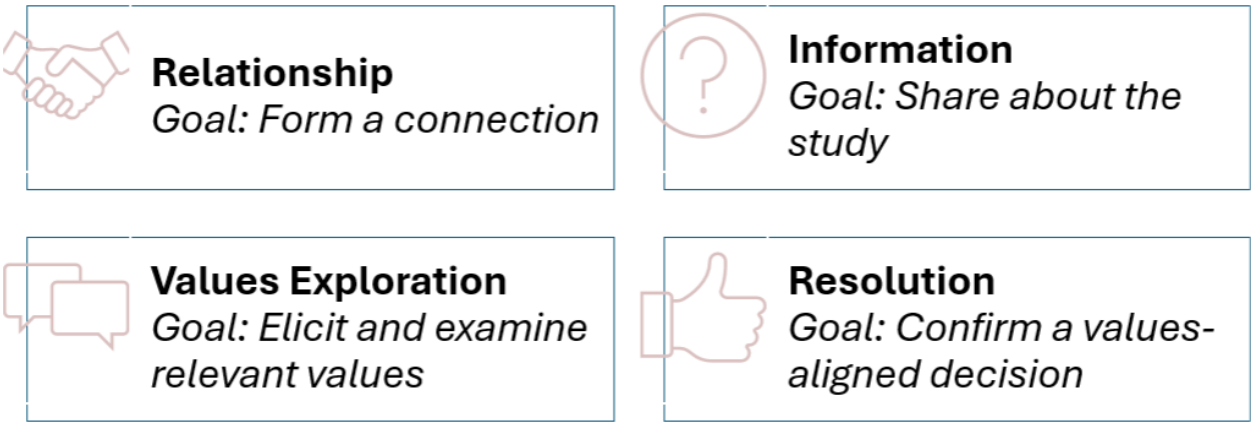
The ENVISION Approach:
A Participant-Centered Informed Consent Process

NED 2026

RIVER Communication Framework



Role Play 1

Study Information

- You are a clinical research coordinator enrolling participants in a clinical trial evaluating the efficacy of a new dual-medication inhaler for asthma.
- Participants are identified and approached following routine asthma clinic visits.
- Eligible participants will be asked to discontinue their current single-medication inhaler and begin the study inhaler.
- The study inhaler will be taken 2 puffs twice daily, every day, for 12 months.
- Every 3 months, participants will complete study surveys and undergo lung function testing.

Potential Participant Information

- Jordan is 20 years old and has a history of asthma. They have used a single-medication inhaler for several years. Jordan continues to experience some daily asthma symptoms, including cough and exercise intolerance, but has not had an asthma exacerbation in a few years.
- Jordan works for an outdoor equipment design company, travels internationally, and lives with their parents and younger siblings.
- Jordan has just finished a routine asthma clinic visit with their clinician. After the visit, you introduced Jordan to the clinical trial and reviewed the study overview and most of the detailed study information.
- Jordan is interested in the study and says they would like to contribute to medical research. But they are also hesitant because they have heard some bad things happening to people who participate in research and are worried about something harmful happening to them.

Instructions

- Choose one person to play the participant and one to play the coordinator
- The other two people should observe and be ready to give feedback
- Refer to the RIVER framework above
- Pick up the conversation by wrapping up the information sharing step, then starting with the values exploration step (7 minutes for role play)

Role Play 2

Study Information

- Your goal is to enroll patients in a qualitative research study to better understand the patient experience at a family medicine clinic
- A random sample of patients at the clinic will be invited to consider participating
- Participants enrolled will complete 3 virtual interviews over the course of one year
- The interviews explore participants' experiences and satisfaction with and perspectives on the quality and continuity of care they receive at this practice
- Data from the interviews will be de-identified and participant responses will not impact the care they receive

Potential Participant Information

- Cameron is 25 years old and attends community college. They recently moved into an apartment with a roommate. They work as a nanny and enjoy online gaming.
- Cameron has received medical care at the same family medicine practice for the past 10 years.
- You spoke with Cameron earlier today and reviewed the overview and detailed information with Cameron. Cameron didn't say much during the conversation, so you offered to continue the discussion later.
- You are now meeting Cameron again, with the goal of exploring values and coming to a resolution. Cameron doesn't know much about research and doesn't know what questions to ask before deciding whether to participate

Instructions

- Choose one person to play the participant and one to play the coordinator
- The other two people should observe and be ready to give feedback
- Refer to the RIVER framework above
- Pick up the conversation with the goal of coming to a resolution (7 minutes to role play)