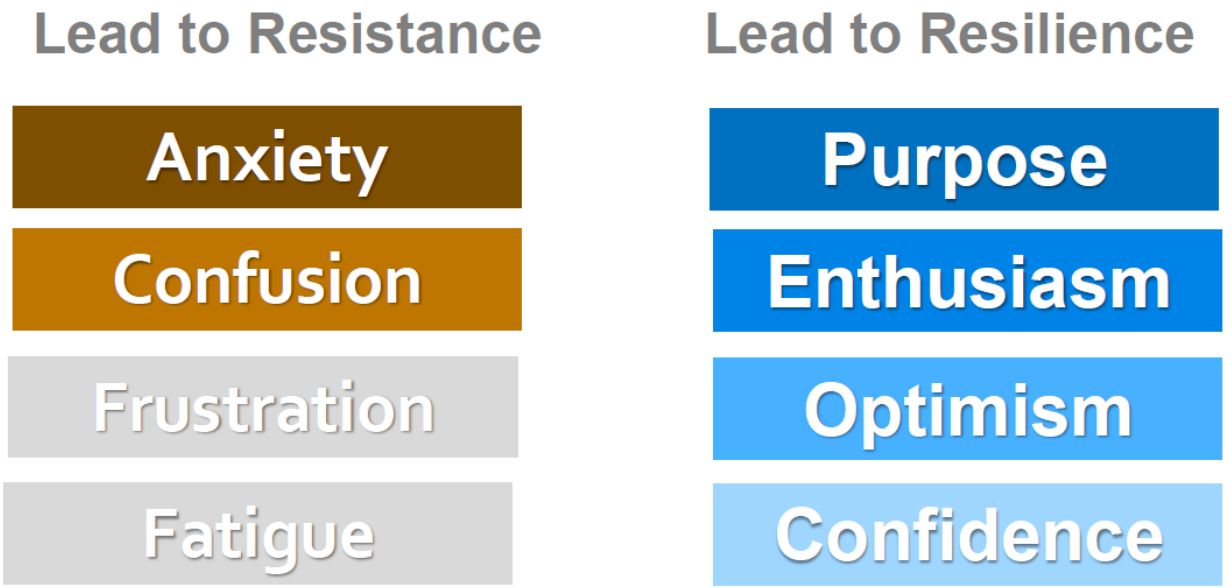


Emotions of Change

An effective message:

- Improves understanding
- Improves engagement
- Leads to meaningful buy-in
- Improves recruitment and retention rates

Be creative and determine what resonates with your target audience(s)



Source: McKinsey Quarterly

Selling Your Study

Participant-centric and engaged	Purposeful consideration of information framing
Meeting people where they are	An informed and skilled recruiter
Awareness, flexibility, persistence, responsiveness	Tailored rather than one-size-fits-all

You have a product (the study) and you need your customer (the participant) to buy it (enroll).

It's your job to introduce the product in a way that conveys value to the participant and encourages them to choose to take time out of their day/life to participate.

To do this, define the needs of your customer(s), the characteristics of your product, prioritize the relevance of each element, and define the core messages that are likely to resonate.

They always get to choose whether or not to buy, but how your frame it and time it has an impact on receptivity and interest.

What stands out?

1. Research Participants Needed!
2. Having a baby changed your life. How did it change your brain?
3. Having a baby changed your life. Help us learn how it changes your brain.
4. Baby blues got you down?
5. Babies bring joy….and exhaustion. Can we help you lift the fog?
6. Have a baby under 1?
7. We need to take better care of new parents - help us figure out how we can help.

Design Your Materials

Get them to stop and pay attention

You have 2 seconds to catch someone’s attention

Elements of Good Materials

EYE CATCHING

Image & white space

EASY TO READ

Clear & Engaging

EASY TO ACT

Hook, Call to Action, Contact Info

RELEVANT

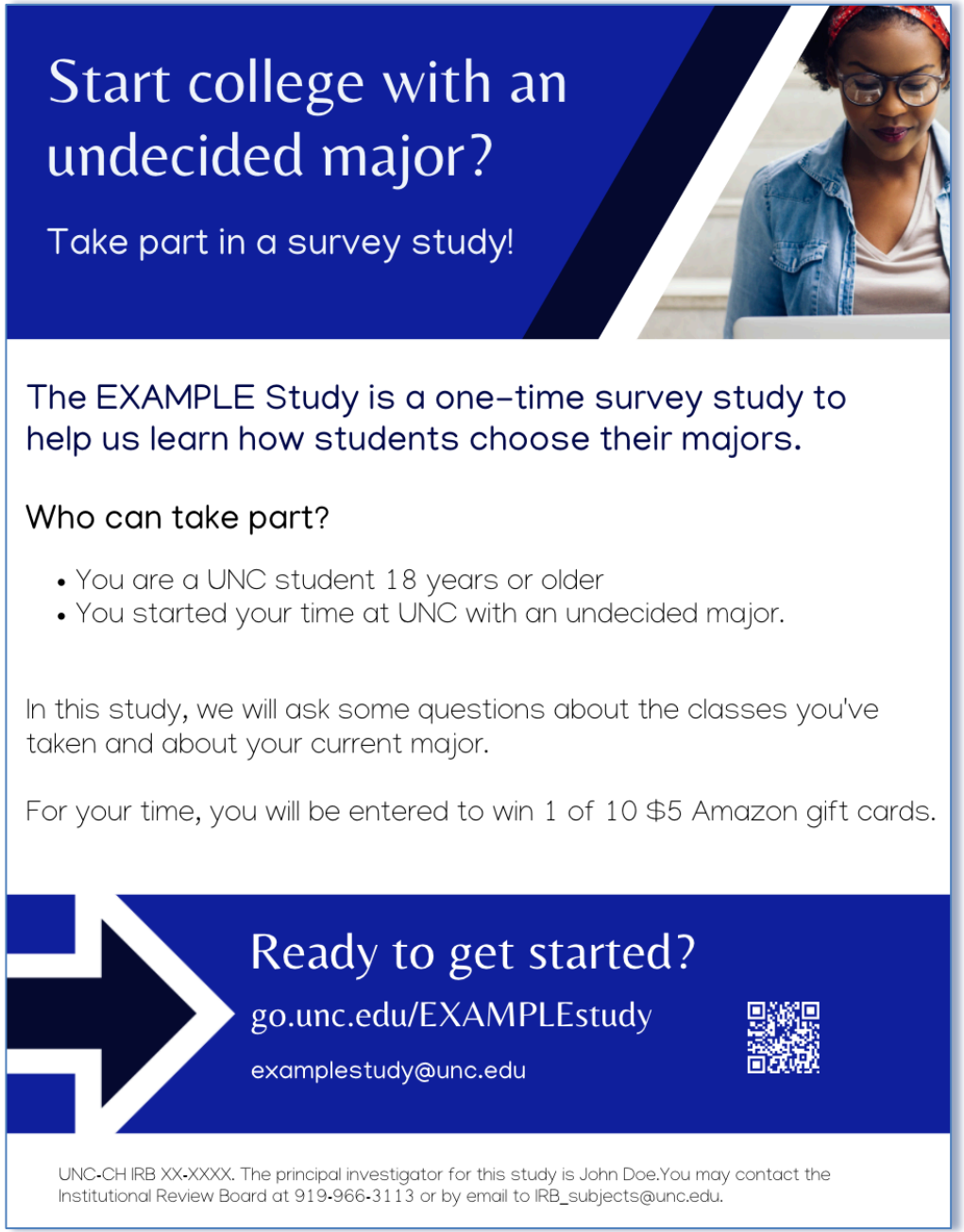
Is it in the right place?

Required Elements

- Hook/Headline
- Basic study summary in lay language
- What you'll ask participant to do
- Simple inclusion/exclusion criteria
- Contact information
- Compensation (if any)
- Study location
- IRB number, PI name, and IRB contact information

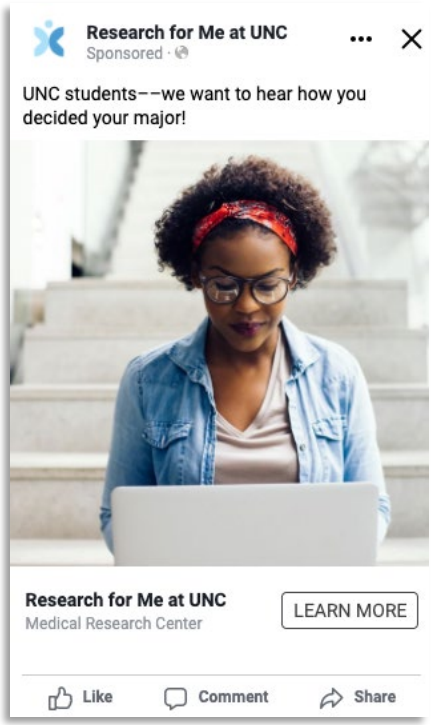
The Goal

- ☑ Pique their interest
- ☑ Answer these questions:
  - What is the study about?
  - What do you want from me?
  - Why should I care?
  - How do I get involved?
- ☑ Encourage action



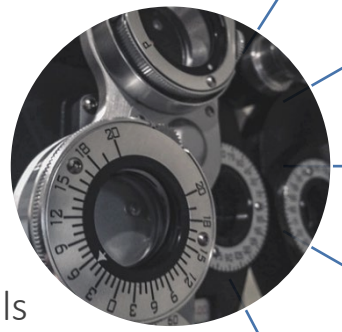
Branding

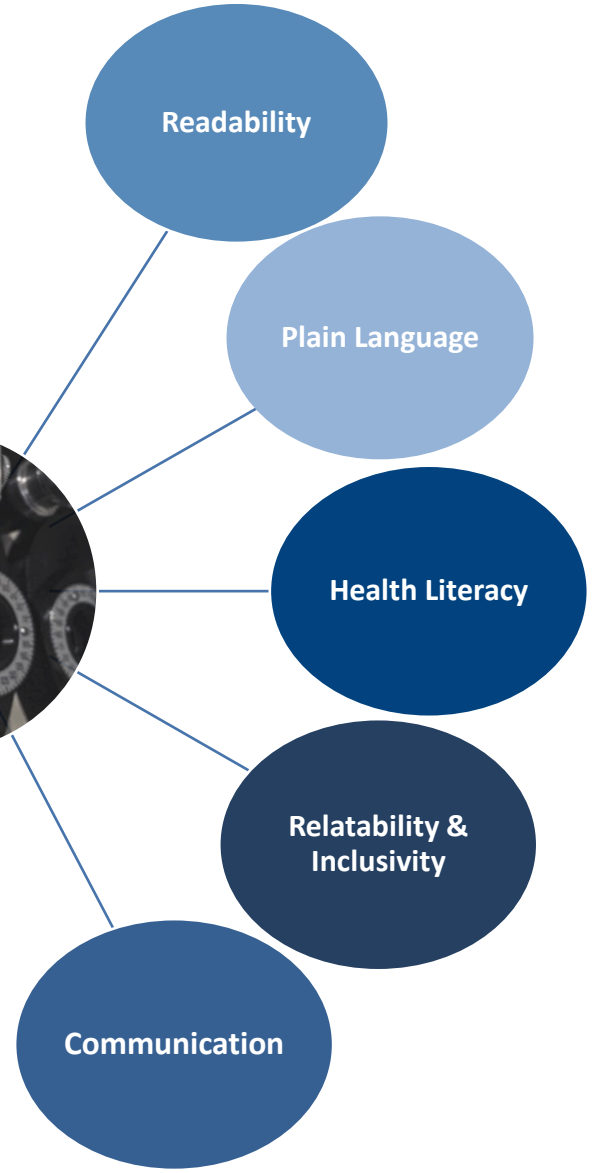
- Be consistent across all recruitment materials you create
  - Rule of 7 – need to see a message 7 times before they'll act
- Create a study logo and/or catchy title
  - To promote legitimacy and trust in the study



5 Lenses for Message Clarity

1. Readability
   - Review recruitment materials for visual appeal (white space, bullets, tables) and use words with fewer syllables. Use readability programs.
2. Plain Language
   - Review content, paragraph structure and word choice for simple, upfront language. Ensure content is at 6th-8th grade reading level.
3. Health Literacy
   - Recognize your audience's understanding of medical jargon & adapt materials accordingly. Use words and examples that are familiar in everyday life.
4. Relatability & Inclusivity
   - Use terms that are relatable and identify language that may potentially be offensive.
5. Communication
   - Ascertain the mindset and behaviors of your audience. Speak slowly, pause for questions and practice, practice, practice!





What will happen if you take part in the study?

If you participate in this study, for three weeks you will: use FASTER daily, have three fMRI brain scans, and will come to the clinic for study visits once a week. Before treatment you will have physical exam. Details of your participation are described below.

Clinical and Health Screening: You will undergo a screening process to determine if you are eligible for the study. In order to protect you from adverse medication effects, you will be screened with a complete medication history, physical exam, and laboratory tests. During your first exam visit and again at your final visit, approximately 2 tablespoons (30 mL) of blood will be drawn to test liver an kidney function. We will also do a blood test to make sure you are not pregnant and to test medication concentration in your blood at the end of the study. The results of your physical exam and laboratory tests will appear in your UNC Health Care medical record. Your medical record will also show that you are participating in this study. During the initial screening, you will be asked questions about your past health, the complications from your surgical incisions, as well as questions about any symptoms you may be experiencing now. You will also be asked to complete questionnaires about your mood symptoms and trauma history. You may choose not to answer any or all of the questions for any reason.

Brain Imaging: You will participate in three brain imaging sessions at the UNC Biomedical Research Imaging Center. In these sessions, magnetic resonance images (MRIs) of your brain will be taken. An MRI is a picture of your brain taken with the use of strong magnetic fields. MRIs do not use x-rays or other radiation, and there are no known risks from exposure to magnetic fields and radio waves associated with MRIs. However, there is the risk of discomfort with confinement inside the imaging machine. In this study, special MRIs (called functional MRIs or fMRIs) will be taken that provide information about what areas of the brain are made active by particular kinds of stimuli. You will complete a safety questionnaire to determine whether you have any foreign iron or ste metal objects in your body, such as a pacemaker, shrapnel, metal plate, or metal debris. If you have any such objects in your body, yo cannot participate in the MRI session unless it is deemed safe to do so by the fMRI team. The fMRI team at BRIC determines the safety of metal objects for potential participants on a case by case basis. For that reason, the study coordinator always contacts the fMRI team any time there is a metal object in a potential participant's body to determine if it will be safe to conduct a brain scan. The fMRI team frequently utilizes mrisafety.com and generally uses clinical procedures as a basis for determining safety. If the team is still unsure after checking the website or referencing clinical procedures, they will verify with clinical radiologists in the hospital. If the metal object is an implant, the fMRI team will check to see if there is an MRI safety indicator on the implant's card. If that information is not available, the fMRI team will contact the manufacturers of the implant to determine if the participant can be safely scanned with the implant. Additionally, before every scan, the fMRI team has a checklist for participants to fill out that asks about metal objects and surgeries to ensure that every participant is properly and thoroughly screened before being scanned in the fMRI machine. You may be asked to participate in an additional 15 minute test brain scan once it has been deemed that there are no safety concerns so that the fMRI team can ensure your brain images are free of any artifact, which is when a metal object can block a part of the brain image. This optional visit would occur before your second study visit. Please ask the experimenter if you are unsure about any metal objects in your body. During the scan, you will see a screen which will give you a simple task that you will perform by pushing a button. This task will involve a scheme in which you hypothetically win or lose money. You will have the task explained to you and will have a chance to practice it before getting into the scanner. Once you understand the task instructions, you will lie down on your back on a platform and your head will be positioned inside a helmet-like circular tube and the platform will be pushed inside the long tube of the MRI machine. The MRI technician will provide padding for your head and knees to make you more comfortable while lying down. If you are uncomfortable or feel pain because of lying down, please tell the technician immediately. You will be able to see outside of the helmet and outside the imaging machine by looking at a mirror. In this way, you will be able to watch the pictures or words displayed on a screen placed near your feet. If sounds are presented, you will hear them through earphones. It is expected that each imaging session will take approximately 2 hours.

Medication Application Procedures: Starting after your first MRI, you will initiate use of either the investigational medication or the standard medication. In either case, you will apply the topical ointment twice a day. The investigational medication is called FASTER, and contains .45mg concentration of the active agent XYZ. The standard medication is called USUAL and contains .01mg concentration of the active agent ABC as well as .5mg concentration of the active agent 123. You will use the study medication for three months and will return any unused portion to us.

Study Visits: In total, you will attend 6 study visits across your participation. In the first, you will discuss the study with the principal investigator or a research assistant, you will provide consent, and your medical history will be assessed. This appointment will likely take 2-2.5 hours. At your second visit, the study doctor will also perform a physical exam at this visit and administer a series of questionnaires. After your exam you will have blood drawn for initial lab work. At the following three study visits you will have an fMRI done, you will complete a second task outside of the fMRI that you will perform by pushing a button, you will be given an interview and a series of questionnaires, you will be given your tube of study medication and you will have blood drawn, about 2 tablespoons (30mL). Each MRI appointment will likely take 3 hours. At each of these visits you will also be given a new tube of study medication and have blood drawn. Each of these appointments will likely take one hour. During your final appointment, you will return all study medication, compete the same interview and questionnaires as before, have a second physical exam to evaluate the progress of your healing, and have blood drawn. The last visit will take about an hour.

What will happen if you take part in the study?

If you decide to join this study you will:

- Apply a cream twice a day, for three weeks to your wounds. This will be either the new medication, FASTER, or the standard medication, USUAL.
- have three fMRI brain scans
- come to the clinic for study visits once a week (parking vouchers provided)

Visit 1: Screening Visit, Medical History
You will come to the ABC clinic for your first appointment. You will meet with the study team to go through this document, discuss what is being asked of you for this study, and to ask any questions that you have. If you decide to join, you will sign this form and continue with the visit. A copy of this form will be placed in your medical record so that if you see another doctor while in this study, they can see that you are taking FASTER or USUAL. We will ask you to complete questionnaires about your:

- Mental health and medical history
- Current mental health symptoms
- Current mood symptoms
- Any history of trauma

You may choose not to answer any or all of the questions for any reason. This visit should last 2-2.5 hours.

Visit 2: Screening Visit, physical exam
You will return to the ABC clinic to meet with a study doctor for:

- Physical exam. The study doctor will listen to your lungs and heart, look at the areas on your belly where you have surgical cuts, and ask you questions about how you are feeling.
- Blood draw. We will take about 2 tablespoons (30mL) of blood to be sure that your liver and kidneys are functioning properly and to be sure that you are not pregnant (if female).

The results of your exam and laboratory test results will appear in your UNC Health Care medical record. This visit should last about 2 hours.

Visits 3-5: MRI and Medication Visits
For visits 3, 4, and 5, you will go to the UNC Imaging Center to meet with the study team. Each visit will take 3 hours. At each of these visits you will:

- Have an MRI. We will ask you to get into a machine that will take a picture of your brain. This will not hurt, but you may ask to stop at any time if you feel uncomfortable. Some people who are afraid in small spaces may feel uneasy or scared during this procedure. More details about how the MRI works are included in the next section.
- Get medication. The study team will give you a tube of the study medication to use twice every day. You will not know which kind of medication are you are given. You will also be given instructions on how to use it.
- Blood draw. We will again ask for 2 tablespoons of blood to check your kidney and liver function. We will also check to see how much of the medication is in your blood.

Visit 6: Final Visit and Exam
For your last study visit, you will come to the ABC clinic. This visit will include:

- Return medicine. The study team will collect any study medication that you have left over.
- Answer questions. We will ask you to answer some questions about how you are feeling.
- Physical exam. The study doctor will do another exam just like the one at Visit 1.
- Blood draw. We will again ask for 2 tablespoons of blood to check your kidney and liver function. We will also check to see how much of the medication is in your blood.

This visit will last 1 hour. At the end of this visit, we will give you $200 (gift card) to thank you for your time and effort. Your participation in the study will be over at the end of this visit.

Know What You Need

Monitor progress and trends; Advocate for necessary adjustments

What can you do?

Analyze	Accept	Address	Advocate	Adjust
Collect data on your recruitment and retention efforts. Be consistent.	Accept the things you cannot (realistically) change and remember that some attrition is normal	Address the things you can change preemptively based on your knowledge	Advocate for adjustments and what you know to be true or for a new approach. Easy and effective are not the same thing.	Use everything you learn from this experience to inform how you approach recruitment planning for the next study

Metrics to Track

- Enrollment rate – are you on track with your timeline?
- How did people find out about you?
- Why do people decline?
- Why are people ineligible?
- Your effort (time)
- Implementation of various recruitment methods/materials/messaging
- Cost per method; cost per enrolled participant
- Feedback provided from participants

You are the expert here

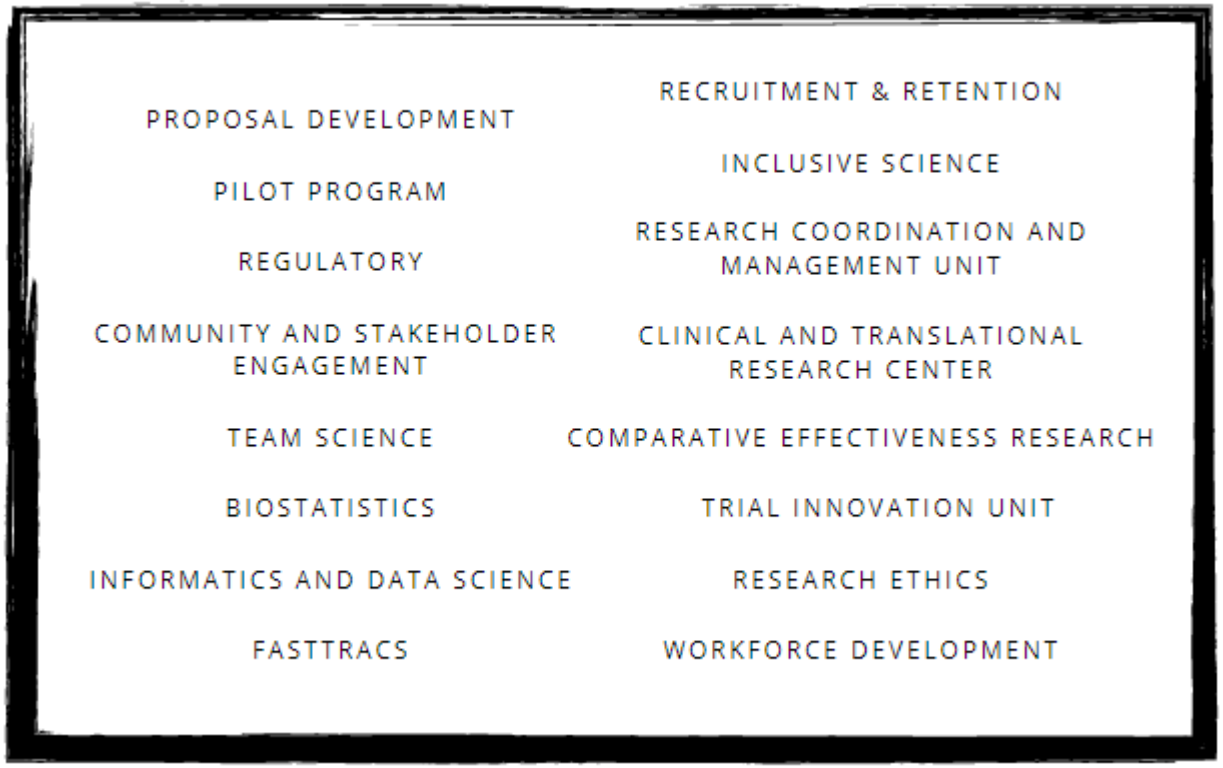
- Be intentional about continuous evaluation of your recruitment efforts. Even the best-laid plans require attention and fine-tuning.

- Arm yourself with data. Not only will this help you to be more efficient and directed in your efforts, but it will allow you to make a strong case to your PI, Sponsor, or the IRB when changes are needed.

- Changes might be as simple as changing the value statement or as foundational as changing an eligibility criteria

Lean on NC TraCS

We're here to help!



TraCS has programs that offer specific support in every step of your research project. Each of our services:

(1) provides expert consultations

(2) develops novel methods and technologies for translational science

(3) educates and trains the translational research workforce

Whether you are in the middle of a project or just starting out, our dedicated staff is ready to help.

TraCS Overview

TraCS Menu of Services

Consultation Request Form (any service)

Thank You!

- **Participant Recruitment Resource Center**: go.unc.edu/prrc
  - Design Resources
  - Plain Language Resources
  - Resources and Best Practices for diversifying participants
  - Templates
  - IRB policies (pgs 21-25)
  - Compensation Best Practices
- NC TraCS: tracs.unc.edu

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL
NRP
Biomedical Behavioral Translational Social
Network for Research Professionals

NRP Researcher Appreciation Week!
May 16-20, 2022

https://nrp.tracs.unc.edu/researcher-appreciation/

Request a Free Recruitment Consultation: go.unc.edu/recruitment-intake
Recruitment Office Hours – 3rd Wednesday of every month (Zoom link)

Resources

Deeper Dives

- Webinars and Trainings:
  - Material Design
  - Messaging and Value Proposition
  - Plain Language
  - Trial Innovation Network Webinars
- DEI and Bias Tools for Self-Introspection
  - Harvard's Project Implicit (quick tests to see where your biases may lie)
  - Allegories on Race and Racism (TEDxEmory – Dr. Camara Jones)
  - UNC DEI Certificate Program through our DEI Office

Recruiting with Research for Me

Components for submitting and managing your listings

IRBIS and REDCap

Researcher

Submit recruitment listing

Section B.1.2

Researcher Dashboard

Researcher

Edit and Manage listings

researcherdashboard.unc.edu

Research for Me @UNC

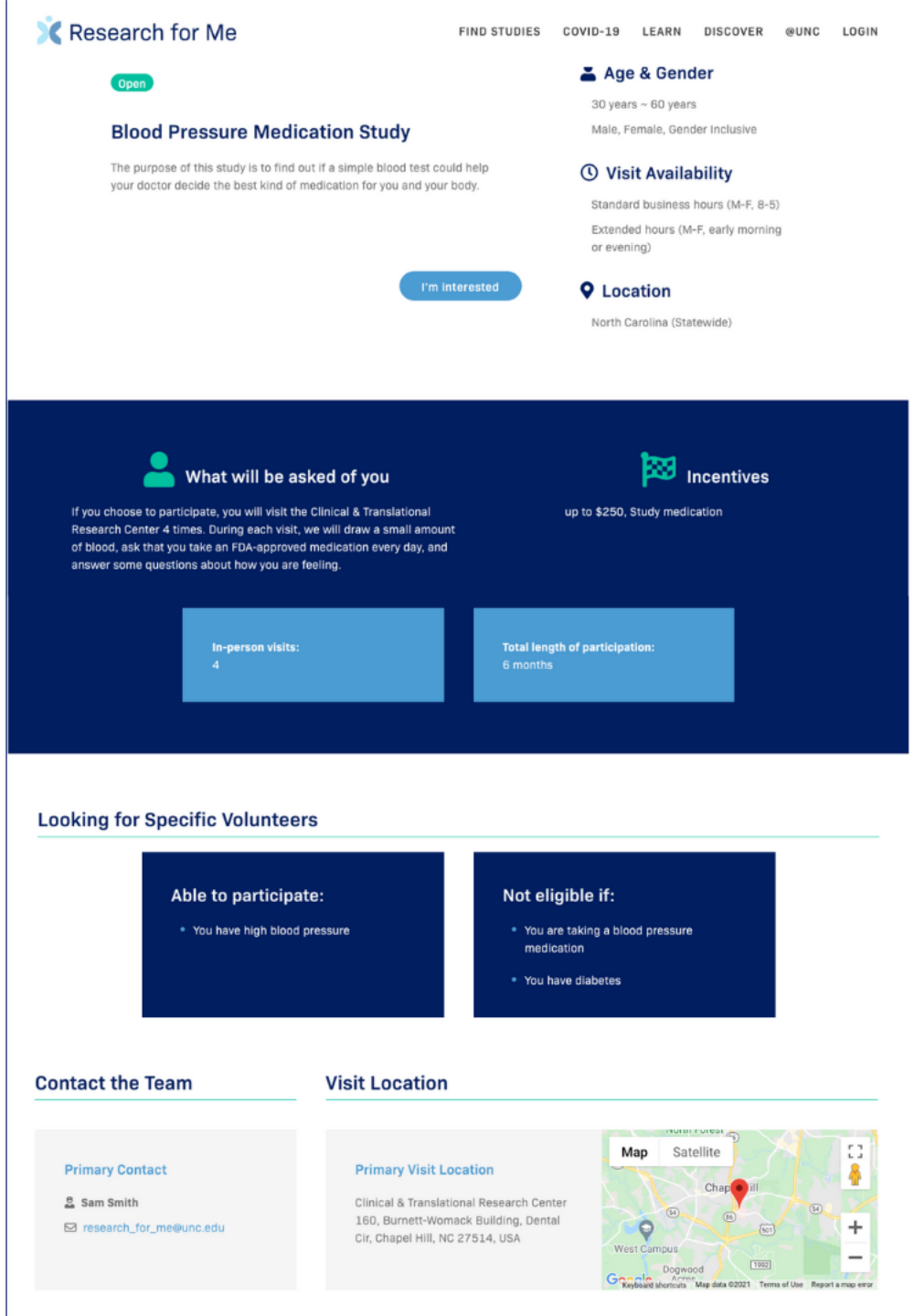
Patients and the Public

Learn and Search

researchforme.unc.edu

Recruitment Listings

- Utilize RFM as a free recruitment tool and landing page
- Low effort, passive recruitment. Complete the form once and let potential participants find/contact you
- Request free language and search optimization
- Eligible for promotion on RFM social media
- Direct participants to an online screener or survey
- IRBIS integration helps to keep things current
    - Listed from IRB approval to completion of enrollment
    - Recruitment information only displays during a recruitment window YOU specify.
- Update any time via the Researcher Dashboard



Designing Print and Digital Materials

PRINT	DIGITAL
Material selected and designed based on where it will be placed or presented	Graphic designed for the promotion platform (Facebook, Instagram, etc.)
Create 1-2 versions for different placement options and different material types.	Create more than one option for slightly different audiences
Use images that fit your target audience	Use images that fit your target audience. Consider more out-of-the-box options to optimize advertising efforts
QR code & link to screener/more information	Link to screener/more information
Ask a screening question about where potential participants found out about the study	Ask a screening question about where potential participants found out about the study