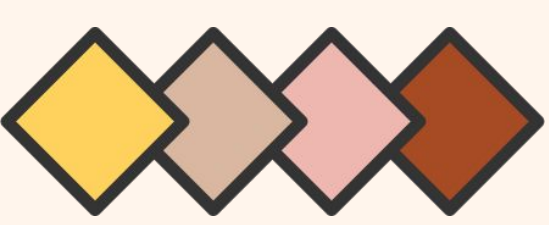




Training Session:

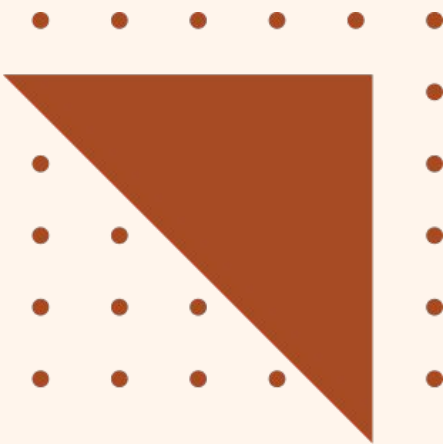
Role of CHRs, Understanding Data Flow, REDCap Training

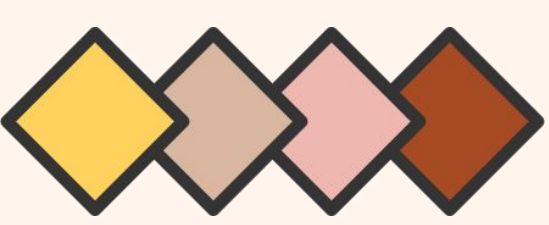




Agenda

1. IceBreaker
2. Overview of CHR Responsibilities
3. Study Visits Timeline & Compensation
4. Overview of Dataflow
5. REDCap Training



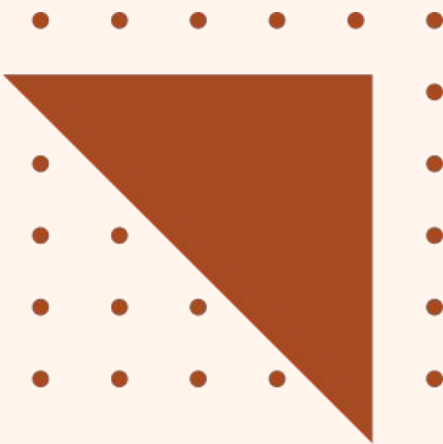


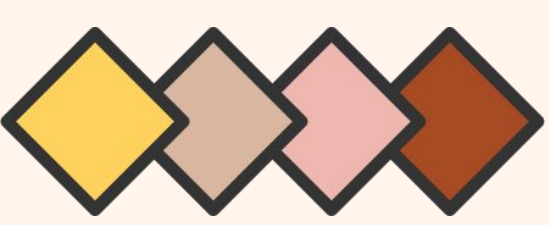
Icebreaker

What's the best advice you've ever heard?

What would you like to be known/remembered for?

What was your dream job as a kid?





Overview of Community Health Representative (CHR) Responsibilities

Participant Support and Rapport Building:

- Maintain open and empathetic communication to ensure participants feel comfortable seeking assistance and guidance.
- Establish a strong rapport with participants to foster a supportive and trusting relationship.

Administering Assessments & Complete screenings

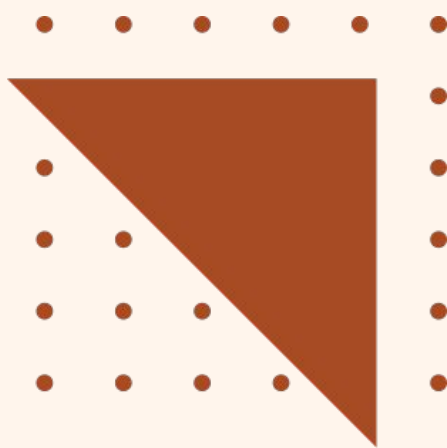
- Administer assessments to participants and ensure assessments are conducted accurately and in accordance with established procedures.
- Offer assistance and technical support to address any difficulties participants may encounter while watching modules and completing assessments

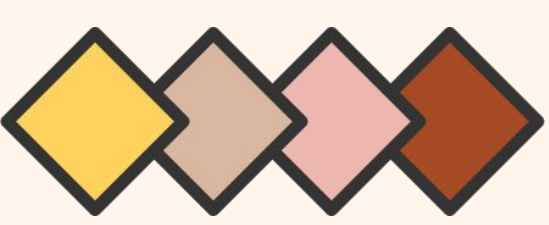
Documentation and Reporting:

- Keep detailed logs of all interactions with participants, including phone calls and outreach attempts
- Following up with participants, and community partners in a timely manner

Training and Skill Enhancement:

- Attend training sessions and workshops to enhance knowledge and skills including a Good Clinical Practice training, Community Health Workers in Clinical Research Training
- Stay updated on program content, assessment techniques, and technology to provide effective participant support.





Overview of Community Health Representative (CHR) Responsibilities

Referral to Community Partners (mental health/legal/housing)

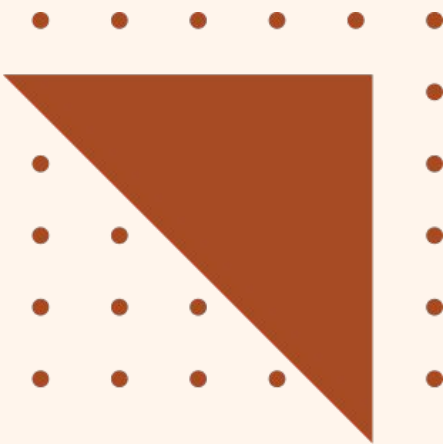
- Facilitate referrals to appropriate community partners for those in the IHRI arm
- Document progress made, outline next steps, and follow up consistently to ensure successful connections to needed services

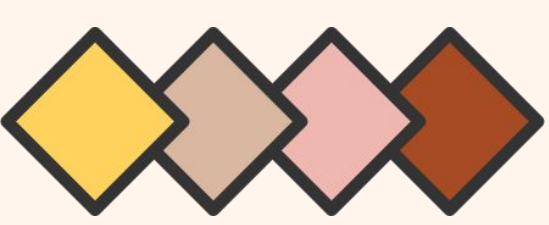
Team Collaboration:

- Share any participant feedback with IHRI team for continuous improvement.
- Maintain open and transparent communication with participants, research staff, and community partners

Community Harm Reduction Organization (CHRO) Collaboration:

- Work closely with our partnered CHRO's.
- Actively engage in collaborative efforts, seeking guidance and insights from the organization to enhance participant support.





Overview of Community Health Representative (CHR) Responsibilities

Data Privacy and Confidentiality:

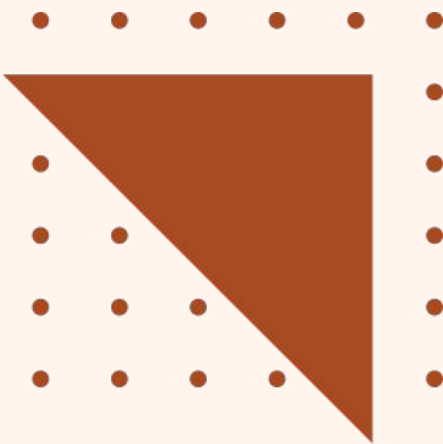
- Strictly adhere to data privacy and confidentiality.
- Handle all participant information securely and in compliance with relevant regulations.

Serious Adverse Event Reporting

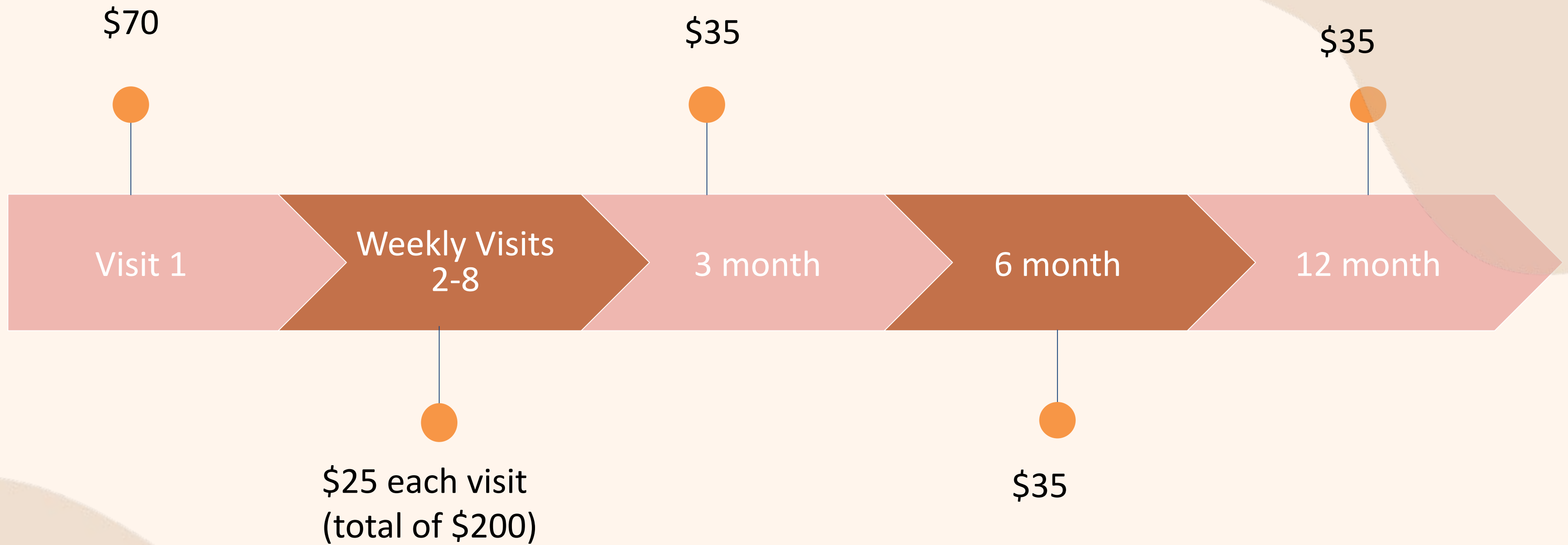
- Promptly document and report any serious adverse events (SAEs) that occur during the program to research staff.
- Ensure that SAEs are reported in a timely and accurate manner, following the established procedures to prioritize participant safety

Emergency Response and Crisis Management

- Follow established protocols for IHRI Project and CHROs for reporting and providing assistance.

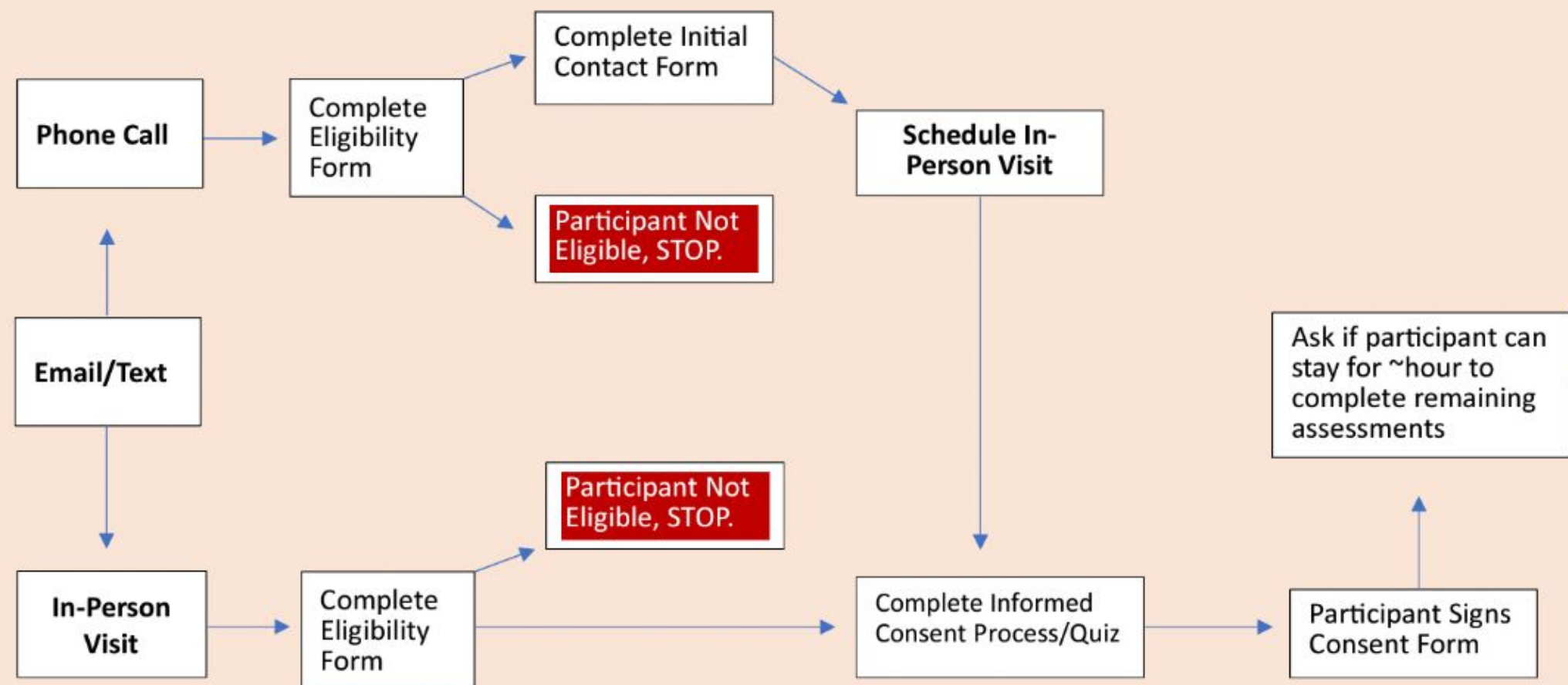


Participant Visit Timeline & Compensation

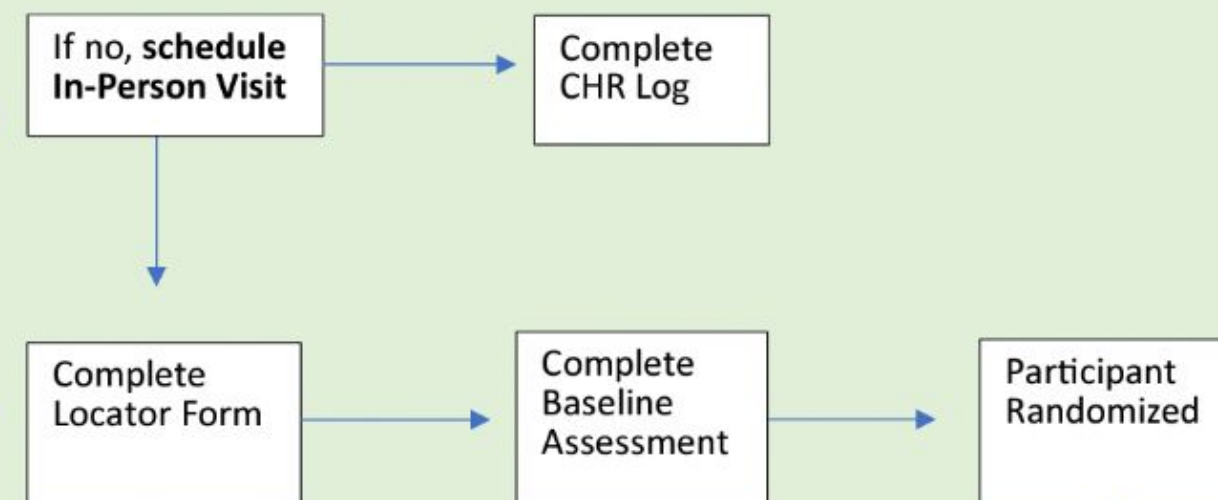


Total: Up to \$375

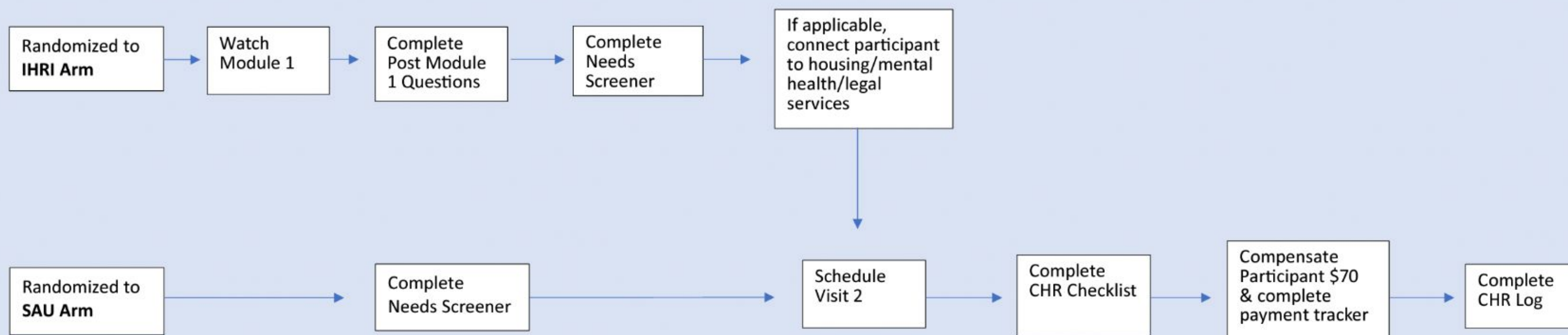
1. Screening & Informed Consent Process



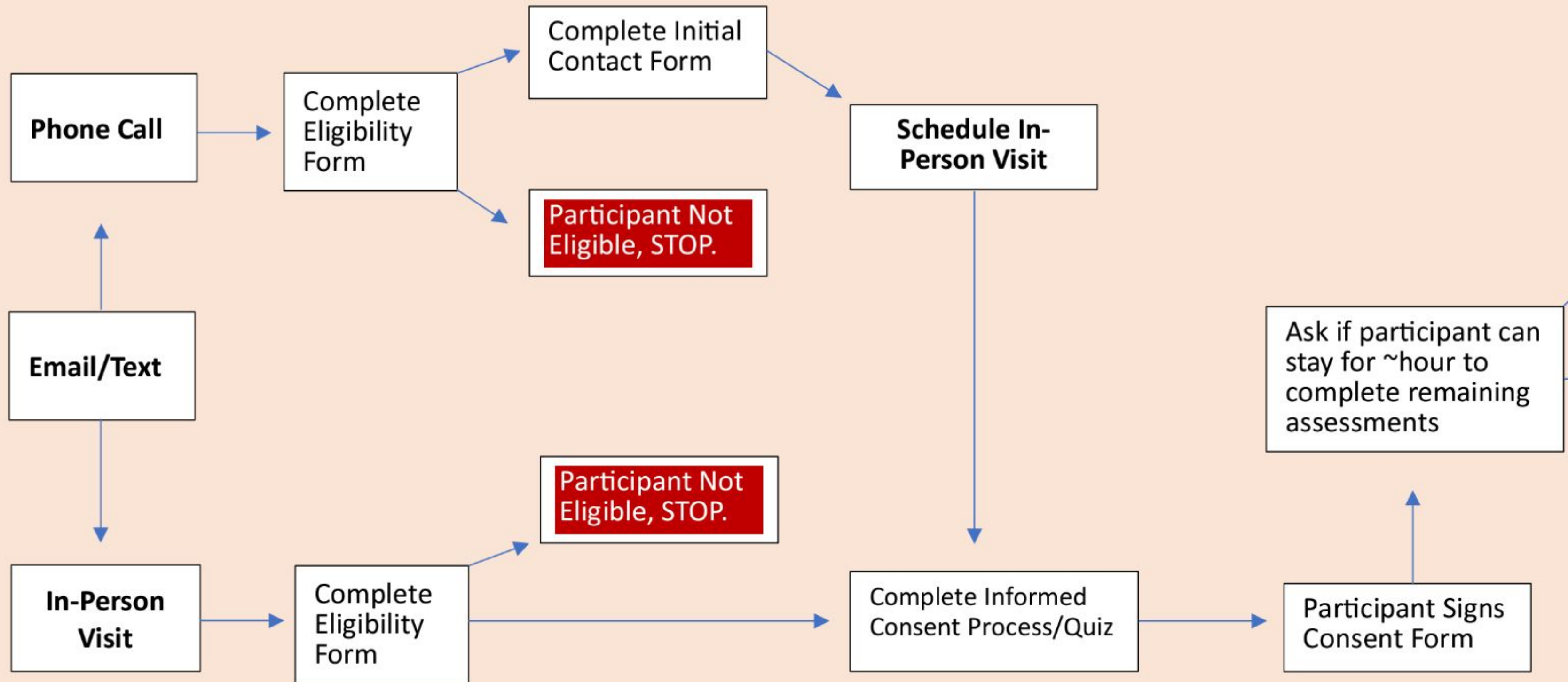
2. Pre-Randomization



3. Post-Randomization



1. Screening & Informed Consent Process



Email/Text Response Draft

Hello [Add Name]

I hope you're doing well. Thank you for your interest in the Harm Reduction Project. We would be delighted to provide you with more information.

To get started, we'd like to see if you are eligible to participate in the study. Please:

1. Give us a call at XXX-XXX-XXXX

2. Stop by our location at [ADDRESS] on [Add Available Days]

We would be happy to tell you more about the study or answer any questions you have.

I look forward to meeting you.

Kind regards,

[Your name]

Sample Script for Phone Call

Hi! This is [Your Name] at the Harm Reduction Project.

person on the other line allowed to speak

Great! I'm a community health representative for this project. Do you have a few minutes so I can share more about this research study and check if you're eligible?

- If not: No worries, I can call you back at a time that's more convenient for you. May I note a suitable time and day for our callback?
- If Yes: More about the study: The study is a randomized clinical trial from NYU School of Medicine to see whether connecting Black and Latinx people who use drugs with community resources and providing education on harm reduction can improve their outcomes. We're partnered with [St. Ann's Corner of Harm Reduction/SWAN in the [South Bronx/New Haven] where you'll be expected to attend weekly in-person visits for 8 weeks, with a follow-up visit at 3, 6, and 12 months. We will pay you for your time, and you could receive up to \$375 in cash, depending on how many visits you attend. Before we move on, I want to make sure that you're eligible for the study.

*** Complete the eligibility form***

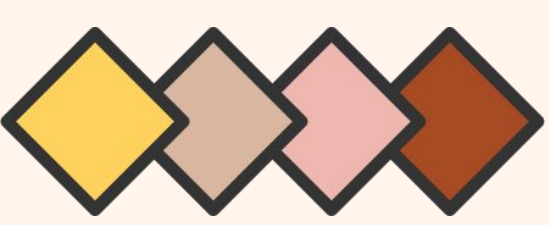
Thank you for answering our questions. It looks like you're eligible for the study! The next step is to set up a meeting in person. Before we pick a day and time, I'd like to collect your contact information.

Complete the Initial Contact Form

Lastly, I want to **schedule you in for our in-person visit**. During this time, I can answer any questions you have about the study, review and complete the consent form together, and complete an assessment. The entire visit should take about [two hours max], and you'll be compensated [\$70] for your time.

I have some open slots for [this or next week], on [Add CHR's availability] Could you please let me know which date and time works best for you, and we'll get that scheduled for you?

Ok great, you'll meet me at [Insert Address] on [repeat date and time]. I'll send you a text right now with this information and give you a reminder call the day before we meet. I look forward to meeting you! Feel free to reach out if you have any questions in the meantime.



Eligibility Form

Purpose - To see if interested individuals can participate in the study, determined by our inclusion and exclusion criteria:

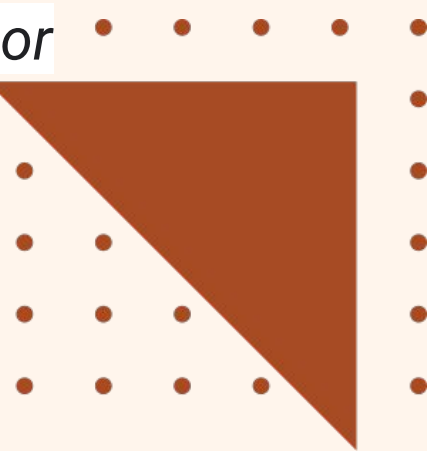
Inclusion Criteria:

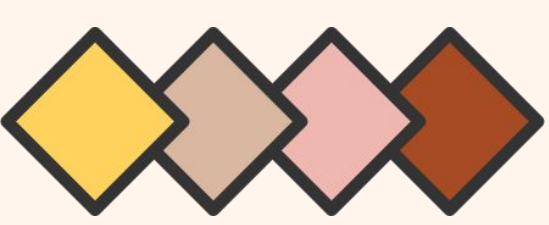
- (1) Be at least 18 years of age
- (2) self-identified as misusing opioids in the past 30 days, can be using other substances, confirmed by interview
- (3) English or Spanish speaking
- (4) able to provide informed consent.

Exclusion Criteria:

- (1) an inability to provide informed consent or participate in the study procedures as proposed in the consent
- (2) active suicidal or homicidal ideation or an **unstable psychotic disorder** (schizophrenia, schizoaffective disorder) or mood disorder with **psychotic features**
- (3) an unwillingness to be randomized.

Psychosis is when people lose some contact with reality. This might involve seeing or hearing things that other people cannot see or hear (hallucinations) and believing things that are not actually true (delusions).





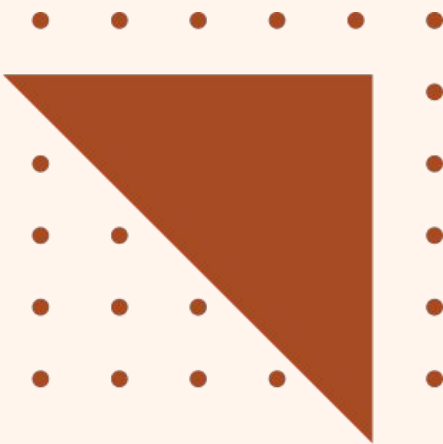
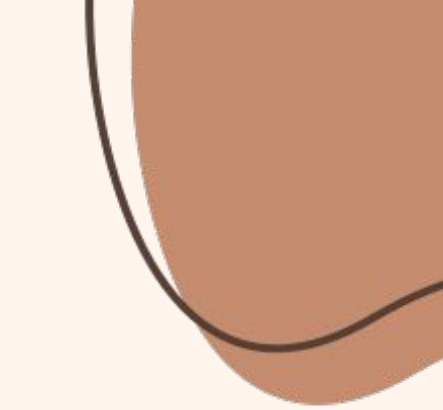
Initial Contact Form

Purpose - for collecting contact details from people who either cannot stay for the entire in-person visit or have called and need to be scheduled for an in person visit

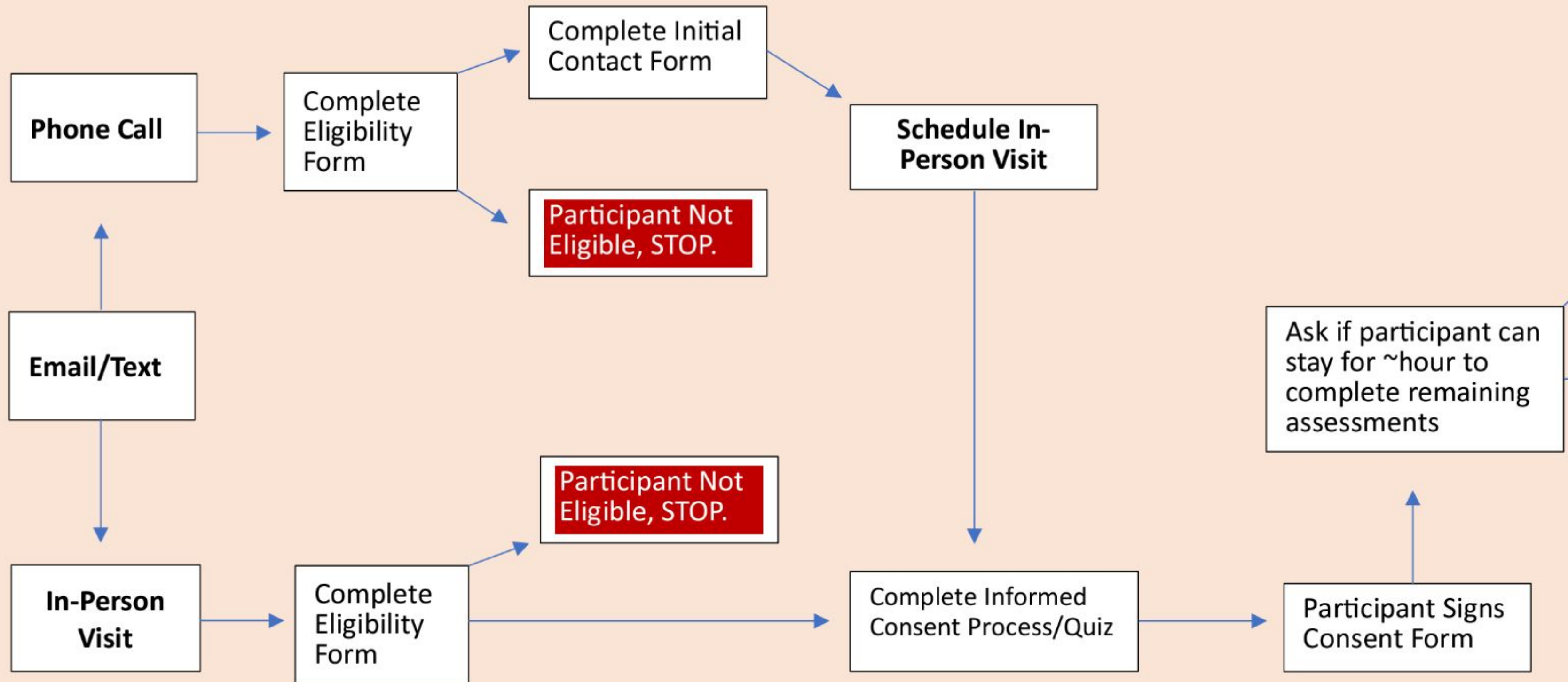
Confidentiality Assurance: The participant's information is treated with utmost confidentiality. If there's a need to locate them, the study's purpose and their involvement won't be disclosed.

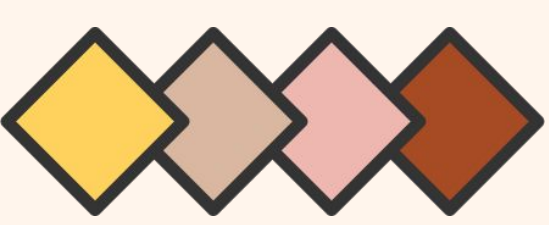
Information Requested:

- full name
- phone number
 - permission to leave a message and/or text
- preferred day/time to call
- preferred method of contact (text vs phone)
- email address
- next best phone number to reach you
 - permission to leave a message and/or text



1. Screening & Informed Consent Process

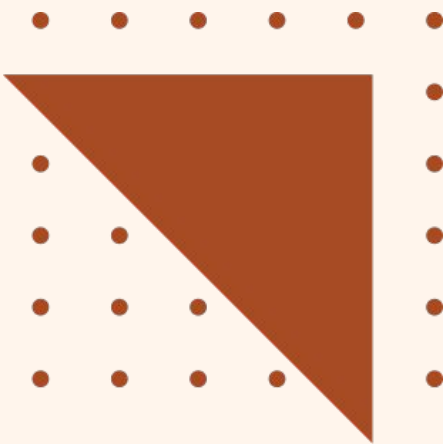


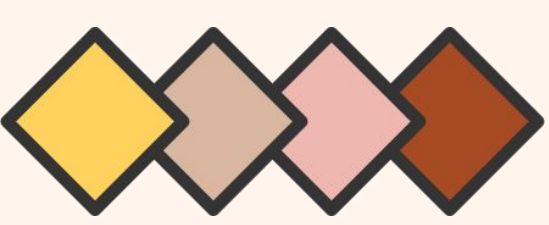


Informed Consent Process

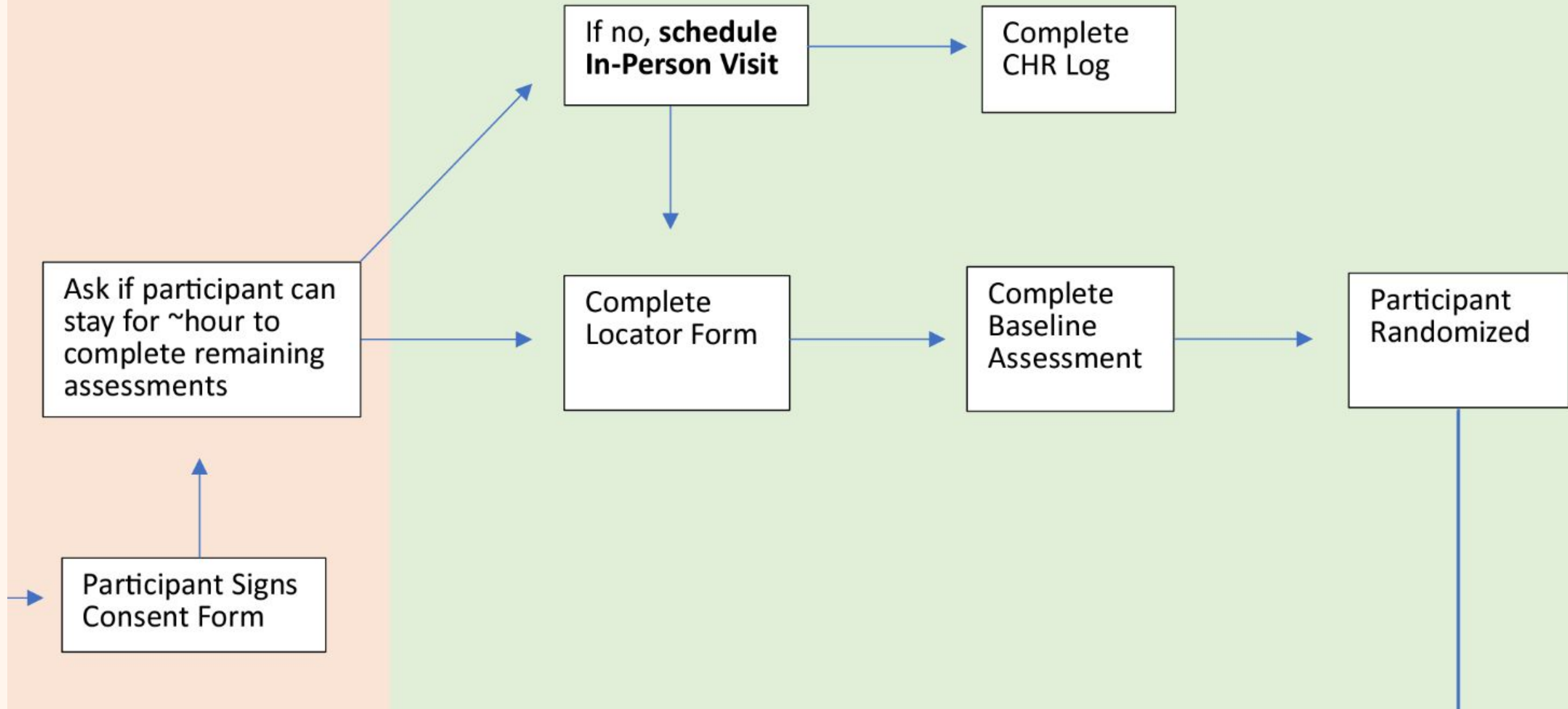
Purpose - Make sure participants understand the consent form. Involves explaining/reviewing the consent form with the participant, discussing potential risks and benefits in a way that matches their understanding. And emphasizing their rights and welfare as a participant. Our next training will cover this in more detail, along with dedicated time to practice.

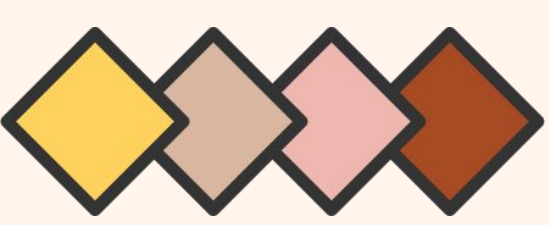
Consent Quiz assesses the participants' understanding of the informed consent process before they sign/consent to participate in the study. We'd aim for participants to score a 71% (5 out of 7 questions answered correctly). Incorrect answers will need to be explained to the participant.





2. Pre-Randomization

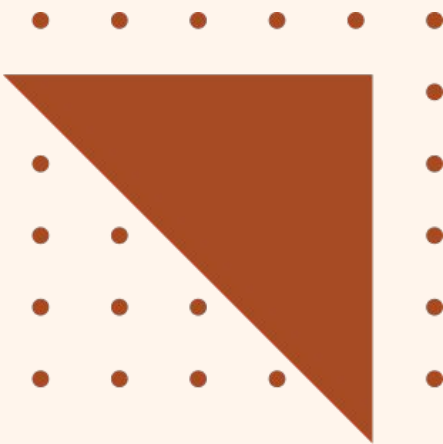
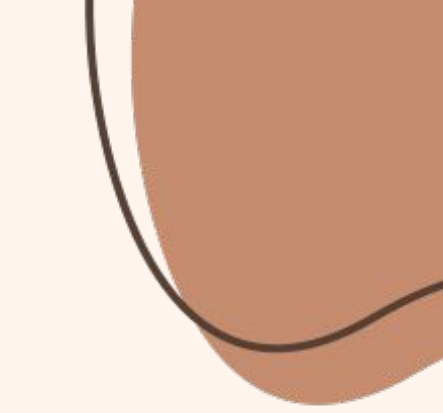


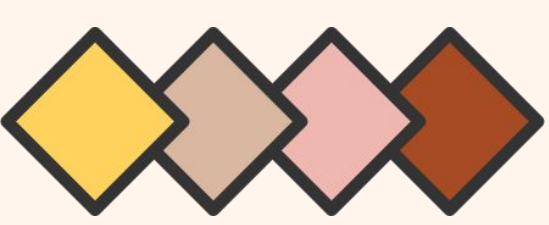


Locator Form

Purpose - for collecting contact details from participants to help locate/contact participants for visit reminders or in case they miss their scheduled visits

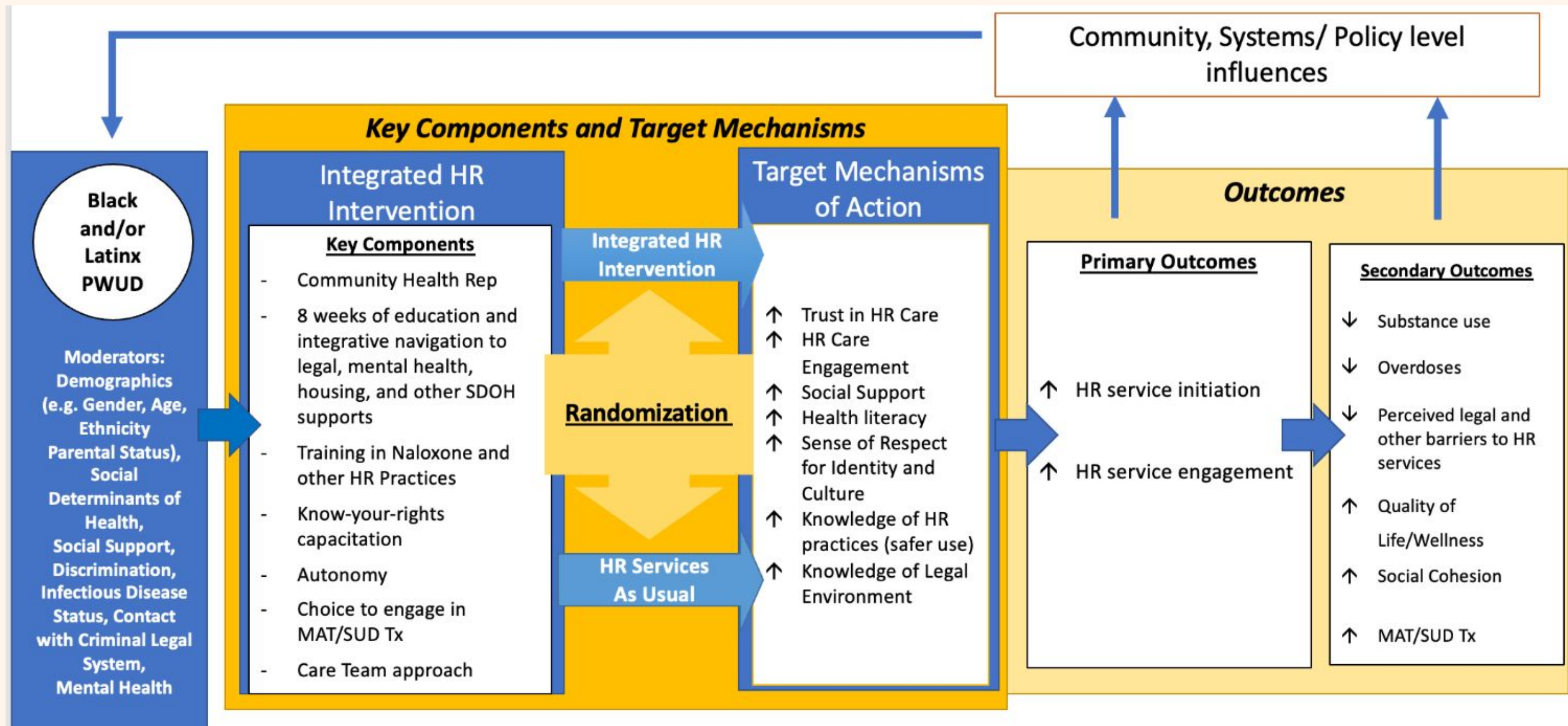
Confidentiality Assurance: The participant's information is treated with utmost confidentiality. If there's a need to locate them, the study's purpose and their involvement won't be disclosed.

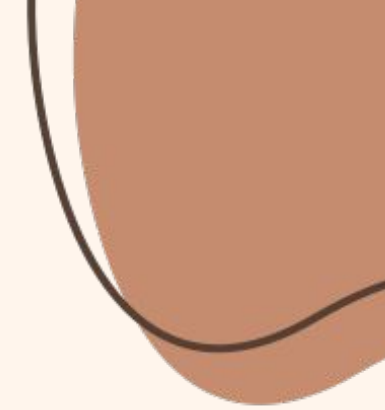
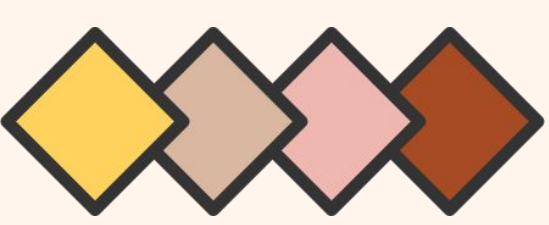




Baseline Assessment

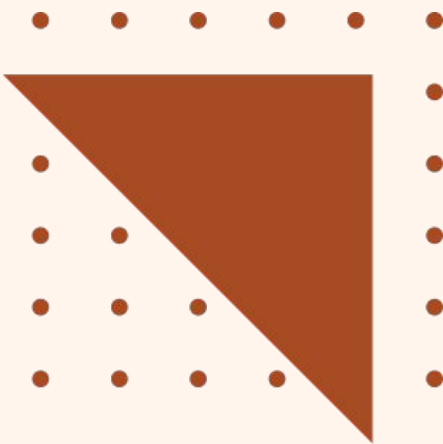
Purpose - Initial Measures taken before the intervention is applied, providing a starting point for comparison, helping researchers assess the effectiveness of the intervention over time.

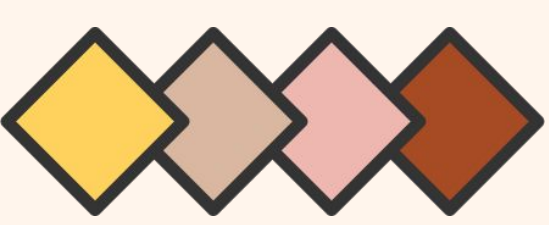




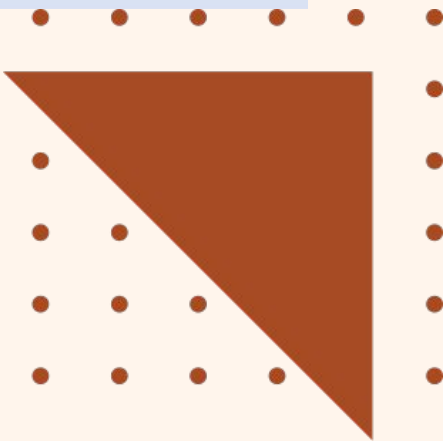
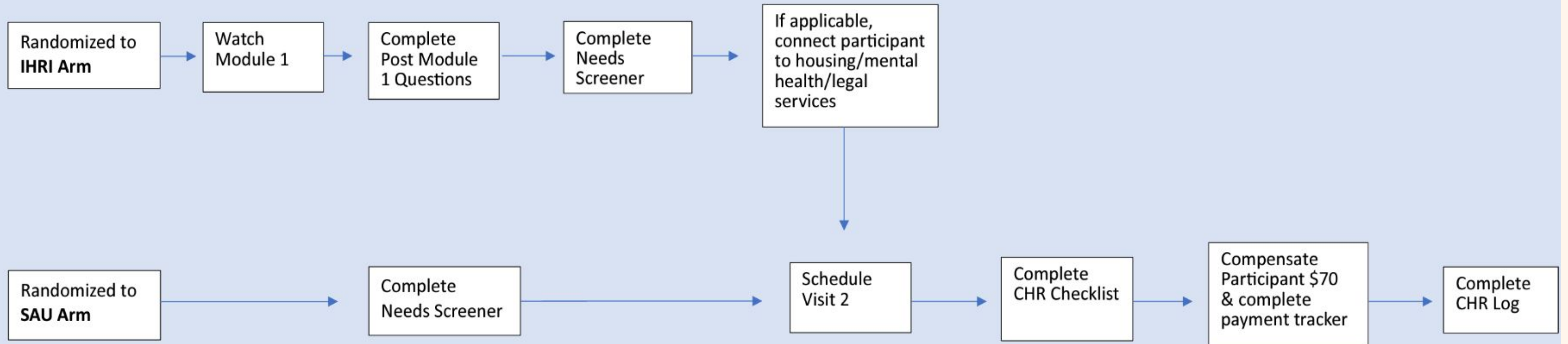
Randomization Form

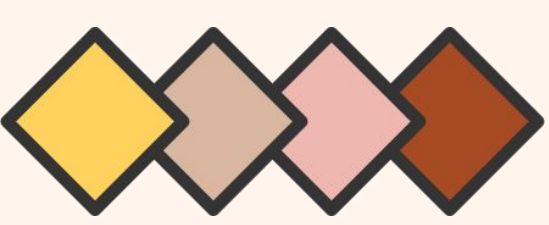
Purpose - Randomly assign participants to either the Integrated Harm Reduction Intervention (IHRI) or Services as Usual (SAU). An randomization program will be used to ensure balance across key variables such as age, gender, substance use chronicity, and substance use treatment history.





3. Post- Randomization





Needs Screener

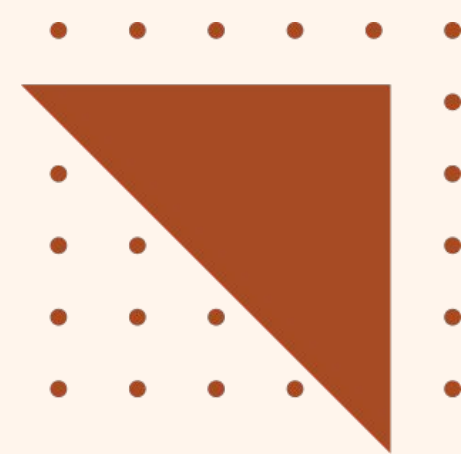
Purpose - understand the needs of participants. For IHRI group, this would help connect them to mental health, legal and housing and understand what their most urgent need is to help prioritize who to reach out to

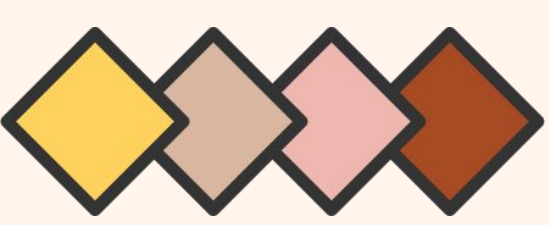
NY Community Partners

1. Mental Health - Samaritan Daytop Village
2. Housing - BronxWorks
3. Legal Aid - Bronx Defenders (legal navigators)
4. Community Harm Reduction Organization - SACHR

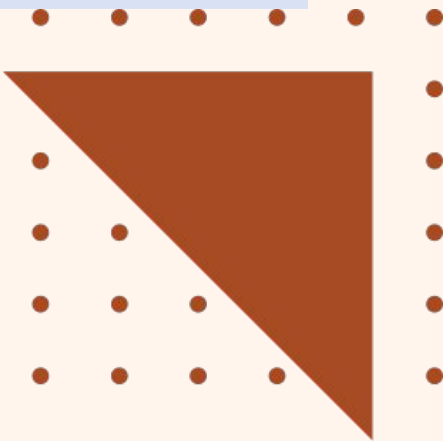
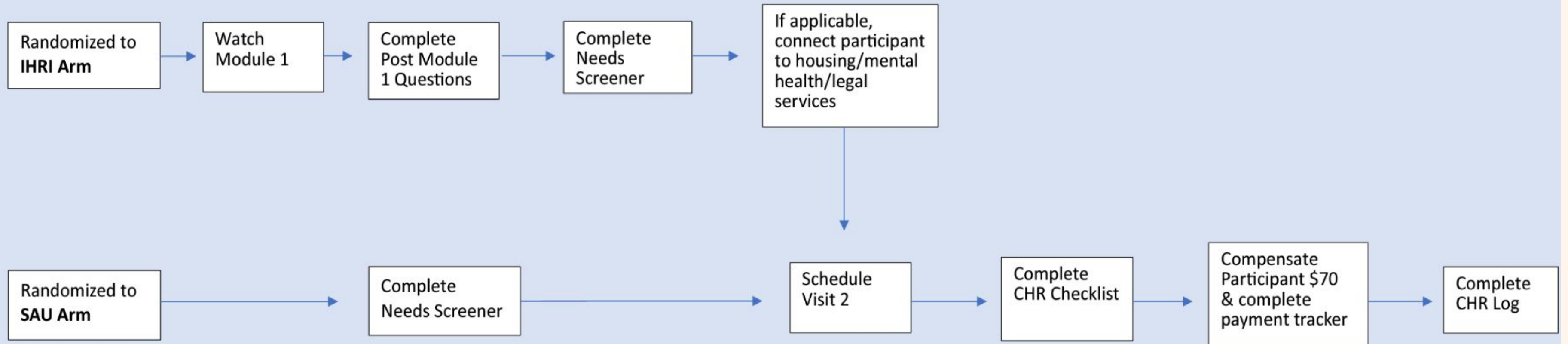
CT Community Partners

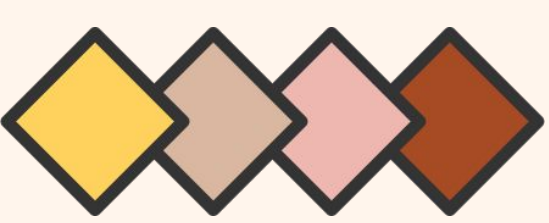
1. Mental Health Services - Continuum of Care Inc
2. Housing - Housing Program
3. Legal Aid - CT Public Defender Services
4. Community Harm Reduction Organization - CTHRA/SWAN





3. Post- Randomization



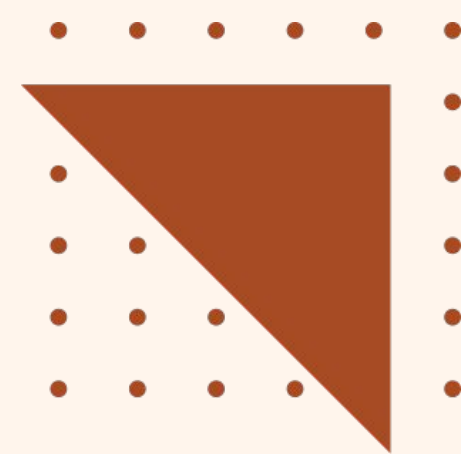


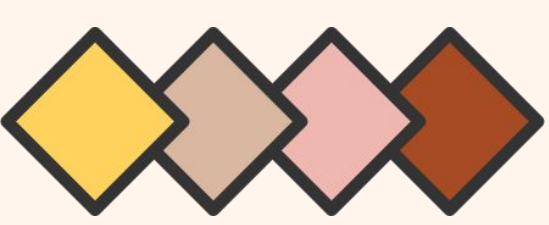
CHR Checklist

Purpose - Serves to organize tasks for each visit, ensure protocols are followed, facilitate communication within the team, promote consistency and quality throughout the research process while also serving as a helpful training and monitoring tool

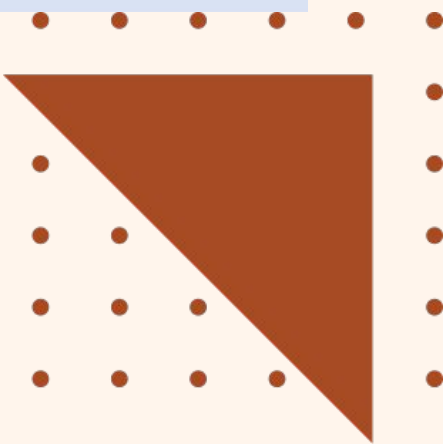
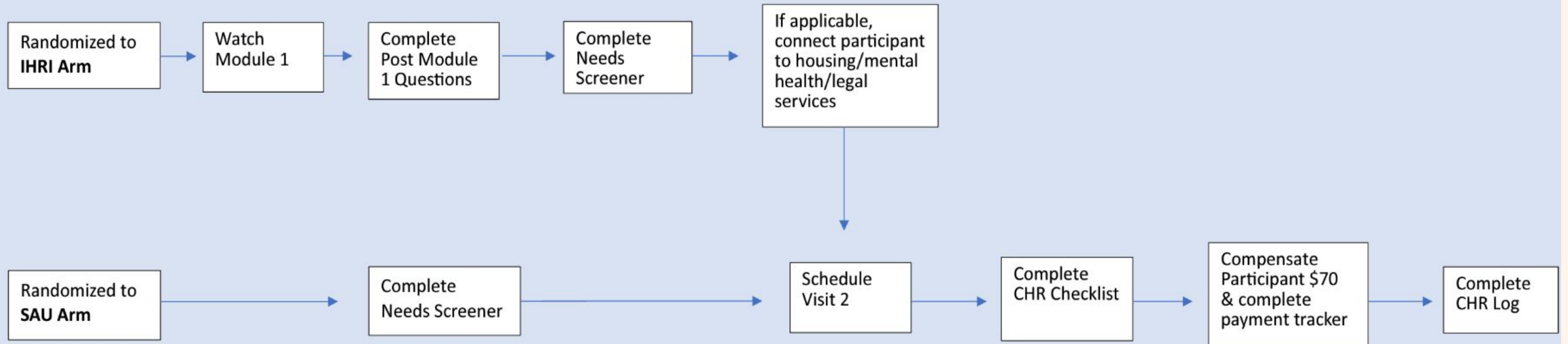
- Participant name:
- Participant assigned ID:

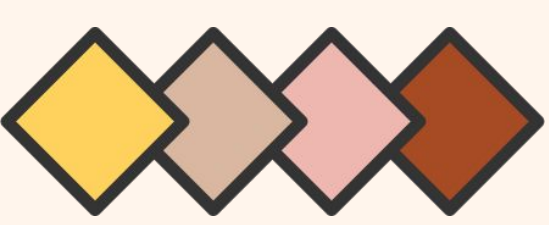
Task
Eligibility form completed. Yes/No
Eligible? Yes/No
Participant voluntarily signed the informed consent for the on ____ / ____ / _____
M M D D Y Y Y Y
Participant completed consent quiz <input type="radio"/> Yes <input checked="" type="radio"/> No
Participant consented prior to any study procedures being conducted <input type="radio"/> Yes <input checked="" type="radio"/> No
Locator form completed <input type="radio"/> Yes <input checked="" type="radio"/> No
Participant offered copy of Informed Consent <input type="radio"/> Yes <input checked="" type="radio"/> No
Baseline completed. Yes/No
Needs screener completed. Yes/No
Participant randomized <input type="radio"/> Yes <input checked="" type="radio"/> No
Group assignment: IHRI or SAU (select one)





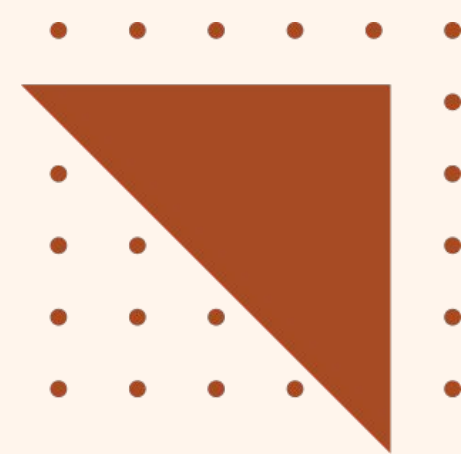
3. Post- Randomization





CHR Log

Purpose - To keep track of all interactions with participants. Covers contact type, referrals made, summary of the visit, next steps, and any serious adverse events



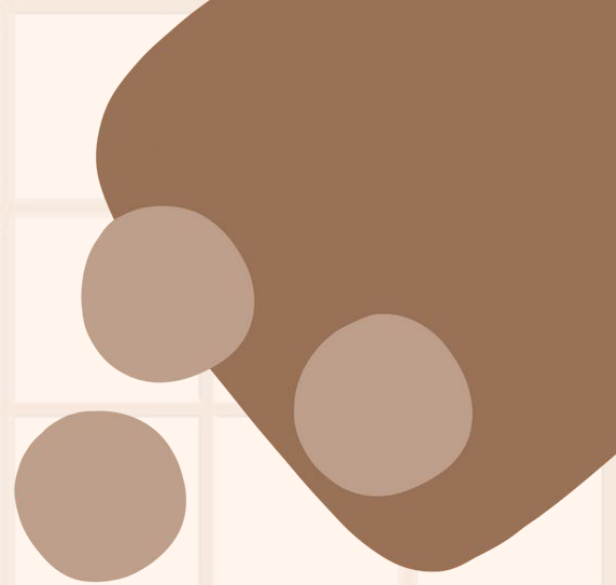
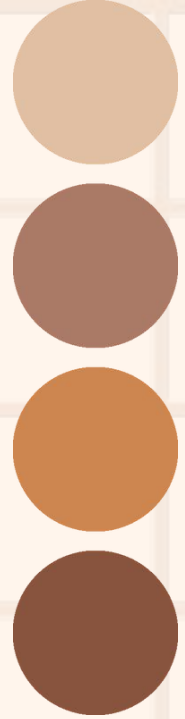


Q

A

**Question
Time**

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THANK YOU
SO MUCH!

