Should I have an Elective Induction?
The SELECTION study
Aim 3 Pilot Trial

Sponsored by:
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Single Site IRB Approval:
USF- Responsible IRB
OSU- Relying IRB
USF STUDY004944
Initial approval 12/16/2022
OSU site approval 2/14/23
Modification #1 approved 3/10/23: Updates to study documents/questionnaires and remuneration plan prior to recruitment start
Modification #2 approved 3/13/23: Correction to error in footer of consent prior to recruitment start
Modification #3 approved 4/17/23: Modification to widen the gestational age for recruitment to 30-38 weeks gestation to accommodate obstetric appointment cadence. No change to study procedures.
Modification #4 approved 5/16/23: Increase allowed consent/enrollment to up to 45 participants per site in order to ensure 60 participants complete the initial study visit as planned

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STUDY TEAM ROSTER

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PERSONNEL AND DUTIES

Contact Principal Investigator/Principal Investigator (PI)

The PIs are experienced in all aspects of the design, conduct and oversight of randomized controlled trials and prospective studies at multiple clinical sites and is an expert in the fields of medical decision-making, decision-assisting tool creation and evaluation. The Contact PI will take a lead role in all aspects of the proposed project, working with the Pi and site PI and staff members to ensure timely and accurate completion of the project. The Contact PI will direct day-to-day activities and provide overall governance and scientific leadership to the study.

Site Principal Investigator (site PI)

The site PI will meet as needed to contribute to the overall study design and ensure each site is executing the study as prescribed. The Site PI is responsible for hiring and training site staff and will provide clinical and research expertise in the design and implementation of study instruments and protocols. The Site PI will monitor study enrollment and troubleshoot any recruitment issues as needed. They will also assist with chart review for participant delivery outcomes as needed.

Research Coordinators/Managers

The Research Managers and Coordinators (RCs) are the primary administrative points of contact for the study. They will prepare and submit all materials for IRB approval including the initial application, renewals, and all modifications. They will pilot and fine-tune study instruments; screen, consent, and interview participants; abstract medical data from charts; and distribute participant remuneration. They will be responsible for following the guidelines for study operations outlined in this protocol and will email the Contact PI in the event of any protocol violations (e.g., erroneous inclusion of subjects in the study, breach of confidentiality). They will participate in conference calls as needed to go over recruitment and data collection activities and targets.

1.0 Study Summary

Study Title	Should I have an Elective Induction? The SELECTION Study
Study Design	Single arm pilot study of feasibility and acceptability of a decision support tool (DST) for elective induction of labor (IOL).
Primary Objective/Purpose	The goal of the proposed study is to perform a pilot test of a patient-centered DST to help women and providers work together in making informed, shared decisions regarding whether or not to opt for elective IOL at 39 weeks gestation
Secondary Objective(s)/Purposes	This study will provide the information needed to plan a randomized trial of the DST for support of the equitable offer of induction of labor.
Research Intervention(s)	Exposure to the decision support tool
ClinicalTrials.gov NCT #	NCT05838313
Study Population	Nulliparous people with singleton, vertex pregnancies at 36-38 weeks who are planning vaginal delivery and do not have a medical indication for induction of labor
Sample Size	60
Study Duration for individual subjects	Approximately 2 months
Study Specific Abbreviations/ Definitions	DST: decision support tool IOL: induction of labor CD: cesarean delivery

2.0 Background and Objective

The ARRIVE trial, a large multicenter study published in 2018, compared expectant management to induction of labor at 39 weeks absent medical indication and found that induction was associated with a decrease in CDs, preeclampsia/gestational hypertension, as well as in the need for neonatal respiratory support, without a statistically significant difference in adverse perinatal outcomes. Subsequently, both the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) issued statements that it was reasonable to offer elective induction of labor to low risk, nulliparous pregnant people (the population studied in the trial and the population who will be eligible for the current study). A study based on birth certificate data published in 2022 showed that the offer of elective induction of labor has been integrated into clinical practice. However, how, when, and to whom this option is offered is unclear. While the improvement in maternal and neonatal outcomes observed in this trial are compelling, little is known about how patients and providers view the routine offer of elective IOL at 39 weeks, which is a significant change in practice. Ultimately, the goal of this study is to support the equitable offer of elective induction of labor to all eligible people, and to support pregnant people in making an informed choice that is concordant with their values.

Cesarean delivery (CD) is the most common inpatient surgery in the US, accounting for nearly one third of births annually. Reducing the CD rate has been targeted as an important public health goal; however, achieving this goal has proven challenging. In parallel, delivery at 39 weeks has been suggested as optimal for the neonate, but controversy about the relationship between induction of labor (IOL) and CD has limited enthusiasm for utilizing IOL as a means of achieving delivery at this gestational age. Finally, the appropriateness of the intervening in pregnancy without a clear medical indication is highly controversial. Given the current professional American College of Obstetricians and Gynecologists (ACOG) guidance that: “Based on the findings demonstrated in this trial (ARRIVE), it is reasonable for obstetricians and health-care facilities to offer elective induction of labor to low-risk nulliparous women at 39 weeks gestation.”, potential complexity of discussions about elective IOL at 39 weeks and the significant population of women who likely will be presented with this option, a decision support tool (DST) may help to improve the efficiency of shared decision making and ensure incorporation of informed patient preferences around this offer. <u>The goal of the proposed study to conduct a pilot study of the impact, feasibility, and acceptability of a prototype decision support tool for elective induction of labor.</u>

3.0 Study Design and Hypotheses

This is a single arm prospective clinical trial to collect pilot data for planning a future study of the impact of the Elective IOL DST, the intervention of interest, on induction rates, cesarean delivery rates, decision quality and resource use. The primary goal of this pilot is to determine the acceptability of the Elective IOL DST, to assess the feasibility of recruiting and retaining study participants in anticipation of future effectiveness and implementation studies, and to finalize outcome and other measures. The descriptive analyses planned include cross-sectional analyses, which will consist of profiles of the sample, including examination of means and proportions, measures of variability, and confidence intervals around these statistics. We also will investigate relationships within and between measurement domains (e.g.

demographics, outcomes), although these will only be exploratory in nature. In addition, we will describe the trajectories of participant responses across time.

As a pilot study, there are no hypotheses to be tested; therefore formal sample size calculations are not appropriate.

4.0 Study Intervention

The Elective Induction of labor decision support tool is viewed on a tablet, phone, or computer. It includes information regarding induction of labor, the potential benefits and risks of induction and expectant management, as well as values clarification questions to help people to think through what matters most to people as they consider their decision. In this single arm pilot trial, all participants will view the decision support tool.

The current project is the third part of a three-part study funded by the NIH. The overall goal of the project is to develop a patient-centered decision support tool to help women and providers work together in making informed, shared, values concordant decisions regarding whether or not to opt for elective IOL at 39 weeks gestation.

We have continued to improve upon the process that our group has used to develop other patient-centered prenatal care-related DSTs, which have been tested in NIH-funded, multicenter, randomized clinical trials among English- or Spanish-speaking pregnant women (R01HD078748, R01HD04968). The design process we have used to develop our DSTs follows the standards put forward by the International Patient Decision Aids Standards (IPDAS) Collaboration, using a systematic development process based on the IPDAS quality checklist. We utilize a patient-centered approach, which always begins by examining the needs, desires, and behaviors of the target population. We rely on published, validated literature for the information included in the decision support tools and utilize an iterative process to obtain input from patients and health care providers regarding their views on informational and decision-support needs. Using this patient-centered design approach, our designers work with researchers, providers, and patients to leverage the expertise of all parties in ways that exceed standard expectations for the engagement of these parties in research. This approach allows us to better connect with the people who are the center of our research, and enables quick and effective transformation of data into actionable ideas/tools.

In developing this tool, we began by conducting formative research to gain an understanding of how women and providers view the potential offer of elective induction of labor at 39 weeks gestation. We interviewed pregnant and postpartum women, to determine what they know and feel about elective IOL at 39 weeks and how they would view being presented with a choice between this intervention versus expectant management. We also interviewed providers (obstetricians, midwives, prenatal nurses and labor and delivery nurses) to obtain their thoughts on elective IOL at 39 weeks, how they view the latest data on its role, and how comfortable they would feel offering this option to their patients. We transcribed and coded these interviews and continued interviews until thematic saturation was reached. Based on our findings and the published literature and professional guidance regarding elective induction of labor, we created the prototype patient-centered DST. The DST begins with the statement “Your health care providers can tell you a lot about these two approaches and the advantages of each, but YOU are the expert about what is important to you” and aims to

present balanced information to support the user in making an informed, values concordant choice between the two options. It presents information on elective IOL at 39 weeks versus expectant management, including information regarding the processes and potential outcomes of each approach to delivery, and incorporating values clarification exercises as well as a summary statement that women can use in discussing this option with their providers. We then pretested the tool in pregnant and postpartum women and reviewed it with providers to obtain their feedback on the content and presentation, iteratively using that process to improve the prototype.

4.0 Study Population

Inclusion and Exclusion Criteria

This study will include 60 pregnant people at two sites. Eligibility criteria will include nulliparity, singleton pregnancy, no contraindication to vaginal delivery, no medical indication for IOL, age 18 years or older and an ability to speak English (as study materials are only available in English at this time). Exclusion criteria will include people not planning a vaginal delivery, eople who have had a baby in the past*, p*eople with a medical indication for induction of labor at the time of enrollment, people younger than 18

Participant Withdrawal

People who experience a pregnancy loss (stillbirth) will not be contacted for any additional study visits. This is expected to be an extremely rare event in this low risk population. People may also request to be withdrawn from the study if they no longer want to participate.

5.0 Recruitment

Each site will utilize the same recruitment methods that we have used successfully in prior studies of pregnant people. We will ensure that all necessary human subjects' reviews and approvals are obtained prior to implementation at any recruitment site.

Potentially eligible participants will be identified by reviewing outpatient charts to identify pregnant people who meet the eligibility criteria. At all sites, both academic and "private" practices are associated with an academic health system, and as such, with IRB approval, study staff is able to remain HIPAA-compliant when they pre-screen patients.

At USF, eligible people will receive a letter describing the study, signed by a leadership representative of their OB practice (as many patients do not have a single provider they see for prenatal care, but rather see a team of providers). A stamped return "opt in/out" card will be included, which the recipients can return to indicate that they are either interested or not interested in hearing from the study staff. The site-specific interviewer's telephone number also will be included for each recipient's use if they prefer to use this method of communication. Respondents who check "opt in" will be called/contacted by the method they state they prefer. Those who opt out will not be contacted. A study staff member will come to a subsequent visit at which time the clinical staff will ask the participant if they would be willing to discuss the study and assess their eligibility and interest in participating. The "opt out" mechanism has been shown to yield a more diverse group of participants than the "opt in" approach, and, in our many studies of diverse populations, has been highly effective in recruiting participants for

studies that require conducting face-to-face interviews with pregnant people at specific gestational ages.

At OSU, eligible people will receive a brochure detailing the study. Those who are eligible and interested will be contacted to set up an enrollment interview.

Participants will be identified starting at 32-34 weeks with the goal of scheduling the initial study visit between 36+0 and 38+0 weeks gestation to allow time to view and consider the information in the decision tool prior to making a decision regarding whether to proceed with an elective induction at 39+0 to 39+6 weeks gestation.

5.0 Study Procedures

The procedures and/or interventions conducted as part of this research are low risk, educational interventions. Elective induction, or induction of labor absent medical indication is an evidence-based aspect of routine pregnancy care that has been endorsed by the OBGYN professional society guidelines as being reasonable to offer since 2018. In clinical practice, the way that this option is offered is currently highly variable and driven by the provider rather than by the patient's preferences and goals. The intervention in this study will be the viewing of standardized information about elective induction of labor prior to making their decision about this option with their provider. Questionnaires will be utilized to understand the impact of the educational intervention on decision quality and the feasibility and acceptability of the intervention.

We will prospectively enroll 60 nulliparous people (approximately 30 at USF and 30 at the Ohio State University) planning vaginal delivery with singleton, vertex pregnancies at 36-38 weeks who do not have a medical indication for IOL to view the DST. During their enrollment face-to-face interview, they will review the DST and complete pre- and post-DST viewing questionnaires. We will conduct telephone interviews a few days later but before 39+0 weeks, and again 2-4 weeks postpartum. During these interviews, we will collect information on the acceptability of the tool and decision quality. We also will include an open-ended question in the postpartum interview to obtain feedback on topics and information the participants wish had been included in the DST.

At the time of enrollment, written informed consent will be obtained by the study research coordinator. The consent form will include information about the purpose of the study, the nature of the subject's participation, the possible risks and discomforts associated with participation, the potential benefits of participation, a statement of the voluntary nature of participation, and a description of the mechanisms used to ensure confidentiality. A study eligibility checklist will be completed prior to any study procedures. Parental consent will be obtained to review the medical records of the infants. Assent is not appropriate given the clinical scenario (review of infant medical records).

- Participation will consist of one face-to-face enrollment interview and two follow-up telephone interviews, along with permission to access the patient's medical chart. Patient-reported data will be collected at 4 time points: at the beginning of the enrollment interview, prior to DST viewing (T1); at the conclusion of that interview, post DST viewing (T2); during a telephone interview at 38-39 weeks gestation, by which time

the decision to undergo or forego elective IOL at 39 weeks will have – or will be close to having been made (T3); and during second telephone interview 2-4 weeks postpartum (T4).

- Participants will initially view the DST on a tablet during the enrollment interview. At the conclusion of the interview, they will be provided with a unique link so that they can revisit the DST content from their personal phone, tablet, or computer if desired.
- During the enrollment interview (T1), we will administer a sociodemographic questionnaire and assess the participant's health literacy level using the Newest Vital Sign (NVS) measure. We also will ask a series of questions related to her inclination to undergo elective IOL at 39 weeks, her attitudes and beliefs about this intervention, her desire for shared decision making in this context, and her feedback regarding the decision tool.
- Attitudes and beliefs (T1, T2, and T3) will be assessed by presenting a series of statements for which participants will be asked to indicate the extent to which they agree or disagree. To measure decisional conflict (T2 and T3), we will use O'Connor's Decisional Conflict Scale, a measure that assesses patients' uncertainty in making a health-related decision, factors that contribute to this uncertainty; and whether they feel their decision making was effective). To measure DST satisfaction (T2, T3, and 2-4 weeks postpartum (T4)), we will use an adapted version of a 3-item intervention-satisfaction scale that we have previously used based on a measure developed by Barry et al. We will use the SDM-9 to measure shared decision making (T3 and T4). During T4, we also will administer the 6-item Birth Satisfaction Scale-Revised Indicator (BSS-RI), which measures stress and emotional response to labor and birth, as well as the Labor Agentry Scale, which measures expectations and experiences of personal control during childbirth and was one of the outcomes measured in the ARRIVE trial. We will include an open-ended question asking what else, if anything, the pregnant person would have wanted to know at the time she made her decision. Outcomes obtained via chart review after delivery will include uptake of elective IOL at 39 weeks, delivery mode undergone (vaginal or cesarean), hospital length of stay (prior to and after delivery), and clinical outcomes (gestational age at delivery, preeclampsia, gestational hypertension, and maternal and neonatal outcomes).
- During the initial face-to-face visit, we will ask participants their preferences for scheduling phone follow up interviews so we can streamline the process as much as possible. Follow up questionnaires can be completed independently via RedCap survey

T1: Prior to DST viewing	**T2: Post DST viewing**	**T3: 38-39 weeks gestation**	**T4:2-4 weeks postpartum**
• Sociodemographics, health literacy • IOL inclination • IOL attitudes • Desire for shared decision making • Provider preferences and social norms	• IOL inclination • IOL attitudes • Decisional conflict • DST impact and satisfaction	• IOL inclination • IOL attitudes • Desire for shared decision making • Provider preferences and social norms • Decisional conflict • Shared decision making • DST impact and satisfaction	• Shared decision making • DST impact and satisfaction • Birth Satisfaction Scale • Labor Agentry Scale • Things you wish you had known (open ended)

link; an appointment will be scheduled so that the participants can ask questions if needed. Clinical outcomes will be obtained via chart review after delivery.

- Subject Costs and Compensation: The face-to-face interview will take approximately one hour (participants will be remunerated with $40); telephone interviews will take 15 minutes ($20 each).

6.0 Risks and Protections against Risks

Risks or discomforts for the pregnant people are limited to those that might be incurred as a result of discussing sensitive or potentially troubling information as well as potential risks to confidentiality.

Some of the questions addressed by the proposed study are of a sensitive nature and require the subject to consider outcomes that they may find distressing (e.g., pregnancy complications). It is possible that these topics may induce anxiety among respondents. While this has not been a problem in our prior studies of potentially anxiety-provoking decision tools (including tools used by pregnant women that discuss the possibility that their fetus may be affected by a serious disorder or that they will experience a pregnancy loss and be unable to give birth in the future) it is important that we carefully consider how we will minimize the likelihood of this problem and how we will assist our participants if their participation does result in some anxiety.

First, all participants will be informed, prior to participation, that they are free to terminate their participation at any time or to decline to answer any questions or participate in any part of the study. During the consent process, we will ensure that the participant understands this principle and they feel free to exercise their option at any time. Participants will have access to their obstetric providers to discuss their concerns as well as to the clinician investigators at each site.

Additionally, participants will be informed that if they develop any feelings of anxiety at any time during their participation, they should contact the study team (they will be provided with an access number). These participants will be contacted within 24 hours by one of the study clinician-investigators. All of these clinicians have extensive clinical experience and are highly skilled in dealing with patients who develop anxiety during their medical care. They are available at any time via their hospital on call system. The responding physician will contact the participant and discuss their clinical situation. If necessary, the physician will meet with the participant in person at their clinical office or the office of the participant's primary obstetric provider (wherever the participant feels most comfortable).

If a participant's symptoms require more intensive intervention, this will be arranged by the clinician-investigator to ensure that the participant will receive all necessary care to address whatever symptoms might occur. The physician-investigator who becomes involved with any participant over any anxiety symptoms will continue to monitor the patient (either by phone or in person) until all symptoms have abated.

Each contact will be reported and tracked as an adverse outcome.

In sum, we have an extensive support infrastructure for the management of mental health issues that arise in the course of study participation. As noted, we have conducted similar studies in the past and have not had problems with anxiety, but we are fully prepared to deal with this possibility at any time should it occur.

Undue influence will be minimized by emphasizing the voluntary nature of the study in all recruitment materials and personal communications. Participants also have the alternative not to participate in the study. Non-participation will not affect clinical care. Participants will be consistently reminded that responses to any queries deemed sensitive or uncomfortable (e.g. country of origin/ immigration status, income, previous history of abortion) should be considered optional, and they may decline to answer any question(s) and can refuse to continue the study at any point. Participants also will be reassured that neither their opportunities for continued health care nor their relationships with health care providers will be jeopardized by study participation.

7.0 Data Management and Confidentiality

We will take extensive precautions to maintain participant confidentiality throughout the study. First, lists of individuals who will be participating will be kept in a locked drawer and in password protected computer files in the office of the study coordinator at each site. Used consent forms will also be locked in a filing cabinet in the office of the study coordinator. Confidentiality of all study-related records will be maintained in accordance with State and Federal laws.

Three databases will be maintained for the study: 1 and 2) Site specific "participant tracking" databases will contain all identifying information that will permit locating participants for their interviews, ensuring that interviews are completed on time, and performing chart reviews. It will include demographic information for all patients who do not meet the eligibility criteria or who decline participation, along with their reasons for refusal (to permit comparisons between those who do and do not enter the study). 2) A single"study data" database will contain all project-related data used for the analyses. Participants will be identified only by a code number in the study database.

Obstetric clinic schedules will be reviewed to screen for eligibility, so that only subjects meeting eligibility criteria will be approached. We will keep the minimum information necessary (Name, MR#, appointment date and time) in the recruitment database so that we know who has an appointment and can make sure recruitment materials are available when they are in clinic. People who decline will be marked as declining so that they are not approached again. Records reviewed will only be from people who are actively receiving prenatal care and scheduled for appointments within the 4 weeks prior to the timeline for the study. Only study staff will have access to the RedCap database. Because we can only identify eligible patients based on medical record review, it is not practical to obtain consent prior to the approach. Identifiers will be removed within 6 months and only information needed to inform the CONSORT diagram will be maintained.

Only the PI and a limited number of study personnel will have access to identified information which will be encrypted and stored on a secure server. As in our previous studies, only code numbers will be used and no individual identities will be retained in the analysis or publications. Data confidentiality will be ensured by using only a coded participant acrostic and code number to identify respondents on the data-collection forms. All data will be entered into RedCap database that will have logic, range, and error checking, and will be kept on an encrypted, security enabled network. Only researchers involved with the study will have full access to subject identities. Datasets used for analysis will be de-identified. As per the USF

guidelines, records will be maintained for 5 years after the study is complete and at that time we will destroy records linking participants' names to study ID numbers. Participant identities will not be revealed in any publication that may result from the proposed study.

8.0 Potential Benefits to Subjects or Others

There is no definitive direct benefit to people participating in the study. However, we anticipate that the results we obtain will result in an elective induction DST that can be testing in a future study. In the future, this tool has the potential to enable pregnant women and their obstetric providers to engage in joint decision making buttressed by an evidence-based approach and to decrease the rate of cesarean delivery and maternal hypertensive complications of pregnancy in this country, without a negative impact on neonatal outcome. We believe that these potential benefits outweigh the minimal risks mentioned above.

Importance of the knowledge to be gained This study will evaluate an innovative decision support tool for women who are considering whether or not to proceed with elective induction. This tool will help women consider their preferences in the context their likelihood of vaginal delivery, along with the chances of other potential outcomes of this decision. If it is shown to have a positive impact on decision quality, we believe that the use of this tool would result in a more individualized, patient-centered approach to this emerging decision in obstetrics, resulting in improved decision quality, quality of care, concordance between patient and provider expectations, and health outcomes, including a reduction in the cesarean delivery rate and improvements in maternal and neonatal outcomes.

9.0 IRB approval, safety monitoring and adverse event reporting

IRB Approval

This is a single site IRB study; USF is the responsible IRB and there is a reliance agreement in place with OSU. The overall consent form as well as the OSU site specific addendum as well as all of the study materials have been reviewed as per the single site IRB protocol. Amendments or modifications will be reviewed by the USF IRB in accordance with the reliance agreement.

The Contact PI or RC will provide safety and progress reports to the IRBs at least annually and within three months of study termination or completion. These reports will include the total number of participants enrolled in the study, the number of participants who completed the study, all changes in the research activity, and all unanticipated problems involving risks to human subjects or others.

Informed Consent: Written informed consent will be obtained from each study participant prior to enrollment using an approved informed consent form in accordance with all applicable regulations. A copy of her signed informed consent form will be offered to the participant.

Safety Monitoring and Clinical Data Review

Research coordinators will report all participant complaints to the investigative team. These will be discussed during research team and investigator calls.

Each study site is responsible for continuous close monitoring and management of adverse events (AE) in accordance with the protocol for AE reporting. The study site PIs are responsible for the initial evaluation and reporting of safety information and for alerting the investigative team if unexpected concerns arise.

Reporting Requirements for this Study

The site PI or RC will report an adverse event to the local IRB and responsible IRB if study staff determines it may qualify as an Unanticipated Problem or Adverse Event because the event meets all three criteria listed below:

- Unanticipated in severity or frequency AND
- At least *possibly* related to the study intervention AND
- Is Serious OR not serious but suggests placing subjects or others at greater risk

In addition, all SAEs will be reported to the study team within 72 hours of recognition by study staff.

Use of Information and Publications: A description of this clinical trial will be available on http://www.ClinicalTrials.gov. Presentation and publication of the results of this study will be governed by guidelines determined by the study team and as necessary and appropriate by their associated institutions policies. Any presentation, abstract, or manuscript will be approved by the PIs prior to submission.

10.0 Analysis Plan

Statistical Design and Power

As a pilot study, there are no hypotheses to be tested; therefore formal sample size calculations are not appropriate.

This is a single arm prospective clinical trial to collect pilot data for planning a future study of the impact of the Elective IOL DST, the intervention of interest, on induction rates, cesarean delivery rates, decision quality and resource use. The primary goal of this pilot is to determine the acceptability of the Elective IOL DST, to assess the feasibility of recruiting and retaining study participants in anticipation of future effectiveness and implementation studies, and to finalize outcome and other measures. The descriptive analyses planned include cross-sectional analyses, which will consist of profiles of the sample, including examination of means and proportions, measures of variability, and confidence intervals around these statistics. We also will investigate relationships within and between measurement domains (e.g. demographics, outcomes), although these will only be exploratory in nature. In addition, we will describe the trajectories of participant responses across time.