PARTICIPANT PERSPECTIVES: INVESTIGATING THE EXPERIENCE OF LOW-INCOME SCHIZOPHRENICS IN CLINICAL RESEARCH TRIALS

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The continued investigation into the experiences of individuals with schizophrenia who participate in biomedical research trials is necessary in order to understand participants’ perspectives, motivations, attitudes, values, and beliefs. As important stakeholders in the clinical research process, participant feedback is significant and can help shed light on, not only their experiences, but also deepen understandings when it comes to clinical trial participants’ perceptions of informed consent and personal autonomy. Conducting ethical research demands the exploration of these issues and specifically targeting this vulnerable group helped to address a gap in the literature.

This study was conducted for InSite Clinical Research and gathered data in the form of in-depth semi-structured interviews and a short survey instrument with 20 low-income adults diagnosed with schizophrenia that participate in clinical research trials. Findings indicate overall positive research experiences, with motivations aligning with previous research when it comes to trial participation including: altruism, personal benefit, access to medications, financial incentives, and psychosocial treatment. Learning about their illness and themselves, autonomy, and debriefing were also particularly important within this group. Unique to this sample were findings of friendship. Trust in the research staff was identified as a major underlying value and shaping factor impacting informed consent decisions. These conclusions have implications for recruitment and informed consent practices at InSite Clinical Research.
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CHAPTER 1: INTRODUCTION

1. Research Site: InSite Clinical Research

InSite Clinical Research (INCR), founded in 2004 by Dr. Raj Shiwach, is located in DeSoto, Texas. INCR helps to serve the mental health needs within the community of DeSoto and the greater Dallas-Fort Worth metroplex through the conduction of clinical research trials. The core staff of InSite Clinical Research consists of eight small dedicated departments, including seven clinical research coordinators, one diagnostic and cognitive rater, one laboratory technician, a regulatory affairs officer, a quality assurance auditor (the student investigator), two study participant recruiters, two transportation drivers, and three as needed contracted workers. Together, this team, under the supervision of one principal investigator, work to fulfill INCR’s mission statement and purpose, “serving the community through research.” Through clinical research trials, INCR meets the needs of its two client bases, sponsors of the research and research participants themselves, while upholding federal standards and industry requirements, in accordance with Good Clinical Practice (GCP) (www.insitecr.com).

INCR is unique in that it is one of the only Central Nervous System (CNS) and psychiatric research facilities located in south Dallas. Another difference that situates INCR in a distinctive position from other research sites is that it is located in the same building as the private practice of Dr. Shiwach and his team of healthcare providers, including two nurse practitioners, two physician assistants, and two licensed professional counselors. This allows for ease in the continuation of care should a private patient decide to participate in clinical research. INCR primarily conducts outpatient phase I, II, III, and IV clinical research trials in which research participants visit the site periodically (from daily, to weekly, to monthly
dependent on specific protocol) throughout their participation but also has the ability to conduct in-patient research, where participants are observed 24/7 for periods of weeks or months at a time at a separate facility located down the street.

2. Client: Raj Shiwach, MD/CEO/PI

Dr. Shiwach is the owner and chief executive officer of InSite Clinical Research. He has served as the Principal Investigator on 167 clinical trials to date, including phase I, II, II, and IV stage trials for disorders such as Schizophrenia, Schizoaffective Disorder, Major Depressive Disorder, Bipolar Disorder, Generalized Anxiety Disorder, Tardive Dyskinesia, Attention Deficit Disorder, Fibromyalgia, Insomnia, Autism, Migraines, Chronic Pain, Alzheimer’s, Smoking Cessation, and Chemical Dependency. He has practiced psychiatry in the Dallas-Fort Worth area for over fifteen years and currently serves as Medical Director at Hickory Trail Hospital, a psychiatric hospital located in DeSoto, Texas.

Trained in Psychiatry in the United Kingdom (Liverpool, Oxford, and Maudsley) and at the University of Texas Southwestern Medical Center in Dallas, where he later served as a member of the faculty, he is Board certified in Psychiatry in the United States and the United Kingdom. (www.insitecr.com). Dr. Shiwach’s mission is to provide a well rounded and patient-centered care facility in this underserved area, in the private practice sphere, encompassing personalized medication management using newly adapted genetic testing alongside counseling and in the research sphere, incorporating the testing of new drug therapies in order to help further scientific advances in research.

In addition, Dr. Shiwach and INCR have been distinguished by Eli Lily as a preferred portfolio research site for schizophrenia research, due to his extensive focus on schizophrenia research throughout his career and his oversight of over 60 schizophrenia protocols. Dr.
Shiwach and INCR are often sought out due to access to a large patient database. Many times, long-time participants will contribute to the research process by participating in several studies over the course of many months/years. This is most frequently seen in participants diagnosed with schizophrenia. This qualitative research marks the first opportunity these participants have had to provide their direct feedback formally, as important stakeholders in the research process.

3. Purpose of the Study

While schizophrenia continues to be studied extensively cross-culturally, there is a relatively small body of work investigating those with schizophrenia in the context of biomedical research. Though there is some research regarding persons with schizophrenia’s experiences as participants in clinical trials, including their perspectives, motivations, attitudes, and values, very few studies have focused specifically on low-income populations. This research aimed to address this gap in the literature while providing data to tackle deeper questions of ambiguity when it comes to the ethical concerns and rhetoric that encompass the issue of conducting research amongst this vulnerable segment of the population spurred by increasingly protective contemporary International Review Board (IRB) measures and the past historical mistreatment of research participants and misuse of confidential information still present in the general public’s collective conscious.

These concerns are centered around those diagnosed with schizophrenias’ capacity and ability to give authentic informed consent and make choices related to their care based on the acknowledgement and genuine understanding of risks and potential harm as well as benefits associated with their participation in clinical trials. Due to their illness, participants with schizophrenia may experience cognitive and/or decisional impairments that have the
potential to impact their understandings and judgments, however it is important to note that schizophrenia and its symptoms are variable and ethical inclusion in clinical research that upholds the dignity and respect for these participants is possible. When facing the possibility of entering any clinical research trial, potential participants become engaged in the informed consent process and are presented with all the information known to-date about clinical trial procedures and an investigational product with which to base their decision.

Some participants’ inclusion demands the discontinuation of current medications, if they are agreeable, potentially risking the status of their health and impacting their current stability or symptomology. This becomes even more momentous should they be randomized to a non-treatment arm of a trial and receive placebo for the duration of their participation. Other decisions relate to genetic testing and the voluntary consent of genomic information and/or potentially uncomfortable lab procedures. Though clinical trial participation is voluntary and able to be discontinued at any time for any reason, the length of time of a clinical trial is a commitment consideration for participants. Considerations such as these are important to recognize as significant choices relating to research participation that require authentic decision-making and further the need for the inclusion of the perspectives of participants themselves within the dialogue of the clinical research industry and increased awareness amongst the community.

Utilizing ethnography, this research helped to uncover the experiences, perceptions, motivations, attitudes and beliefs of research participants diagnosed with schizophrenia who are clients of InSite Clinical Research and provided human-centered insight into the agency and autonomy of this community of participants when it comes to making decisions about their health and the factors that shape these decisions.
The specific aims of this research were:

1. To understand the experiences, motivations, values, attitudes, beliefs, goals, and perspectives of low-income persons with schizophrenia who participate in clinical research trials at InSite Clinical Research.

2. To explore how these low-income participants’ illness, perceptions, and experiences inform their autonomy and decision-making choices in the context of informed consent and investigate the factors shaping these decisions.

3. To present InSite Clinical Research with meaningful findings, feedback, and recommendations based on research conclusions that have practical implications for improving the quality of services provided and inform and tailor processes such as informed consent and the recruitment/retention of low-income research participants diagnosed with schizophrenia.

Prior to the start of this research, following my own intuitions, experiences working in the field of clinical research for over four years, and an extensive cross-discipline literature review, I hypothesized participant attitudes toward biomedical research would be positive, that the data would show that this population are active contributors in their health care decision-making supporting autonomy, and that they value research, therefore lessening patient, industry, and general concerns about vulnerability surrounding the inclusion of persons diagnosed with schizophrenia in clinical trials. I also hypothesized that continued participation over time builds trust between the health care staff and the participants. I was curious to investigate if participants’ low-income status would be significant, as clinical research participation does include financial incentives, and if primary motivations for clinical trial participation would differ in this specific population as compared to what has
been established in the previous literature as it relates research involvement. The following research questions and sub-questions were addressed through the course of this research:

• What motivates this low-income population’s participation in clinical research trials?
  o What are the attitudes, values, and beliefs held by this population in regards to clinical research involving schizophrenia?

• How have participants experienced their participation in clinical research trials?
  o What do participants hope to accomplish by participating in clinical trials?

• How does this population perceive its autonomy?
  o When do they decide to become involved with research?
  o How is informed consent being understood?
CHAPTER 2: CONTEXT

1. Motivations, Attitudes, Values, and Beliefs of Research Participants

*Altruism*

The National Institute of Mental Health describes schizophrenia as a “chronic, severe, and debilitating brain disorder” affecting around one percent of the population (NIMH 2015). Symptoms of this disorder include auditory and/or visual hallucinations, paranoid thoughts or delusions, social withdrawal, thought disorders, and cognition problems (NIMH 2015). Research is vital to the advancement of medicine and the understanding and treatment of schizophrenia. A review of the literature has shown that dynamic and multifaceted motivating factors impact biomedical research participation by those diagnosed with schizophrenia. Previous research has uncovered overall positive feedback and attitudes towards clinical trials from these participants.

The major themes amongst the body of research on this topic show clinical trial participants place emphasis on the importance of altruism, personal benefit, trust in the researchers, positive aspects of science, and on the opportunities available in research (Kaminsky et al. 2003: 282). These conclusions are echoed by Taylor and his colleagues who found that altruism is the number one motivating factor for research participation, along with the value of being involved in research, therapeutic effect, enjoyable experiences, and “the need to be heard,” where participants felt they were given a “voice” and an opportunity to speak openly about their experiences (Taylor et al. 2010: 343, 346). Warner et al. and Roberts et al. corroborate these data, highlighting altruism with their findings showing that “helping others” and “helping science” were primary motivating reasons for research involvement (Roberts et al. 2000: 67, 70, Warner et al. 2003: 227).
The literature also points to this groups’ shared values and attitudes toward research. Kaminsky and her colleagues found that persons with schizophrenia who participated in research had a different set of values than those who did not (Kaminsky et al. 2003: 282). In fact, regardless of clinical diagnosis, research trial participants hold a number of the same “core attitudes or beliefs related to ethical aspects of research participation,” but persons with schizophrenia in particular associate research participation with increased positive benefits and greater social support (Roberts et al. 2005: 360). Level of education has also been shown to influence research participation (Byrd et al. 2011: 480). These findings demonstrate the complex and distinct reasons motivating research participation in those diagnosed with schizophrenia, beyond the scope of financial incentives and spurs the need for further insight into clinical trial participant perspectives.

Trust

A dominant theme found surrounding research participation is trust between the researchers and participants. Trust in the relationship between the two parties is significant and continues to be an underlying fundamental value present in those who participate in biomedical research (Williams et al. 2005: 239, Featherstone et al. 2002: 714). Roberts et al. and Warner et al.’s qualitative findings reinforce the importance of trust, finding that trust alone may outweigh informed consent and personal benefit in terms of prominence to participants (Roberts et al. 2003: 289, Warner et al. 2003: 233).

On the opposite end of the spectrum, distrust has shown to diminish research participation. The literature shows that persons who do not participate in clinical trials tend to voice their distrust in clinicians (Featherstone et al. 2002, Kaminsky et al. 2003: 294, Ford et al. 2013, 30, Byrd et al. 2011). In a study done by Hoblyn et al. regarding motivations for
clinical trial participation amongst veterans with schizophrenia, trust in clinicians was the chief reason for participation or non-participation, in addition to altruism and access to specialized care (Hoblyn et al. 2013: 214).

**Psychosocial Benefits**

The values of altruism and trust associated with research participation are also related to the emergent theme of psychosocial benefit associated with clinical trial participation in this population. This literature encompasses this extensively. Kaminsky et al. found that up to 88 percent of research participants described psychosocial benefits as reasons for participating such as “getting a feeling of hope,” the ability to “gain better insight into myself,” and “having the opportunity to interact with others” (Kaminsky et al. 2003: 288). A study done by Schafer et al. found that higher numbers of persons with schizophrenia in particular valued “talking to others about their experiences” during clinical trial participation as compared to those diagnosed with depression (Schafer et al. 2011: 163). This psychosocial support aspect can be identified as a central benefit and prominent motivator to research participants throughout the literature. Taylor and his colleagues found that links to the care team or staff was one of the key factors in managing participant distress (Taylor et al. 2010: 347).

This psychosocial benefit cannot be under estimated, Hoblyn et al. found that patients who agreed to enter clinical trials in which their medication would be changed upon entry were actually more satisfied with their current medications than those who did not chose to participate, inferring that access to clinical trial medications may not be the primary reason for involvement in research by participants as is often presumed (Hoblyn et al. 2013: 214).

Catering to psychosocial needs has been proven to help support autonomy. According to
Drench et al., “health care providers facilitate a person’s autonomy by helping people express their feelings, educating, and supporting them” (Drench et al. 2007: 274).

Kaminsky et al. surmised that willingness to participate in clinical research trials is related to “knowledge about research and its purposes, clarity about use of personal information and confidentiality protections, trust in the researcher, and congruence with ones values” (Kaminsky et al. 2003: 282). The diverse shaping factors affecting motivation “range from immediate to distal to personal to societal” and the literature endorses that they be conceptualized as a “multi-dimensional construct” in order to understand the value of research as it pertains to individuals in the context of their lives (Kaminsky et al. 2003: 282).

Deepening understandings of the range of complex motivating factors that influence participants’ decisions to be involved in research has implications for the conduct and quality of biomedical research. Future research into reasons those with schizophrenia participate in clinical research from the participants themselves “may enhance ability to enroll subjects, decrease potential sampling biases, and enhance the generalizability of study results,” thereby increasing external validity (Hoblyn et al. 2013: 215).

2. Informed Consent and Autonomy

*Autonomous Decision-Making*

Central to the ethical concerns surrounding research amongst those with schizophrenia are the concepts of informed consent and autonomy. The literature supports that persons diagnosed with schizophrenia have the ability to assert more autonomy than is often thought (Roberts et al. 2000: 67). Roberts et al., among others, have presented data that establishes that participants with schizophrenia “strongly support schizophrenia research and autonomous decision-making” (Roberts et al. 2000: 72). Numerous studies have confirmed
that those with schizophrenia make participation decisions based on risk and potential harm assessments.

Roberts et al.’s findings show that schizophrenics in particular are less willing to participate in research they perceive as having a higher risk (Roberts et al. 2006: 2003). These data “offer reassurance about the ability of some people with schizophrenia to make reasoned decisions” (Roberts et al. 2006: 2003). These findings, in addition to reoccurring themes in the literature relating to altruism, trust, and psychosocial benefit can help to mitigate ethical concerns about harm relating to research in the schizophrenic population.

Ongoing Dialogue

In regards to informed consent, the bulk of the research done thus far has shown that cognitive impairment is the determining factor in the ability to give consent, rather than symptomology in persons with schizophrenia (Carpenter et al. 1999: 221). Therefore, in conducting ethical informed consent, individual context is stressed as cognition varies between persons. Kaminsky et al. put forth that “while ensuring comprehension of study requirements is a necessary component to informed consent, we believe equally important is determining the authenticity or “fit” that the decision has within the context of the individual’s life” (Kaminsky et al. 2003: 299). This individualized approach is frequently reinforced throughout the literature.

In research, “informed consent is at the heart of the processes that protect the autonomy, dignity, and safety of potential research subjects” and has been discussed extensively throughout the literature (Carpenter 1999: 220). Brody et al. endorses that when navigating this process, “procedures for obtaining informed consent (be) altered to be less reliant on a standard form and instead emphasize a form of dialogue between participant and
This tailored and personalized approach is corroborated by findings from Jones that call for attention to cognitive ability on a case-by-case basis and stress the necessity to ensure meaningful comprehension about the risks and benefits involved when participating in research (Jones 1995). The literature also endorses that informed consent should be a continuous process as expectations “are not fixed and instead may be viewed as continuously shaped by multiple inputs that include experience and information received before and during a trial” (Stone et al. 2004: 74). Much research backs this up, as Carpenter et al. found, repeated discussion and exposure to the protocol resulted in higher decisional capacity over time (Carpenter et al. 1999: 221).

**Genuine Understanding**

This meaningful comprehension, discussed throughout the literature on informed consent, makes way for genuine understanding. As discussed by Warner et al., “because ethical problems may arise in research when participants misunderstand the motives and responsibilities of clinical-investigators (i.e. the therapeutic misconception) and vice versa, it is important that relationships between research participants and psychiatric caregivers be based on genuine understanding” (Warner et al. 2003: 227). This genuine understanding in context is at the crux of ethical informed consent. Kaminsky and her colleagues argue that decisional capacity alone is “not sufficient for understanding the motivations, experiences, hopes, and fears that potential study volunteers bring to their decisions about research participation (and) this understanding is vital, as it represents the basis for informed, thoughtful, and authentic choice in research consent” (Kaminsky et al. 2003: 280). This reaffirms the relevance and need to further understandings into participant motivations, perspectives, values, and experiences in order to promote and understand genuine informed
consent decisions in this schizophrenic population. Such efforts “may help guide efforts to make research processes more attuned to participants” (Roberts et al. 2004: 283).

*Perceptions of autonomy*

Carpenter et al. found that informed consent that is done by a caregiver or family member takes away autonomy and is often found to be “unwarranted and stigmatizing” in the minds of participants (Carpenter et al. 1999: 222). This ethnography allowed for the opportunity to inform research practices through feedback from participants in their own words. Feedback regarding the subjective experiences of research participants is needed in order “to explore the experiences, preferences, and concerns of people with mental illness…so that they may have a greater voice in the conduct of psychiatric research in the future” (Roberts et al. 2000:72).

*Debriefing*

Tied to this autonomy in decision-making is the theme of debriefing, present throughout the literature as a meaningful area of importance to participants with schizophrenia. Roberts et al. and Schafer et al. found that participants strongly approved of being debriefed of any relevant findings by the research staff after the study had ended (Roberts et al. 2003: 284, Schafer et al. 2011: 159). Wilson adds to the collection of literature on this topic with the finding that debriefing is empowering to the patient and remains an integral part of the research experience (Wilson et al. 2007: 445).

3. **Context and Culture**

*Social Context*

The literature thoroughly supports the need for attention to culture within biomedical frameworks. A large body of research focuses on the necessity of consideration of the
interpersonal, psychosocial, social, and cultural context of the individual. According to Dahlberg, illnesses such as schizophrenia are linked to cultural models, which shape and are shaped by experience (Dahlberg et al. 2009). These cultural models relate to “ideas about causation, responsibility, outcome, and personal character” which can be meaningful when it comes to treating illness (Dahlberg et al. 2009: 286). It is important to consider these models and look past the “physical reality” of disease often focused on from a biomedical perspective and explore the many areas illness impacts (Dahlberg et al. 2009: 283). The ability to meet the psychosocial needs of individuals, as is often experienced by participants in clinical trials, can help narrow the gaps between paradigms and improve communication.

A central tenet within medical anthropology is the framework put forth by Kleinman that focuses on treating illnesses in their situated contexts and exploring explanatory models, bringing culture into focus as a critical aspect impacting the entire illness experience. According to Kleinman, “where only disease is treated, care will be less satisfactory to the patient and less clinically effective than where both disease and illness are treated together” (Kleinman et al. 1979: 256). Both constitute the human experience of sickness (Kleinman et al. 1979: 252). A study done by McCabe et al. found that patient satisfaction is higher when there is concordance between patient and provider explanatory models, further demonstrating the crucial need for increased understandings of illness models when it comes to providing care (McCabe et al. 2004: 29). This is salient in all biomedical spheres but particularly relevant when it comes to treating chronic mental illness as mind, body, and society are integrated in the experience, impacting all facets of life.

The consideration of culture is paramount when approaching health as “illness is experienced by the individual within the frameworks of culturally constructed worlds”
Research has found culturally specific differences in hallucination type and content amongst schizophrenics, substantiating culture’s impact on disease and observed variations in illness experiences and the cultural adaptation of disease symptoms (Bauer et al. 2011: 320, Vega et al. 2008: 225, Lorenzo Myers 2012: 115). For example, non-Western traditional cultures often interpret schizophrenia symptoms as possession by spirits rather than mental illness as in Western countries (Bauer et al. 2011: 319). In Zanzibar, hostile spirits and actions of ancestors are accepted belief models that allow for the allocation of blame to the family, not solely on the individual experiencing psychosis (Lorenzo Myers 2012: 125, McGruder 2004). This provides meaning for disease symptoms, cultural rituals to help in management of the disorder, and greater acceptance of the individual, thus impacting the illness experience (Lorenzo Myers 2012). Research has also shown that hallucinations in traditional cultures are also more likely to be visual, rather than auditory or cenesthetic due to varying cultural patterns (Bauer et al. 2011: 319).

Research that examines cross-cultural examples of schizophrenia, in which social context plays a role in those with schizophrenia’s treatment by others, has found that some cultures are more socially protective than others (Lorenzo Myers 2012). For example in India where marriage and family are strongly held values, research has shown that women with schizophrenia who are married with children have better outcomes and are more likely to stay married and cared for by their family during the course of their illness, versus unmarried women with no children (Lorenzo Myers 2012: 115, Thara and Srinivasan 1997). The overarching message in the anthropological literature is “people with disabilities are not simply disabled, they are disabled within a specific culture that determines the meaning of
their experiences” (Lipson et al. 2000: 213). This takeaway allows us to better understand illnesses as they are individually experienced and interrelate in culturally negotiated settings.

**Stigma**

Schizophrenia has been found to be one of the most socially stigmatized disorders (Vauth et al. 2007: 71). Persons diagnosed with schizophrenia are not limited to the experience of symptoms alone but also experience a so-called “second illness” or “the reactions of the social environment to the stigma associated with the disorder” (Vauth et al. 2007: 71). Sadler et al. found that “65-74 percent of respondents believed people with addictions or schizophrenia to be violent” (Sadler et al. 2012: 916). It is known that persons with disability engage with and negotiate “intersubjectively with stigmatization and other impediments to full societal participation” (Kasnitz and Shuttleworth 1999: 21). This stigma and isolation associated with mental illness, and particularly schizophrenia, has the possibility to impede recovery “by eroding individuals’ social status, social network, and self-esteem” (Vauth et al. 2007: 78). This also has the ability to impact social functioning. Thornicroft et al. found that even when actual discrimination was absent, anticipatory discrimination was still high in persons with schizophrenia (Thornicroft et al. 2009: 414). The literature on stigma and mental illness shows that the subjective experience of internalized stigma can be protective or detrimental and can impact the trajectory of an illness such as schizophrenia (Thornicroft et al 2009, Zäske et al. 2006: 41, Park et al 2013). Again, culture plays a role in an individuals understanding of, reaction to, and social response when it comes to schizophrenia.
Social Support

Roberts et al. found that research participation in those diagnosed with schizophrenia was associated with having greater social support (Roberts et al. 2005: 362). Jenkins et al.’s research echoes this and shows the importance of social support among persons with mental illness. The authors stress that “schizophrenia related illnesses and recovery need to be situated in relation to multiple stakeholders” and treatments need to be focused on the whole person (Jenkins et al. 2005: 407). Sibitz et al. found that having a social network as well as receiving outpatient treatment, was associated with higher stigma resistance (Sibitz et al. 2009: 316). Williams et al. adds to this, arguing that social relationships can be used to undermine stigma and even make living with schizophrenia a less “isolating experience” (Williams et al. 2002: 307). During a clinical trial, three of the most common stigma coping strategies (secrecy, withdrawal, and diagnosis concealing) are removed and participants can feel “free and safe to openly acknowledge and discuss their condition” (Vauth et al. 2007: 71, Jenkins et al. 2008: 387). This stigma resistance was found to be positively correlated with self-esteem, empowerment, and quality of life (Sibitz et al. 2009: 316). The development of relationships that sustain hope and encourage positive expectations, according to Williams et al., should “be used more deliberately by professionals to encourage hope and feelings of self-worth in clients with schizophrenia” (Williams et al. 2002: 307).

Race/Ethnicity

Analysis through the lens of race and ethnicity has shown that participants with schizophrenia of all races and ethnicities experience stigma however, it appears to be a prominent theme in the narrative accounts of African Americans, who remain more guarded and concerned about their clinical labeling (Carpenter-Song et al. 2010: 224). When it comes
to involvement in biomedical research, in addition to socioeconomic and psychosocial barriers to clinical research participation documented in the literature, trust and meaningfulness in the lives of participants remain important when it comes to the recruitment and inclusion of minorities in research (Ford et al. 2013: 34, Brown 2004: 23, Shavers et al. 2002: 255).

Barriers to participation can be navigated using trust. Ford et al. found that for Latinos and African American participants, increasing levels of trust were imperative to their participation (Ford et al. 2013: 31). This is reaffirmed by Byrd et al. who found that lack of trust was the main reason African American males were unwilling to participate in research (Byrd et al. 2011: 480). Further supporting the importance of trust, Ford et al. found that physician recommendation was the primary reason that African American participants chose to participate in a research trial (Ford et al. 2013: 30).

Shavers et al. advocate the need for researchers to build trusting relationships and rapport with minority communities in order to conduct truly ethical studies and suggests the involvement of minority populations as invested partners, in order to give the community ownership of the research and simultaneously generate community interest and involvement (Shavers et al. 2002: 255). In African American populations specifically, previous research has found community organizations and churches advantageous for recruitment (Brown 2004: 20). These findings remain relevant as women along with minorities have been found to be underrepresented in clinical research, “insufficient representation of racially and ethnically diverse groups and women in clinical trials result(s) in inequitable distribution of the risks and benefits of research participation and reduces the generalizability of trial results” (Ford et al. 2013: 29). African American males in particular are underrepresented in
biomedical research (Byrd et al. 2011: 480, Shavers-Hornaday et al. 1997). Efforts to improve the accuracy and generalizability of biomedical research require recruitment of minority populations.

CHAPTER 3: PROJECT DESIGN

1. Sampling and Recruitment

The staff of InSite Clinical Research facilitated initial recruitment for this study. Following official International Review Board (IRB) approval, the staff used patient records to identify subjects who met criteria to participate. These criteria specified that all participants were eighteen years or older at the time of participation, had a prior documented clinical diagnosis of schizophrenia, were considered low-income (as indicated in their patient charts at the clinic based on whether participants were receiving Supplemental Security Income (SSI) due to their disability), and had participated in or were currently participating in a biomedical research trial at InSite Clinical Research. These subjects were informed of their potential eligibility to participate in this study by the staff of InSite Clinical research either during regular clinic hours when they were on-site at the clinic or over the phone. Once informed, if the subject expressed interest in participation, staff facilitated contact between the student investigator and the potential participant. Only basic information such as the title of the study and name and contact information of the student investigator were shared. Again, this contact was largely in person and sometimes over the phone. The student investigator then engaged the potential participant, informed them about the study, solicited informed consent, coordinated an interview day and time, and conducted all data collection thereafter. No flyers or ads were used for the purposes of this study. Due to the fact that the student investigator is a staff member at InSite Clinical Research, the student investigator
performed no initial recruitment. Great care was taken to express and reiterate to participants that participation in this study was voluntary and would have no effect on their current or future treatment, care, or participation in clinical trials.

The IRB approved sample size was no more than twenty participants. A range of participants with varying race/ethnicity, gender, and age were sought for recruitment however, due to the largely African American/Black population of DeSoto, Texas- 68.6 percent according the United States Census Bureau, higher numbers of African American/Black participants were expected (United States Census Bureau Quick Facts 2014). Participants received a $20 stipend for their time and travel during their participation in this study, at the expense of the client, which was discussed and formally included in the initial research proposal.

2. Data Collection Methods

The bulk of data collection in this study was largely qualitative in the form of in-person, semi-structured, in-depth audio recorded interviews. Prior to these interviews the student investigator conducted informed consent using an IRB approved consent form with each participant, ensuring adequate time was given to read over the entire form, explain the purpose, procedures, what to expect, the possible risks and benefits associated, and discuss confidentiality as well as probe for comprehension and understanding in the participant’s own words about the study and their willingness to participate. Time was also allotted for participants to ask any questions they may have before agreeing to participate and each participant was sent home with a copy of the signed informed consent form. Twenty participants were formally interviewed once for up to an hour and a half by the student investigator in a quiet office at the offices of INCR using an IRB approved interview guide.
with open-ended questions over the period from April 2014 until July 2014. These interviews were recorded using the student investigator’s password protected iPhone.

These interviews were conversational in nature and allowed for spontaneous responses and the natural progression of follow up questions. These interviews provided the opportunity for participants to narrate and share their experiences over a significant amount of time, allowing for grounded and reliable insight into their attitudes, values, perceptions, and beliefs based on the wealth of information that they shared and provided rich data with which to draw conclusions. The student investigator was conscientious in maintaining the informed consent process by probing participants as to whether or not they wanted to continue when any participants became emotional. Past extended contact with this population as a clinical research coordinator and a cognitive rater over a four year time period provided the student investigator the experience needed to be able to recognize signs of any exacerbation of symptoms or distress. No interviews were discontinued due to these reasons in this study. Breaks were also offered to participants by the student investigator during the course of these interviews.

In order to corroborate, supplement, and triangulate data, quantitative methods were also utilized. Using both qualitative and quantitative methods helped to provide depth of understanding in this research. An IRB approved Likert scale instrument, created by the student investigator, was distributed to study participants at the end of each interview in order to gather quantifiable data on participant perspectives. This instrument was designed to use non-leading questions and contained questions and language that could be easily understood by respondents. These surveys proved useful in gathering basic demographic
information in order to gather a more detailed profile of this community and gauge viewpoints and attitudes relating to the research questions.

Twenty questions were asked in each survey, seven relating to demographics and thirteen attitude statements. These were measured using a 5-point Likert scale to quantify whether participants 1) “strongly agreed” 2) “agreed” 3) “neither agreed nor disagreed” 4) “disagreed” or 5) “strongly disagreed” with the statements included in the survey. In addition to basic demographic information, asked in questions one through five, the surveys assessed participants’ frequency of participation in clinical trials both in the past year and over their lifetime and their opinions relating to their research participation and care. Each confidential survey was designed to take no more than twenty minutes; many participants took a considerably short amount of time filling it out.

3. Data Analysis

Preliminary data analysis began during the data collection process and throughout transcription of the participant interviews, using grounded theory to identify emerging trends and themes. Data was analyzed primarily using ATLAS.ti after the transcription process was completed. All audio recorded interview files were transcribed word for word by the student investigator for accuracy and transparency into Microsoft Word documents over the period of two months, from June to July 2014. These files were then uploaded to ATLAS.ti. Utilizing this software, the student investigator was able to analyze the data in-depth and sift easily through the data for meaning and themes and the connections between them as well as highlight notable participant quotes for use directly in this report. Data was coded using key words that fit the themes and patterns found in the data (e.g. altruism, debriefing, personal autonomy, trust etc.). These codes were then assigned to relevant participant responses and
used to answer the research questions. The transcription, reading, and re-reading of transcripts also aided in the analysis process and helped in conceptualizing codes and recognizing general trends.

To inform qualitative findings, quantitative data was analyzed using SPSS. Following the data collection phase, all twenty completed surveys were entered into SPSS. The data set was then analyzed utilizing some of the programs functions, including frequencies and crosstabs. SPSS and PowerPoint were used to create visual representations of detailed data in the form of bar charts, pie charts, and histograms for use in this report and during presentation of deliverables.

4. Limitations of the Study

The potential limitations of this study include the following:

- Distributing the survey to interviewees at the end of the interviews may have resulted in rushed or fatigued responses, a couple of surveys contained responses that did not align with the respondents’ other survey responses and/or lengthy detailed responses in the interviews. The timing may have impacted the possibility for errors and/or mistakes.

- Interviewing and including non-clinical trial participants diagnosed with schizophrenia in the sample may have offered a unique opportunity to uncover different perspectives when it comes to reasons for non-participation.

- Asking participants to reflect on their experiences with informed consent process on the same day as they took part in it may have led to better recall and could have possibly elicited clearer responses, rather than asking participants to recall their
experiences after many days, weeks, or months had gone by, as in the case of this research.

- Adding a question to the semi-structured interview guide asking participants in their own words what the purpose of informed consent was could have helped in further understanding these participants’ perceptions of the process and aided in addressing the question of how informed consent is being understood.

- Quantifying and having the respondent rank the importance of financial incentives within the survey instrument may have helped to corroborate qualitative findings relating to low-income status and clinical trial participation motivations.

- The position of the student investigator as a staff member of InSite Clinical Research may have had the potential to create response bias.

5. Participant Demographics

A total of twenty participants diagnosed with schizophrenia took part in this study. Demographic data was collected via written survey instrument with five questions regarding participant age, gender, race/ethnicity, education level, and occupational status at the time of the interview. Income level was not quantified and gathered via the survey as it was considered inclusionary criteria to be low-income to take part in this study. All participants were receiving Supplemental Security Income (SSI) checks at the time of these interviews based on their disability that pay for medications and living expenses (most participants lived in group boarding homes where food and lodging are provided in exchange for a certain percentage of their check). As of January 2015, the maximum dollar amount an individual receiving SSI can obtain per month was $733.00 (Social Security Administration 2015). This
amount fluctuates based on cost-of-living and has increased 1.7 percent as of last year when these interviews were conducted (Social Security Administration 2015).

Age

Inclusion criteria stated that participants be at least eighteen years or older at the time of their involvement in this study. Participants age range spanned from twenty-three years old to sixty years old. The mean age of participants was forty-four years old. Slightly higher numbers of fifty to sixty year olds were represented in the sample.

![Participant Age](image1)

Figure 1. Participant Age

Gender

When looking at gender, males were heavily represented in the sample, thirteen participants were male (65 percent) and seven were female (35 percent). Though efforts were made to recruit a representative sample, previous research has indicated that schizophrenia has a male: female incidence rate of 1.4:1 (Abel et al. 2010).

![Participant Gender](image2)

Figure 2. Participant Gender
**Race/Ethnicity**

Diversity in race/ethnicity was not seen amongst this sample. No Asian/Pacific Islander, Hispanic/Latino, Native American, or other race/ethnicity was represented. Eighteen participants (90 percent) identified as African American/Black and two participants (10 percent) identified as White/Caucasian/Non-Hispanic. The substantial representation of individuals identifying as African American/Black was anticipated due to population demographics of the research site.

![Figure 3. Participant Race/Ethnicity](image)

**Highest Level of Education**

Highest level of education reported on the surveys showed that seven participants (35 percent) had attended some college but had not received a diploma, five (25 percent) had attended a trade or technical school, four (20 percent) had attended some high school but did not have a diploma, two (10 percent) were high school graduates, and two (10 percent) held an associates degree.

![Figure 4. Participant Highest Level of Education](image)
**Occupation**

Occupation was another demographic data point gathered through the survey. At the time of the interviews, seven participants (35 percent) were unemployed, seven participants (35 percent) were disabled/unable to work, 3 participants (15 percent) were employed part time, and three participants (15 percent) were retired.

![Figure 5. Participant Occupational Status at the Time of the Study](image)

**Number of Clinical Research Trials Participated in the Past Twelve Months**

Ten participants (50 percent) reported they had participated in only one trial in the past twelve months, eight participants (40 percent) reported they had participated in two, one participant (5 percent) had participated in three, and one (5 percent) took part in four trials in the past twelve months. Generally, clinical research trials are designed to continue for no less than three months in order to gather a significant amount of data, with most averaging participation lasting from four to six months, including criteria for minimum amount of time between enrollment in subsequent trials.

![Figure 6. Participant Number of Clinical Trials in the Past 12 Months](image)
Number of Clinical Research Trials Participated in Over the Course of Lifetime

There was a range of participant responses when it came to reporting the number of clinical trials participated in total over a lifetime. The lowest participation rate was one clinical trial, with four respondents (20 percent) reporting they had only participated in one trial over their lifetime. Five participants (25 percent) responded that they had participated in two clinical trials, one (5 percent) reported participation in three clinical trials, three (15 percent) reported participation in four trials, two (10 percent) reported participation in five trials, one (5 percent) reported participation in six trials, one (5 percent) reported participation seven trials, and one (5 percent) reported participation in eight clinical trials over their lifetime. The highest number of clinical trials reported was ten, reported by one participant (5 percent). One participant response was missing from the data set. Overall, there was a greater representation of respondents who had participated in five or less clinical trials over the course of their lifetimes in this sample.

Figure 7. Participant Number of Clinical Trials in Lifetime
CHAPTER 4: QUALITATIVE AND QUANTITATIVE RESULTS

1. The Experience of Schizophrenia

Individuals diagnosed with schizophrenia may face a number of physical, psychological, emotional, and social challenges relating to their illness. An examination of an individual’s illness experiences in various contexts allows for insight into how they may process and understand the world around them. Exploring these experiences may also shed light on how they shape and interface with decision-making, treatment seeking, and autonomy. Almost all participants spoke about the isolation, loneliness, confusion, and fear they faced as part of their illness, especially at the time their symptoms of schizophrenia first started and during acute times when symptoms caused them to become reclusive.

*Isolation*

Isolation was a major theme present amongst participants’ reported illness experiences. Schizophrenia often caused them to isolate themselves and made communication difficult due to fear, paranoia, and stigma. A large majority of the participants reported during critical times in their illness they shut themselves off, alienated themselves, were withdrawn from others, some left their jobs and families, and even lived homeless or became suicidal. Many participants touched on this, describing their schizophrenia symptoms, their reactions to them, and their experiences isolating themselves due to their illness,

I isolate myself…that’s when it you know, it’s a heavy feeling in my heart and then I start hearing voices.
(Participant 3)

I stay behind closed doors…I stay to myself…it’s just, it made me draw away from people.
(Participant 15)

My schizophrenia is when I’m not on medication. I seem to walk a lot. I’m edgy. I tend not to be around people, I think they’re after me or out to hurt me for that matter. I’m
irritable, cranky; I’m very on edge at all times…Sometimes I can’t be still. Sometimes I don’t eat very much. I don’t sleep very well. I don’t have activities…I don’t do none of that. I’m mostly all by myself everyday you know.
(Participant 14)

When I was at Tom Thumb in Highland Park I was sitting there, I was working. I was doing my job and every time I’d look up I felt like someone’s watching me. I felt like somebody’s whispering about me, talking about me. And it’s all on camera. People fired me for it. It’s all on camera. The people fired for me, fired me for it. I mean the people thought I was just crazy… I’ve been hesitating about going back to work. I’ve been out of work for like two years now. They say I can get a part time job, but I don’t think I should. Cause I think if I get the job, I’m gonna get fired. I’m gonna lose my check…Sometimes it gives you surprises that you don’t expect…You know kind of, bear through it and just keep your self calm at all times and find a secluded area where you can be by yourself because if you find someone else, if you just do that, they’re gonna call the police and the police are not gonna handle you the way a hospital does.
(Participant 17)

Sometimes it seems like the room is underwater, I’ll see people that aren’t there, I’ll hear things like people talking to me, they’ll seem like someone's talking right around the corner when I know no one is there. It’s always very random. Most of the time I’ll go to my bedroom and shut myself away till it stops. It’ll happen daily, but it varies in how much it bothers me, the intensity is different each time…I get this feeling of unease, and then paranoia starts revving up and uh from there, I’ll either start seeing things or I’ll start hearing things and the worst ones I can say I've heard is just screaming…usually if I’m in my living room I’ll separate myself, go to my room, shut the door...Sometimes I feel like my friends are out to get me that nobody’s on my side, I feel like I'm being watched, I feel like I'm being listened to all the time. Um, feels like just walking down the street, it feels like if I pass someone that they're going to come up behind me and attack me. Its definitely a varying scale on the paranoia as well...it'll be miniscule at times and then other times ill be looking over my shoulder at every little thing.
(Participant 10)

Another participant shared his experiences in prison dealing with forced isolation, with devastating effects on his illness.

For four years I was isolated, I was in a five by ten room by myself for four years. I wasn’t able to go with the public or with the regular inmates for that matter. I had to stay isolated. It could have made it (the illness) worser because I think when you isolate someone like that, when you do it to that amount you don’t know what could happen or what could become of that person for that matter.
(Participant 14)
Previous research has shown that social withdrawal and social isolation are risk factors for poor outcomes in those diagnosed with schizophrenia (Bhugra 2006: 19). A growing body of literature continues to substantiate that when it comes to chronic mental illness, along with varying expectations and reactions that shape illness experiences in different cultural contexts, strong social support networks can be protective (Bhugra 2006: 19, Lorenzo Myers 2010: 126).

Others reflected on their illness’s impact on themselves throughout the one-on-one interviews. When discussing their own feelings regarding their schizophrenia, participants shared their views and experiences,

I’m growing to accept it…I ain’t got no choice. It’s been with me all my life. It’s took me the last twenty years…but I’ve learned to deal with it…in society, instead of hiding and being hidden. You got to come by and to talk to people and hold a regular conversation…because usually I don’t even go around people…There’s a big, how do you put the word, stigma, cause like if I told someone, most people don’t know I have schizophrenia, unless it’s a real, real close friend and they’re around me and they see. They accept me, but a lot of society don’t. Like my grandparents or my parents they don’t, that’s why they threw me in the hospital. Because they didn’t wanna deal with it or they couldn’t accept it…that’s the way most of society is, they'd rather just throw you away…But that don’t work, cause the problems still there. (Participant 19)

I feel like I’m suppose to be a better person than what I am. So it makes me feel kind of down sometimes that I got it and I just want to get rid of it. And I just feel like, I feel sad. (Participant 17)

I don’t like it. But, it’s something that I've had to continue with about me. You know, it has me sometimes where people think my personality’s not good you know. (Participant 18)

I think it’s made me stronger in some cases I have to deal with things other people don’t on a daily basis, other times it seems a hindrance because it affects my daily life…I have a different perception on life, I tell them that I see things that others don’t, hear things, feel, smell, and sometimes it seems that they don’t understand what's going on, other times it seems, like they're trying to get the gist of it but don’t quite understand what I go through. (Participant 10)

I really didn’t understand what it (schizophrenia symptoms) was at that time because I was a young kid, you know? Who knows what you’re going through as a young kid? So
as I got older it started getting worser…Back in 98’, I killed my best friend. We had got into an altercation. See I can talk about it now because I think I guess I done let it go, so to speak…We got into an altercation. It was about a girl and it was a stupid thing to do at that time. Now that I realize it now. I shot him. And killed him. So I wound up doing prison time for that and I’im not proud of that you know. Everyday I still have nightmares and dreams of it, you know. Because that was my best friend you know…a lot of stuff was going on…up here… I did a lot of meditation. Soul searching you know. Trying to find out why did I do what I did. I still haven’t come up with an answer for that yet. You know, I talk to his mom on a regular basis. Even though me and her went out to his grave site and put flowers on his grave. I still don’t feel good about it. I guess they thought I was a cold-blooded killer for that matter, but I’m not. It was just a freak accident, something that happened you know, I didn’t mean for it to happen. If I could take it back, if I could turn back that hands of time I wouldn’t have done that.  
(Participant 14)

(I) tried to kill myself a few times. Just couldn’t deal with anymore, so I thought that was my only way to figure out…like blow my brains out…it’s not going to talk to me no more. You know, but knock on wood. Thank God that things have changed. You know, (Dr. Shiwach) helped me a lot.  
(Participant 19)

I mean, I've tried to commit suicide, you know, because, I get at that point where its so bad I just say 'oh I wish I was dead' there's nothing I can take, there's nothing I can do…Because of the voices, everything is because of them, my life is centered around them…I was in Terrell state Hospital and I tried to jump out of this window, but the window wouldn’t break and I ate rat poison one time before, hearing the voices real bad, living by myself. I don’t live by myself right now, right now I have a roommate and its hard because I've never had a roommate before, I've always lived on my own, but it got to the point where I lost my section in housing because of my voices, so now I got evicted because I went and bought a car and didn’t pay my rent. I wrote a rent check out that was gonna bounce so I didn’t pay my rent, I went and bought a car ‘cause I got tired of riding the bus, got tired of walking everywhere so I kind of made a stupid move so now, I'm paying back money on that now, and it’s a thousand and some dollars.  
(Participant 6)

You’re not irregular if you are schizophrenic, you know, it doesn’t mean that you're you know crazy or threwed off or something like that, it means that you know, you're still a person, you're still a human being.  
(Participant 7)

Treatment Seeking

When it came to treatment, many participants had been diagnosed for the first time in a psychiatric hospital after experiencing a psychotic episode during which family or police
brought them in. Since then, many had seen multiple healthcare providers throughout their illness history and had a wealth of experience with mental health clinics prior to their participation in clinical research trials. Overall, participants identified with a biomedical paradigm when it came to treating their schizophrenia; this was apparent in their nearly unanimous responses related to treating their illness through taking medicine as prescribed by their healthcare provider. In addition to taking medicine, which was predominantly reported first when asked about how they treat their illness, participants commonly responded that they manage their illness in other ways.

Six participants in the sample reported taking medication only. The remaining sample reported that along with taking prescribed medication they did the following to treat their illness: came to the research clinic, talked to people and communicated with others, tried to relieve stress and stay calm by listening to music, watching television or movies, listening to the radio or playing video games, went for walks, stayed active, did chores, “stayed busy,” maintained proper nutrition and physical health, drank water, smoke cigarettes, smoked marijuana, went outside, rode a motorcycle, lay down, stayed focused, prayed, and attended church. As one participant mentioned, in addition to compliance with medication,

I pray a lot. I ask God to deal with it because I can’t.
(Participant 14)

Participants in this sample voiced diverse responses relating to the cause of their illness and onset of their symptoms, including stress. As one participant explained,

(There was) a lot of pressure...like lost a job that I had for a long time. A job, a girlfriend, all at the same, everything, you know all at once. My job, my girlfriend, my car, my....everything, I lost it all at once, I just went into, started gettin’ depressed you know. So uh, just not bein’ around my family, stayin’ to myself, not communicating with people. And they started to notice.
(Participant 5)
Others reasoned it was their past drug or alcohol-use that brought on their schizophrenia,

   Basically why I’m in the situation I’m in is because of drugs. I got a bad batch of some stuff and I flipped out…I was smoking marijuana but they put some angel dust, they say they found traces of that, of angel dust mixin’ it in with the weed, and that what caused me to kind of go off the edge.
   (Participant 13)

   I believe it started when I started using drugs and drinking and stuff…crack cocaine…a lot of times when I was going on one of them binges, I’d be out there, I’d be up two, three, four, five days. You know just moving around then when I started trying to sell the stuff, seemed like people be calling, sometime I walk way and they’d say ‘I didn’t call you’ the truth or not, in my mind they were playing with me, they’re tryin’ to get me busted, you know, all that stuff couldn’t been nothing but the devil and the drugs…I start thinking crazy.
   (Participant 4)

   Doing drugs…any drug I ever touched…it suits me right. It’s what I get for doing drugs. (Participant 16)”

   Other participant responses included: previous concussions or head injury and lack of family. One participant cited genetics specifically while another two participants alluded to it, stating that they believed had developed schizophrenia because other family members had it. Six participants replied that they did not know what caused their illness. Despite the variation in understandings reported related to the cause of their illness, most participants were in line with biomedical perspectives or reported they did not know what caused their schizophrenia. Previous research has shown that “a biological explanatory model of illness among patients with schizophrenia is associated with greater treatment satisfaction and better therapeutic relationships” (McCabe et al. 2004: 30). Tracing the trajectory of chronic schizophrenia, from the first psychotic break to subsequent relapses during the course of their illness, acute stages of psychosis are commonly tied to outside life stressors. These stressors increase the risk of mental illness and oftentimes coincide with lack of compliance with medication or treatment plans.
The exact cause of schizophrenia is unknown, however research has established that a complex and multi-faceted interaction between genes, structural and chemical brain abnormalities, and the environment influence the risk of schizophrenia (National Institute of Mental Health 2015). According to the National Institute of Mental Health, ten percent of people with a first-degree relative diagnosed with schizophrenia will also develop the illness, showing a significant genetic component, however many outside risk factors have yet to be identified (2015).

Outside of these interviewees’ responses, some participants cited alternative non-medical explanations when discussing their illness. It is interesting to note however that despite these participants’ differing explanatory models, they touted standard biomedical treatment with medication as the best way to treat their illness. One participant stated the Pentecostal religion was what brought on her illness. She concluded,

‘Cause it’s so strict, you cant make a mistake and all that. Some religions is okay. But the one I was brought up in, you couldn’t join no sports, you couldn’t do this. You couldn’t do that. And I was afraid to make a mistake and I wouldn’t say anything cause I was afraid…it’s too strict…I was just too afraid to make a mistake and that’s where the voices came from.

( Participant 3)

Another interviewee described it was grief that caused their symptoms,

My mom’s death. She died in 2000 of, June 2000, and after her death, that’s when I went in a depression state, because my sister, she noticed it and she took me to the hospital she took me to Parkland Hospital and they, got me there and they admitted me... so that’s kind of how it started. And then from then on it’s been like that. Basically, voices that I hear is like of loved ones, of my mom, of my family, friends, and you know…some of the voices will tell me you know ‘don’t do that’ or ‘that’s gonna hurt you.’

( Participant 7)

Other participants reported eating too many sweets and fear brought on their illness. Prior research has shown differences in interpretations of illness among varying races and ethnicities and found that African Americans in particular may express “alternative, non-
biomedical explanations for problems,” including supernatural or demonological forces due to differing sociocultural contexts in which non-biomedical explanations are the norm (Carpenter-Song et al. 2010: 234, 237). Though this was not widespread amongst this particular sample, it was observed in a couple of interviews,

These voices, whatever the voice or whatever spirits, shadows, ghosts or whatever that is. (Participant 8)

They're spirits like God and they can touch you, touch your head, they can make your head itch, they make me sneeze, make me sneeze, make me cough, feel like something is in my throat, make me bite my tongue… (Participant 6)

Another participant recalled his experiences and his family’s reaction to treating his illness, which, in this case, lead to delayed biomedical treatment.

You talking about seeing things. As a kid scared of a nightmare, it was like Nightmare on Elm Street for me as a daily thing throughout my childhood. Nobody never knew. I found out what was wrong when I got in jail and they told me it was schizophrenic paranoia…I would hide under my covers. I would hide in my closet. My mom would be coming in there, ‘What you be doing in the closet son?’ ‘Oh! I don’t know mom, I don’t know what’s going on.’ Then she never knew, but as I got older as I got about nineteen or twenty she took me to a preacher and she said, ‘can you help my son because I think he’s crazy and he doesn’t know it. He doesn’t want to believe it. So just help him.’ I told him I actually took offense to it and disregarded the help. And told him, ‘hey man, I’m not crazy bro.’ But when I was in jail it was like, I be on medication. Come to find the medication, it kind of worsened the symptoms, but when they got me the right medication it helped. (Participant 17)

Responses such as these shed light on how illness is interpreted and experienced by individuals within varying cultural contexts and allows for understanding into the differences in how biological symptoms are reacted to and explained, both on a personal and sociocultural level.
Getting back to myself

Participants’ narratives reflected the social and cultural aspects related to the process of disability and relayed the meaning these experiences held in their lives as they navigated the trajectory of their illness. During the interviews, numerous participants shared that they felt their illness had changed them as a person. This is well documented throughout the literature as the experience of “otherness” related to disability (Williams et al. 2002: 302). Participants spoke to this feeling,

It’s just not the same. I don’t feel like I am the same person as I was before.  
(Participant 2)

I’ve taken on a different demeanor, I’m not the same person it seems like.  
(Participant 18)

Many participants shared their personal life stories, how their mental illness had impacted their own as well as their families’ lives, their own perspectives on illness etiology and management, daily struggles, and hopes relating to their own lives. A sense of how they have attempted to manage and understand their illness as it progressed was observed throughout the in-depth interviews. A salient quote from one participant surmised the general sentiments of interviewees when it came to their healthcare and their own hopes for receiving treatment through participation in clinical research.

My own expectations, what I need, I needed to get some help, I needed to get, back to feeling, get back to myself as I used to say, you know, I wanted to get back to myself.  
(Participant 13)

One participant described the change they noted in themselves after participating in clinical trials at INCR,

I wasn’t really talkin’ that much then, I was like in a shell but after I got on the meds and you know, started doin’ the study, it got better, everything got better for me.  
(Participant 5)
Clinical Trial Participation Experiences: Motivations, Beliefs, and Perceived Benefits of Participation in Clinical Research

Respondents were asked questions during the semi-structured interview about how and when they became involved in research, what interested them about the opportunity, their beliefs about the research process, the benefits and/or disadvantages, and their research experiences in order to uncover underlying motivations, attitudes, values, and beliefs. Respondents were also questioned about their expectations, experiences, and goals relating to their participation in clinical trials at InSite Clinical Research and were asked about their illness in order to understand their own perceptions as well as connections between their disorder and their experiences. In alignment with previous research, data showed that motivations for participating in, perceptions of, and experiences with clinical research trials are multifaceted and unique; however several prevalent themes emerged amongst the sample.

Altruism

Confirming literature review findings, one of the most common participant responses regarding motivations for partaking in biomedical research was helping others. Many comments were made during the interviews that supported this altruism as motivation finding. Others named helping others as a benefit of their participation. As one participant stated,

I mean it’s a big deal because it not only helps one person but it can help millions of people.
(Participant 3)

Participants were mindful of the long-term benefits of their research participation. Responses echoing the quotations below were frequent throughout the interviews. A sense of purposefulness in aiding others diagnosed with schizophrenia was coupled with a forward
thinking outlook about the possibility for an investigational drug to become accessible to all when available on the market, a sentiment shared by many participants.

The benefits is not just that immediate gratification but I believe it’s a long term deal, you know the benefit of this, whatever I’m taking, will benefit not just me but somebody else and if I hear it on the news one day I can say ‘I took part in that.’

(Participant 4)

If it helps or doesn’t, it might help someone down the line.

(Participant 19)

It’s helping others too, and I like helping other people.

(Participant 2)

Help others and help yourself. I mean you gotta help yourself and you gotta help others because it’s more blessed to give than receive.

(Participant 18)

Quantitative results reiterated and reinforced many of the conclusions drawn from the qualitative interview data, including findings regarding altruism. A overwhelmingly large majority of respondents supported attitude statements that people with schizophrenia should participate in research, that clinical trials were beneficial to society, that clinical research about schizophrenia was important, and that participation in clinical trials was helpful to science. There were however responses on the quantitative surveys that did not match up. The majority of these outlier responses were from one participant. In this case, the lengthy responses in the interview did not correlate with these survey responses. It is my belief that this participant either misinterpreted or reversed the questions when filling out the survey. This reinforces the need for in-depth qualitative approaches to enrich understandings when it comes to research and bolsters appreciation for the key strengths applied anthropology has to offer. Anthropological research methods provide the opportunity to probe for and explore additional information, eliciting human-centered and experience-based insights with which to base practical solutions and recommendations. In this case, qualitative methods allowed for
clear understandings into participants perspectives, outside the realm of surface survey responses alone.

Of the twenty participants in this study, seventeen (85 percent) reported they agreed with question nine on the survey instrument, “people with schizophrenia should participate in clinical research trials.” Nine respondents (45 percent) reported that they “strongly agreed” that people diagnosed with schizophrenia should participate in research, eight (40 percent) reported that they “agreed,” and three (15 percent) “neither agreed nor disagreed.” No respondents reported that they “disagreed” or “strongly disagreed” with participation in research.

![Figure 8. People With Schizophrenia Should Participate in Research](image)

Resonating qualitative findings regarding altruism further were the responses to question eleven on the survey, “participation in clinical research is beneficial to society.” Nineteen participants in the sample (90 percent) reported they agreed that research participation was beneficial to society. This confirms the theme of altruism and helping others as motivation for clinical trial participation as a major research finding. Nine respondents (45 percent) indicated that they “strongly agreed” that clinical research participation is beneficial to society, nine (45 percent) reported that they “agreed,” one (5 percent) “neither agreed nor disagreed,” and one (5 percent) “strongly disagreed.” One respondent, participant 14, marked “strongly disagree” which does not support qualitative data reported during the interview.
Similarly to survey responses above relating to persons diagnosed with schizophrenia being involved in clinical research and research being beneficial to society, participants were in agreement that clinical research about schizophrenia was significant. In response to question eighteen on the survey “clinical research about schizophrenia is very important,” nineteen respondents (95 percent) of the sample agreed. Eleven participants (55 percent) responded that they “strongly agreed” that clinical research about schizophrenia was very important, eight (40 percent) “agreed,” and one (5 percent) “disagreed.” This highlights and corroborates qualitative results regarding the value of research to participants as a strongly held belief.

Question nineteen “clinical research participation is helpful to science” evoked similar responses from participants, with nineteen respondents in the sample (95 percent) agreeing that research helped science. Fourteen respondents (70 percent) marked that they “strongly agreed” that clinical research participation is helpful to science, five (25 percent) “agreed,”
and one (5 percent) “neither agreed nor disagreed.” No respondents reported that they “disagreed” or “strongly disagreed.” These survey findings echo the theme throughout the interviews and throughout the general literature discussing altruism as a major motivation behind research participation.

Figure 11. Clinical Research is Helpful to Science

Personal Benefit

In addition to the theme of helping others through participation in research, prevalent throughout the data was the theme of helping oneself as a motivating factor. Bettering oneself and one’s health through research participation was reported by a majority of participants, as is widespread throughout the literature on this topic. Comments relating to managing symptoms associated with schizophrenia were cited frequently, most commonly regarding improving thinking. This finding may be due to the fact that eighteen participants (90 percent) of the sample had reported participating in one or two clinical trials over the past twelve months at INCR, of which dealt with cognition improvement. Participants reported,

Anything to help my thinking, improve it would be good for me. Yeah, I think that my thinking process, if it helps it get better then it would be something I’m willing to do. (Participant 3)

It was something I was going through at the time, my illness…and it was something that may help me. (Participant 2)

Basically I was kind of thinking, you know…how it would help me. (Participant 7)
I was just looking for some help...I thought I needed the help, it would help me get better. So I was all for it...It was to help me, help for my illness.
(Participant 5)

I use ya’ll guys, you know, to try to help myself.
(Participant 13)

To see if it would better me and my illness that I was facing and going through day to day
(Participant 12)

Quantitative findings support these interview conclusions. In response to question eight on the survey “overall, I feel like I have personally benefited from my participation in clinical research,” seventeen respondents (85 percent) in the sample agreed. Ten respondents (50 percent) reported that they “strongly agreed” that they had personally benefited from their participation in clinical research, seven (25 percent) reported they “agreed,” two (10 percent) “neither agreed nor disagreed,” and one (5 percent) “strongly disagreed.” One participant wrote “I don’t know if the medicine is working for me” as a reason underneath their response of “neither agree nor disagree” with whether or not they had personally benefited from their participation in clinical research. Despite one “strongly disagree” result, no participant reported that they did not benefit during the one-on-one interviews. I believe in this case, the qualitative data more accurately reflects participant attitudes as the interviews provided the opportunity for participants to explain and discuss the benefits of clinical trial participation from their perspective.

![Figure 12. Personally Benefitted from Participation](image-url)
Tied to personal benefit, question sixteen in the survey assessed overall satisfaction with clinical research experience at InSite Clinical Research to which eighteen respondents agreed. Thirteen participants (65 percent) reported they “strongly agreed” that they were overall satisfied with their clinical research experience(s) at InSite Clinical Research, five (25 percent) “agreed,” one (5 percent) “neither agreed nor disagreed,” and one (5 percent) “strongly disagreed.” Despite the strongly disagree response, no participant expressed this viewpoint during the interviews further confirming the possibility that the participant misinterpreted the question.

Figure 13. Participants’ Overall Satisfaction

Access to Medications

Encompassing both the motivating factors of helping oneself and helping others was the theme of access to new medications that are not yet available on the market. This confirms what is known in the literature regarding trial motivations. Helping oneself through management of symptoms, either decreasing or eradicating them, and helping others by participating in the drug to market process was important to participants. Many of the participants were hopeful about the potential benefits of trying a non-widely available medication that may work better for them, even if only for a relatively short period of time. One interviewee reported “possible better days with the medication” as motivation for
participation. Others reported the medication they were on or had tried during participation in a clinical trial had been “life changing.” Another participant reasoned,

If I want to try to get my disease under control, I mean, I have to try new things…find a medicine that might work, (and) help to get a medicine that actually works for schizophrenics out there…I feel that it gets me more help, that isn’t on the market, and if you if you have problems with medicines I mean, it comes down to trying to get something that works and yeah it’s a risk, but I'm willing to take it. You get more of a care system with it.
(Participant 10)

**Financial Incentives**

Financial incentives remained a shared theme amongst interviewees, though it was most commonly not discussed as the most important aspect relating to participants’ decisions to be involved in research. Within this sample of low-income patients, many participants stated they were receiving money from social security and lived with little income and used clinical research trials as means to supplement their income. Of the twenty participants, seventeen (85 percent) were either unemployed, retired, or disabled. Only three participants (15 percent) reported that they worked part time. In this sample, though not the main reason given for participation, money was still a source of worry in participants’ daily lives and therefore financial motivations were regularly mentioned throughout the interviews.

Participants stated,

It helps to put a little finance in your pocket.
(Participant 4)

I’m on social security but the money helps me buy food, it helps me buy medication.
(Participant 6)

I want a job now. I want one. I want it really bad. I want to go back to work. I wish I was never crazy. If I were never crazy, I’d probably be making means to be a lot more than six hundred dollars a month.
(Participant 17)
Participants repeatedly said the money received for their time and travel related to research participation helped them buy food, medicines, bus passes, etc. In many cases, financial incentives were part of the initial reason they became interested in research participation; however, after experiencing trial participation, while they still viewed the opportunity to earn money as a benefit, it was not the most important positive aspect of research participation in their view overall. Only one participant reported financial incentives as the sole motivation for research involvement.

Psychosocial support

Digging deeper into participant responses, beyond the motivating factors and underlying values of altruism, helping oneself and one’s illness, access to medications, and financial incentives, an overwhelming theme of clinical trials as psychosocial support for participants emerged in the interviews as a benefit for participants. This was a major finding in this study. Despite a growing body of research proving the need for psychosocial support, the availability of such mental health clinics and providers that incorporate such resources and cater to this low-income population are few. A large number of participants identified that they used clinical trials as a means of talking to and being around others, namely the staff at the research clinic. Opportunity for communication was a major topic throughout the interviews and was reported to be helpful by a majority of participants in managing and/or treating their illness and even improving social skills. A substantial percentage of participants touched on this,

Probably the best part would have to be actually talking to the people about what's going on. They’re asking things that doctors normally wouldn’t ask…it definitely feels like they’ve been more of a support system.

(Participant 10)
It gives me someone to talk to…and someone professional that has seen it before to talk to about it.  
(Participant 8)

…Easy to talk to and you can explain things and ask questions and he’ll answer them for you.  
(Participant 2)

Other participants reported experiencing psychosocial support, citing that their participation in clinical trials at INCR was therapeutic and helped them cope with certain aspects and stressors relating to their illness. Many reported they do not discuss their illness outside of healthcare settings.

I kind of use y’all guys as a stress reliever. If anything go wrong or said something wrong to me at where I live at, instead of acting, reacting right then and there with people, I come here and sit down and talk to you about it. You know, I just want your opinion.  
(Participant 13)

It’s made me come to grips with a lot of what's going on in my life…its giving me something to look forward to…something that’s giving me a way, a leeway of communicating what's been going on. Something to grasp at, and I can give them some kind of picture about what I thought about, what I've been through… I’m able to talk to people more, open up, and talk a bit more…I’ve been able to come to a place…where you know, you get along with everybody you smile, you say hello, you know just the regular things that you do to get along everyday…  
(Participant 18)

Quantitative results spoke to this theme as well. To question fourteen, “the doctor and staff at InSite Clinical Research care about my health,” 100 percent of respondents agreed. Eleven respondents (55 percent) reported that they “strongly agreed” they felt the doctor and staff at InSite Clinical Research cared about their health and nine respondents (45 percent) “agreed.” No respondents reported that they “neither agreed nor disagreed,” “disagreed,” or “strongly disagreed” with this statement. This finding highlights the overarching psychosocial aspect of participation in clinical trials frequently discussed as a benefit by the interviewees.
In the same vein as question fourteen above, question fifteen “the staff and doctor I work with at InSite Clinical Research really listen to me” elicited overwhelmingly positive reactions from participants. Fourteen participants (70 percent) “strongly agreed” that they felt that the doctor and staff really listened to them, five (25 percent) “agreed,” and one (5 percent) “disagreed.” Similarly to survey questions eight and ten above, the “disagree” respondent (participant 14) reported contradictory information in the interview, leading the student investigator to believe qualitative responses more accurately reflect the viewpoint of this participant.

Incorporated within the theme of psychosocial support is education about schizophrenia itself and learning about oneself in the process. This was reported by participants as both a motivating factor and/or a product of their experience(s) in clinical trials. Many of the participants spontaneously described that they had become more knowledgeable about
schizophrenia and learned information that helped them understand more about themselves due to their participation in research. This finding was distinctive in this sample population. This included learning about symptoms, management, and treatment options. Several of the participants reported feeling they were not told enough about their illness when they were diagnosed, many were diagnosed in hospitals and then discharged; one participant reported he was diagnosed in jail. Many described their struggle to understand what they were experiencing. Many responses during the interviews corroborated this theme of wanting to learn,

I used to have bouts with schizophrenia so, I thought, I should go see what they knew about, how it looks and new concerns with it…(So) people could explain more about what I’m going through and stuff and help me understand a little more about it. (Participant 18)

I thought maybe it could help me to understand my condition, you know, and get some information about it… It was a good way to find out more about my disease. (Participant 9)

Remarkably, several participants explained that they learned significant health information during their research participation. As explained by one participant,

(Name) explained to me that I have an ultra metabolism and that’s probably the reason why when I take medicine it don’t work. It wind up stop working for me. (Participant 1)

This increased understanding into one’s own biological and physical response to medication stuck out in this participant’s mind and helped to conceptualize past experiences with medication and illness through a different perspective. Similarly, four other participants learned about underlying health conditions that presented no outward bodily symptoms through testing done during their participation in a clinical trial at INCR. Participants brought up and discussed their reactions and understandings related to the uncovering of these conditions.
I had a kidney infection …So they told me ahead of time and I went to the, I’m going to the kidney specialist and they say everything was alright…but I still go to the kidney doctor for follow ups.  
(Participant 2)

Other participants with abnormal EKG results reported they also got follow up care after being informed at their clinical trial visit. Another dosage of diabetic medication was adjusted after a blood test came back high.

I went to the hospital the next day, sure did.  
(Participant 11)

See I have a heart murmur…and when the first discovered it they said something was wrong.  
(Participant 12)

Upon further questioning, all participants responded that they did not believe that they would have found out this information at that time otherwise, including through routine mental or primary health care. Other respondents reported that while perhaps initially, learning was not a motivating factor for becoming involved in research, they had undoubtedly experienced learning through participation. Comments such as,

Well, the attraction believe it or not the guy was telling me you could make some money you know, if you do the study, alright, so I did that, but I start learning other things.  
(Participant 13)

I get to…learn some things and I get to make an improvement in life…It’s been a life learning experience.  
(Participant 17)

Interviewees were resolute in their testimony and feedback regarding learning about themselves and their illness through research participation, a very strong theme found throughout the data. Learning about oneself is a common finding both in this study as well as in the catalogue of literature relating to clinical trial participation. Participants stated,

I do strongly agree with understanding my condition and myself by participating in this study, I strongly do understand more.
To give a person a chance to know themselves. To give them a chance to know other people and themselves.

It’s just like a child, we’re inquisitive. We need to know everything! That will help us to make a better choice in our care.

Prior research has shown that when it comes to chronic illness, “helping the client to understand the diagnosis and prognosis facilitates adaptation and coping,” furthering the need for increased education when it comes to treating the person (Drench et al. 2007: 234).

Question ten on the survey instrument “I understand more about my condition and myself since participating in clinical research” responses reflected this as well, with eighteen respondents (90 percent of the sample) in agreement with this statement. Eleven respondents (55 percent) reported that they “strongly agreed” that they understood more about their condition since participating in clinical research, seven (35 percent) “agreed,” one (5 percent) “neither agreed nor disagreed,” and one (5 percent) “disagreed.” Similarly to the previous questions, the “disagree” respondent (participant 14) reported, in great length and detail during the interview, how they had come to understand more about themselves and their illness through their research participation.

Figure 16. Participants Understand More about Condition Since Participating
Responses to question twelve in the survey, “I am satisfied with the amount of information given to me about my health during participation in a clinical research trial at this site” shed light on participant experiences. Nineteen participants (95 percent of the sample) reported they agreed they were satisfied with the amount of information given to them regarding their health during their participation in a clinical research trial at InSite Clinical Research. Twelve participants (60 percent) reported they “strongly agreed” they were, seven (35 percent) reported they “agreed,” and one (5 percent) “neither agreed nor disagreed.” No respondents reported they “disagreed” or “strongly disagreed” with this statement. This finding helps to support conclusions that participants are making decisions based on information relating to the concepts of autonomy and informed consent, central to research participation, and also further demonstrates the importance of debriefing to participants of clinical research trials.

Figure 17. Participant Satisfaction with Information About Health Given During Participation

*Sense of Participation/Something to Do*

Throughout the interviews, a sense of participation and engagement accomplished through clinical trial participation was noted as meaningful in the minds of participants. This theme ties into the psychosocial support facet of research participation and was a perceived benefit for many interviewees. Several respondents shared their viewpoints,
One thing, it gets you out of the house. It gets you out for yourself thinking of all the things that’s wrong with you. What you cannot do and what you will not do. It gets you involved in another. It helps you participate in something that’s for you. You don’t know how it works, because they hadn’t told you, but it gets you out of the house, which is important...Because if you stay in the house so much you’ll go batty. No one to talk to. It helps your social skills, your coordination skills, all those things. It helps.

(Participant 12)

I feel like I'm able to participate, you know not just going to events and observing. I really love to participate you know, once again as if I was in school and still doing and still being part of the participation other than just sittin’ back observing others enjoyin’ themselves as if I'm sitting back in a condition where I can’t do the same thing that I love to do as far as participating is. I’d like to be one of those that likes to participate just as well. So if I can get back on my feet and be able to do that, I'm quite sure the next person who is lookin, and learning, listening and understanding can do the same. And not to be the one, don’t be the one being left out you know, and don’t feel sad because you got an appointment to make with the doctor or nurses, don’t feel disappointed cause its gonna help you, its gonna benefit you to get out the house and make those appointments cause you know cause you never can tell what a person when you get there, you never can tell what a person might say to just brighten your day, you know. Make you feel a lot better, and less depressed, less stressed out.

(Participant 8)

During research involvement, clinical trial participants will generally spend a considerable amount of time at the research clinic, working closely with the staff and doctor to complete study procedures. Detailed assessments and questioning is routine, as biomedical psychiatric research involves, not only physical and biological testing but psychological testing. Thorough documentations of life histories elicited via the patient are recorded, in addition to medical records, in order help to provide accurate data collection. Participants described these procedures and their experiences throughout the interviews. Other participants mentioned that participation in research was not only something to do but a reason to “stay clean” and “stay out of trouble.” As one participant mentioned,

I used to do marijuana. but I quit since I was doing the research center cause I knew I couldn’t do it...I know I shouldn’t have anything to do with marijuana because of my illness anyway.

(Participant 6)
All participants are counseled to adhere from illicit drugs during their clinical trial involvement and often held accountable through testing for prohibited substances on a consistent basis, depending on the protocol.

**Self-Esteem/Sense of Accomplishment**

Participants seem to feel participating in clinical research gives them a sense of accomplishment by being proactive in their health management. Participants reported feeling more independent and accomplished through their involvement with research trials.

Interviewees cited,

I feel like it’s something I needed to do…to address my illness, so it’s like an accomplishment, it’s an accomplishment that I needed to make. (Participant 9)

It was interesting because anything that would make you feel better about yourself you should want to try that. (Participant 14)

(I) get to make an improvement in life. (Participant 17)

I’ve been trying to get in some studies for a long time and when I finally got into this one, I was happy. I said maybe my thinking could get better, maybe I can keep a stable job part time and focus more on things I need to be focused on. I thought after I made the decision, it’s a good way to make extra money and I think it’s a good way to get better and I thought it was a win-win. (Participant 3)

I'm doing something right, you know…I'm listening to a little bit of wisdom, tryin’ to help myself, I'm not so much into the drugs, the drinking, because that don’t do nothing. You know but make it even worse and then I just, you know, I have to take my medicine the correct way. (Participant 13)

**Friendship**

An unforeseen motivation for and product of experience of participation in clinical trials noted by interviewees was friendship. Many participants described the longing to be treated
as a “normal person,” not “talked down to.” As previously stated, the opportunity for communication and the sense of being listened to were cited as a major benefits and motivations for research participation and the treatment by the staff seemed to make a lasting impression on interviewees. Several participants spoke about feeling like participating in clinical trials at INCR was akin to friendship or even family,

Doctors can do a lot of things, they can be a friend to you, you know, more than just your doctor, some doctors really are concerned about your situation, you know they would show me a sense of care-ness about me and such a loving feeling you know and that’s what I like about this clinical study. They show me love you know, and I show love back… Dr. Shiwach, he’s real concerned about his patients and people that comes through his study.

(Participant 7)

I have a friendship with the staff.

(Participant 15)

They’re great, they’re super. I like these people here. This is my family you know. They treat you like you are a person instead of somebody’s that got an illness or somebody that is sick. They treat you just like you’re part of their family. Just as well like your own family. Everybody treats me like I’m a big brother or an uncle or whatever around here.

(Participant 14)

Another participant described the doctor as,

A person with great integrity. To look at people that are coming in to see them, and look at them as you would look at your son, your daughter, your mom, your dad, your cousin, your grandmother, and your family member or even as yourself.

(Participant 4)

Close Continued Care

Participants described their experiences with clinical trials as a source of close continued care. Participants, while recounting their interactions at INCR, designated the research clinic as a “good resource” and a “one-stop shop” for treatment of their illness. Others reported that it made their quality of life better. In one case, a participant reported the eradication of movements associated with tardive dyskinesia due to long term antipsychotic use for
schizophrenia during her research participation that drastically improved her life. A majority of participants stated they felt they were treated with genuine concern. Care and respect were the two most commonly used words by participants when describing their experiences at the clinic. Many participants spoke about the compassionate nature of the staff and openness and “ease” in dialogue they found at INCR that made them feel comfortable. Interviewees who had participated in biomedical research at other facilities were asked to describe and compare their experiences. One participant, when comparing their participation in research at another research institute remarked,

That place is so huge, it be so big you know, it ain’t like close-knit.
(Participant 4)

The smaller size of the clinic was mentioned by several participants as a benefit.

Interviewees noted other differences between InSite Clinical Research and their historical experiences at other care facilities,

I’ve been spoken to like I’m an adult…not like other places.
(Participant 10)

Before I came here and got in with you, ya’ll guys, I was seein’ a doctor that had me on maybe ten pills, zombie-fied…I mean walking around zombie-fied, slobberin’ all out the mouth and all of that…after I got here and talked to Dr. Shiwach…he got me straightened out… I’ve just come a long way... Ya’ll the best as far as I’m concerned, I like dealing with ya’ll you know.
(Participant 13)

Overall, comments regarding healthcare experiences reflected systemically lacking psychosocial aspects of support. Prior research has argued that the “close monitoring provided and the psycho-educational programs associated with the research clinic may result in more substantial compliance…than would be expected in standard care” (Carpenter et al 1999: 223). According to the National Institute of Mental Health, psychosocial treatment for those with schizophrenia can facilitate greater medication compliance, reducing risks for
relapse or hospitalization (NIMH 2015). Participants described a feeling of peace of mind they got from participation. Other feedback echoed these themes as well; the staff of INCR was described as,

Very respectful, very caring, That’s what keeps me coming back. And I know it helps a lot of other people that come here because most doctors office, MHMR, any doctor’s office, you don’t get that, you really don’t. When y’all talk, I learn more here. The doctors in Austin, you get your money, you get your meds, and that’s it. It’s not where they just throw the pills at me here, my MHMR doctor don’t even do that, they just (throw the pills at you) I get to say ‘hello, how ya doin’ and that’s the only three words I get to say, he’s writing a script and you’re gone.
(Participant 19)

He has a great staff, very organized, they care about you, they not only do it just for their job but they care about the patients too and you know, sometimes they go out of their way to do things for you know like you need something...
(Participant 5)

I get satisfaction, I get honesty, I get professionalism, and I get a bunch of hugs from everybody here.
(Participant 14)

Transportation

InSite Clinical Research is unique in that it provides transportation services to its research participants; many other research facilities do not offer this door-to-door transportation service. During the interviews, participants cited this as a positive aspect of their clinical trial experience(s) and a reason for continued participation at InSite Clinical Research. It was apparent that when it comes to management of their illness through attending appointments with healthcare providers, a common obstacle to care is transportation. Other aspects of participants’ routine mental health care that were identified by participants as negative were very long wait times at clinics such as MHMR, Lifenet, Adapt, etc.
Debriefing

Another major theme and participant expectation found to be of significance to every individual that was interviewed is the importance of debriefing to participants, confirming findings in the literature. Participants expressed they wished to be informed of the results of any physical, cognitive, or diagnostic tests done during their involvement in clinical trials as well as overall study results. Participants were eager to gain access to the investigational drug should it work for them during the trial and become approved. This finding has implications for the possibility of greater dissemination of information on behalf of InSite Clinical Research and could potentially be applicable to other research facilities as well. Interviewees adamantly agreed they wanted to be debriefed and were invested in the outcome of these studies for effective therapies because they themselves had become invested through their research participation.

Yeah! You know, I don’t wanna wait no five years or ten years down the road to know, is this stuff I’ve been takin’ gonna be a deal or a dud you know.
(Participant 4)

I’m interested in knowing because if it works I mean when it comes on the market, I’d like to try it.
(Participant 10)

Quantitative results reflected these participant viewpoints as well. To question twenty “knowing the results of the clinical research trial or trials I participate in is important to me,” nineteen participants (95 percent) in the sample agreed. Thirteen participants (65 percent) reported that they “strongly agreed” that knowing about the results of the clinical trial or trials they participated in was important to them, six (30 percent) “agreed,” and one (5 percent) “disagreed.” All twenty participants narrated debriefing was important to them during the qualitative interviews.
Stigma about Research

Most participants voiced feeling stigmatized, not only by their illness but also by their participation in research from the view of outsiders. Many shared that they were aware of the stigma that participating in clinical trials can have. Several reported their friends, acquaintances, or family members’ responses to their participation in research as unenthusiastic at first. Others reported they had heard the words “guinea pig” or “lab rat” as stigmatizing reactions in the past. It is important to distinguish these sentiments were not shared by the research participants themselves, rather they were comments received when sharing that they had begun or wished to begin participating in biomedical research for schizophrenia. Perceptions of stigma related to research participation were mentioned by a majority of participants interviewed, highlighting a general widespread lack of public awareness and knowledge about clinical research.

Worry About Risks

Assessment of the risks associated with research participation by a potential clinical trial participant is essential for ethical informed consent. When focusing on quantitative results, question seventeen “I worry about the risks of clinical research trials (includes procedures and study medication)” showed varying responses by participants. Three participants (15
percent) responded that they “strongly agreed” that they were worried about the risks of clinical research (including study procedures and study medication), four (20 percent) “agreed” they were worried, two (10 percent) “neither agreed nor disagreed,” ten (50 percent) “disagreed” that they were worried about risks, and one (5 percent) “strongly disagreed.” One participant wrote in “blood draws” next to the question, and several respondents reiterated this aspect of participation caused the most worry for them regarding their involvement with biomedical research during the interviews. Despite this potential barrier to research participation, Taylor et al. found that “participants may experience distress related to particular aspects of the study, but still maintain the overall value of the research” in congruence with this study’s findings (Taylor et al. 2010:347).

Figure 19. Participants’ Worry About Risks of Clinical Trials

3. Autonomy, Informed Consent Experiences, and Trust During Participation in Clinical Trials

Respondents were questioned regarding when they made the decision to participate, their experiences with the informed consent process, and their perceptions of their own autonomy and assessments of risk when it came to clinical trial participation in order to further understand how the informed consent process is being comprehended. Focusing specifically on informed consent was somewhat difficult to illicit clear responses during these interviews, however patterns and themes emerged amongst the data.
Decision-Making

Interviewees adamantly agreed with their ability to make decisions for themselves and their own personal autonomy and independence. Stipulations to this autonomy were mentioned by some participants, such as stability on medication and severity of their illness at the time. Given this, most participants expressed it was not unreasonable for others (family members or caregivers) to be involved in their decision-making should their illness be very acute. Others did not want anyone else involved in their decisions. Acuteness in patients with schizophrenia would be easily identifiable to experienced clinicians and almost all clinical research trials include criteria that excludes those with schizophrenia experiencing a recent or current period of exacerbated symptoms, removing the possibility for those with experiencing a severe acute phase to become involved in research. The ability to make their own choices, not only in the realm of research participation, but in all spheres of life was significant to participants in this sample.

…They shouldn’t, you know deny us because we have an illness, they shouldn’t deny us. Like most of the doctors that I come across.

(Participant 7)

It is important to note that stability or lack of acuteness does not always mean complete absence of symptoms in those with chronic schizophrenia. Many participants voiced they experienced symptoms of schizophrenia frequently, despite stability on medications. One participant when describing his illness stated,

It started out seeing things and hearing things through cars and seeing things through cars. Seeing things through ceiling fans and stuff like that. I just saw a purple dog right there. Like pink and yellow…but I’m not freaking out, don’t worry about it, I’m on my medicine. Don’t be alarmed.

( Participant 17)
In congruence with the overall affirmation of personal autonomy by participants in this sample, a majority of interviewees agreed that others diagnosed with schizophrenia should make their own decisions, though many expressed that the ability to do so was dependent on the specific person and situation. Along the same lines as the personal autonomy responses, the severity of their illness was named as the most common deterrent to autonomous decision-making. Stability on medication(s) and “thinking straight” was also cited as important when it came to autonomy. In cases such as these, participants stated others with schizophrenia may need help with decision-making. Several participants’ responses aligned with literature review findings that the ability to make an informed choice was related to cognition and should be assessed on a case-by-case basis. There was a general recognition amongst participants that schizophrenia was a subjective experience and different for each individual in context.

I think it really depends on the person, I mean there are different levels of every disease, I mean some people are functioning, some aren’t, some people know exactly what's going on, some people don’t. I mean it really just depends on the person, if they’ve been deemed by the court unable to function… I mean I don’t think they should be involved in research trials…
(Participant 10)

Some could be worse than others you know. We’re all not the same so one that can’t make a decision for themselves they might need some help with making a decision like that or they might not want to do it in the first place. They might be scared for whatever reason you know. But if you’re able to make a concrete decision like that then you should be able to.
(Participant 14)

I understand that there is some people a lot worse than I am might have difficulties understanding.
(Participant 19)

They should try to understand each individual as a schizophrenic, because I think there’s different levels of schizophrenia, I don’t think we should all be categorized in the same category…
(Participant 9)
Research Involvement

Participants interviewed presented a range of experiences when it came to deciding to become involved in biomedical research. A large majority had decided to become involved in clinical trials based on the recommendation of a trusted individual. This included recommendations from a trusted healthcare provider (most commonly Dr. Shiwach) or other trusted individuals, such as boarding or group home managers. Other participants became involved based on word-of-mouth referrals from trusted family or friends. In terms of advertising by InSite Clinical Research, only one participant reported they became involved in research due to seeing an ad in the newspaper. Field recruitment methods appear to be more fruitful in reaching this specific population, six participants reported they became involved with research at InSite Clinical Research due to face-to-face recruitment efforts. These methods include direct contact with potential participants by the recruitment staff of InSite Clinical Research via the development of established relationships with over thirty boarding homes in the Dallas-Fort Worth metroplex, where participants diagnosed with schizophrenia are regularly recruited. Recruiters at InSite Clinical Research frequently distribute IRB approved clinical trial specific flyers and brochures at these boarding homes, as well as at physician offices, mental health clinics, and at community events.

When asked about their experiences with informed consent many of the participants commented on the large amount of information presented and the length of the process. Several participants reported understanding the informed consent form materials and the way it was explained by the staff at InSite Clinical Research, including the aims and procedures of the study, and the possible risks and benefits.
I understand that there is some people a lot worse than I am that might have difficulties understanding but from my experiences ya’ll pretty much explain, break it down to where my dog can understand.

(Participant 19)

They keep the lines of communication open. They don’t spring anything on you. They explain everything before it happens and when it’s gonna happen that day. And while your there if you have problems, they help you with that problem so you can get back to what you were originally suppose to do.

(Participant 12)

Interview data shows that in this sample, several participants had already decided to participate in clinical research trials at InSite Clinical Research before reading and signing the physical informed consent form(s) and participating in the consenting process.

Interviewees appeared to make their own assessment of benefits and risks prior to this formal discussion. This was most commonly based on trust and history with the medical provider recommending research participation, as in the case of five participants interviewed, or by their own risk assessment beliefs, as in the case of five other participants in this sample. Trust emerged as a major shaping factor affecting participant decision-making. Of the participants who based their decisions on trust, many mentioned they were long-time patients of Dr. Shiwach,

…Dr. Shiwach asked me if I wanted to be in it, in the study, and he explained to me about the study and I told him I would try it.

(Participant 2)

One general theme was identified when it came to participants’ reasoning and personal risk assessments, several interviewees elicited the belief that medications are risky in general and the clinical trial investigational drug might help them. All ten participants who reported making their decision before reading the informed consent form reported they trusted the doctor and staff at InSite Clinical Research.
…My opinion is, I take psych meds anyway, I take meds anyway and it’s supposed to help me get better. That’s why I do it, I don’t want to take meds everyday and I usually do it anyway. And there is a risk for those too, but I still take it. So I’m doing the same thing everyday, even with the study and without the study…

( Participant 3)

Two others explained it was faith or spirituality that guided their decisions,

I kind of got that it was meant for me to go, because if not he wouldn’t have been there at that particular time and place, place and time, so I agreed to come into the trial…

( Participant 8)

Through the grace of God it became the right decision.

( Participant 4)

Eight participants reported they made the decision to participate in research after going through the informed consent process. Many of these participants reported they involved others in their decisions. They took the informed consent forms home with them to re-read or discuss with family, friends, or church members before making their choice. One shared that they informed their primary care practitioner before they agreed to become involved. Many said they asked questions before signing their consent to participate. These findings indicate that perhaps informed consent does not have a defining impact as a process to all of the participants in this sample and elucidates the shaping forces influencing decision-making, the largest of those being trust. Brody, Gluck, and Aragon uncovered similar findings with research that showed less than twenty percent of their sample of undergraduates taking part in psychological research viewed the informed consent process as a decision point (Brody et al. 1997: 285).

Trust was a central theme found in every interview, reaffirming what is universally found throughout the literature. Every participant interviewed reported that they trusted the staff and doctor at InSite Clinical Research. Trust was not only identified as a factor shaping participation decision-making, as in the case of involvement based on the referral of a trusted
healthcare provider, but also as a common value and belief held by participants when it came to how they perceived the relationship between themselves and the study doctor and clinical trial staff. As described by one interviewee who was referred to clinical trials by a healthcare provider,

> From what I had observed you know, Dr. Shiwach, pretty nice doctor, he knew exactly what you going through with and I know he know whether or not you utilizing tools that will help you and he's not, he's has never gave medicine that’s not going to benefit you or nothing like that. (Participant 8)

> They should know more about the study, and I trust that they do. (Participant 1)

> I don’t feel like they would tell me or do anything that would harm me. (Participant 18)

When questioned about why participants trusted the clinical research staff and doctor, a majority of responses resonated back to interpersonal treatment. In alignment with the reply below,

> ’Cause of how they treat you, so well. You know, they don’t just act like it’s all about the money, they care about you. The patient. (Participant 5)

Other reasons for trust participants mentioned included, professional experience, credibility, and responsibility.

Quantitative results strongly echo these conclusions. In response to question thirteen, “I trust the doctor and staff I work with at InSite Clinical Research,” eighteen respondents (90 percent) agreed. Twelve respondents (60 percent) “strongly agreed” that they trusted the doctor and staff at InSite Clinical Research,” six (30 percent) “agreed,” and two “neither agreed nor disagreed.” No respondents reported that they “disagreed” or “strongly disagreed” with this statement. These findings corroborate qualitative findings relating to trust. As
mentioned previously in this paper’s discussion of results as well as a prominent topic throughout the literature, trust is a strong theme when it comes to factors affecting research participation and it is continuously shown to be central to the relationship between health care provider and patient.

Figure 20. Trust of Doctor and Staff

*General Knowledge about Clinical Trials*

Interviewees were asked about their basic knowledge regarding clinical research trials. Overall, interviewees identified the general purpose of clinical trials and clearly understood the voluntary and confidential aspects of participation. Interviewees were cognizant of many aspects of clinical trials including the potential risks and benefits. Though trust appeared to shadow some of the risk aspects in participants’ minds as well. Previous literature has shown that “clinicians are known to have difficulty expressing uncertainty,” therefore it is advocated that other members of the research staff be involved in discussing risk and uncertainties relating to the trial as well (Featherstone et al. 2002: 718). As one participant mentioned,

> You don’t get any medication that’s harmful to you.
> (Participant 1)

Participants were asked about their knowledge of placebo during the interviews; it was most commonly identified as a “sugar pill,” an “undercover medication,” a “dummy drug,” or a “water pill.” Clarifying research terms such as this could be beneficial in furthering understandings. Several participants explained the purpose of research,
I think y’all guys are trying to find out exactly how different medications work, and you know, there's nothing wrong with that. There's nothing wrong with that. Because I know that you have to. I think it’s a two way thing between us, doctors and guys like me, I'm like you know you kind of trust me, I kind of trust you. You know, it makes a good relationship and then all at the same time it’s a positive thing and help for my, my mental status.

(Participant 13)

To try to help further understanding of the disease, because not much is known about it, why it is caused.

(Participant 10)

To test the medicine’s effect on as many people as they can.

(Participant 1)

To see if medication will work in different people in different circumstances and to see if it will help them or harm them.

(Participant 2)

To help people with mental illnesses, so the FDA has full demonstration for putting drugs on the market that can help people. So these drugs have already been tested and if they can work for other people, maybe they can work for other people also.

(Participant 6)

It’s to see if the medicine helps you. And if the medicine helps you then those people that makes the medicine can put it on the market for those people that maybe can’t afford it for that matter.

(Participant 14)

In the vein of altruism and gaining insight into themselves and their illness, others comprehended the purpose of clinical trials in a different way, as a way to not only help themselves, but also the opportunity to pass along information and help others. One interviewee was eager to share what they had learned with others with schizophrenia, they stated,

If there's something that I learn from the person that I'm havin’ discussion with about my mental illness, if it’s a related advice or something to take in consideration I pass it along to the next folk.

(Participant 8)

I think it’s to show the patients, make them see themselves and how they handle things and how to communicate with people.
Participant Recommendations

Food Options

The disadvantages noted by interviewees when it came to research were mainly centered around the discomfort of blood draws and fasting. Several participants made suggestions that more food should be offered to research participants to help assuage this distress. InSite Clinical Research currently offers small snacks for clinical trial participants, including vending machine items such as soda, chips, and/or candy and participants are given Lunchables after blood draws. Snacks and coffee are often supplied for participants coming early in the morning, if they are not required to be fasting at that time. One participant mentioned, not only the need for more food to be available, but specifically nutritious foods, which in combination with medication, he felt could better treat his illness. This particular participant commented that he did not have access to nutritious choices where he lived at a boarding home,

They serve three meals a day there. Not compatible with my cholesterol diet sheets…I don’t get very much of what’s on my diet sheet that I should be receiving for my cholesterol problem.

(Participant 8)

Based on the frequent comments relating to food and the considerable amount of time spent at the research clinic during clinical trial participation, the opportunity exists to meet these low-income participants’ needs by offering healthy nutritious snacks for clinical trial participants at the research clinic.

In addition to participants’ comments regarding the discomfort of blood draws, difficulty of fasting, and lack of food options, lack of access to clinical trial medication after participation was completed was also cited as a disadvantage by interviewees. Some
participants also suggested more phone contact be made between the staff of INCR and the participants sporadically in between visits to the clinic to keep communication ongoing. Commentaries that resonated the importance of communication were noted. As one participant indicated, they would like to be able to call a counseling phone line for support,

To get something off your chest, they should have something like where you can call and talk directly to someone.
(Participant 5)

Currently phone calls are placed to participants by clinical research staff based on the need to confirm or reschedule appointments, gain more information regarding a trial related matter, or as required by specific protocol criteria for follow-up calls to check on the safety and condition of the participant, should they have experienced any adverse events during their participation. Making an appointment to speak with a clinician, as a clinical trial participant, requires scheduling and while participants may call a 24-hour emergency hotline that reaches the Principal Investigator directly, there is no phone line, outside of normal clinic business hours, to speak directly to research staff.

Talk Simple

Other interviewees voiced they had trouble understanding some terms and “fancy words” contained within the informed consent forms or requested that the information be summarized simply in order to further understandings. This research finding demonstrates the need for educationally, linguistically, and culturally appropriate informed consent to be given in a meaningful way that fits the context of the participant’s life.

Only thing I have a problem with is when you're talkin’ to me, talk simple, because I don’t understand the big definitions and the big words and stuff like that.
(Participant 8)

Some people, like myself, don’t read through that day all at once, so they can explain it to them, give them in a summary, it helps.
One participant, when asked what skills a person explaining informed consent should have reported,

Communication skills, directional skills, understanding skills, explanatory skills, they should have all the skills you need when you’re coming into something new. It’s just like you’re coming into a classroom. You orientate this student to everything that’s in there that they will use and utilize. That’s what they need to have.

(Participant 12)

Survey Comments

Participants were asked to include any additional comments they may have had regarding their experiences and/or suggestions at the end of the survey. The following table lists the participant comments received:

<table>
<thead>
<tr>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>“I feel good about myself, may y’all keep up the good work.”</td>
</tr>
<tr>
<td>“Listen to the patients feedback and decide as to whether or not they are not very very ill.”</td>
</tr>
<tr>
<td>“The love the staff and workers show, being patient.”</td>
</tr>
<tr>
<td>“Good people, promote.”</td>
</tr>
<tr>
<td>“I believe it a good, the studies need pay more.”</td>
</tr>
<tr>
<td>“It helps me a lot and just learning.”</td>
</tr>
<tr>
<td>“It has given me a good overall view of what has existed and is to come from these trials.”</td>
</tr>
<tr>
<td>“I love everyone.”</td>
</tr>
</tbody>
</table>

Table 1. Participants’ Survey Comments
CHAPTER 5: CONCLUSIONS AND DISCUSSION

As in the majority of cases surrounding vulnerable populations and research, ethical concerns about harm in the schizophrenic population are often raised due to variability in cognition and severity of illness and the personal risks associated with clinical trial participation (Taylor et al. 2010: 343). Despite a substantial catalogue of literature across disciplines reaffirming the possibility for autonomy in those diagnosed with chronic schizophrenia, narratives surrounding the ethicality of conducting research in this mentally ill population are frequent and require a vast amount of continued research that address and target these concerns. In the meantime however, the need for biomedical research that furthers new psychiatric therapies is vital.

Decades old, long-used anti-psychotic medications continue to be currently used primarily to treat symptoms of schizophrenia. Many of these are related to the development of numerous side effects, including tardive dyskinesia, an often-permanent condition that causes abnormal involuntary movements throughout the body and may contribute to a decline in quality of life (NIH 2015). Other side effects of these currently used psychotropic medications include metabolic disorders that may cause diabetes, weight gain, or lipid disorders. The need for constant improvement in technologies and drug therapies is pervasive within the healthcare and pharmaceutical industry, it is important however to balance these driving forces by including the patient perspective, humanizing and maintaining the patient at the center of the care model.

These data directly from clinical trial participants themselves support the positive aspects related to research participation, as hypothesized, and help to substantiate the ethical viability of conducting research in this low-income schizophrenic population. Overwhelmingly positive feedback from clinical trial participants at InSite Clinical Research, not only verify previous research regarding those with schizophrenia’s involvement in research but also shed light on the
underlying values, motivations, beliefs, attitudes, and perceptions in this population. Participants in this sample are using clinical research trials not merely as a source of financial means and/or an opportunity to access medication, but as source of close continued care and psychosocial support as is seen in previous literature specific to those diagnosed with schizophrenia in clinical trials. This particular low-income sample did not significantly deviate from prior research in regards to their motivations for involvement in research. While receiving money for their time and travel related to research participation was considered a benefit and money undoubtedly was a source of worry in their every day lives, participants did not discuss financial motives as the primary or sole motivator for their participation. This is important to recognize as often low-income populations are considered the most vulnerable when it comes to mentally ill groups.

Research participation in this group is viewed as a personal benefit and a way to help themselves and help others in the process, validating altruism as a leading motivator in this population as is seen in prior literature. Participants shared a wealth of rich experiences during the interviews surrounding how their participation in research touched many aspects of their lives, furthering the argument for increased focus on the whole person when it comes to treatment of one’s illness. The findings contained within this report speak to the social context of illness as is evident by respondents’ reports of psychosocial therapeutic benefits not found elsewhere according to this population. Important aspects include, being heard, being around others at the clinic, participating and having something to do, feeling independent, and the opportunity to communicate with others in a caring and respectful environment, free of stigma. Unique to this sample is also the theme of friendship with the research staff, cited by many participants as a product of their experiences in clinical trials. Through empowered learning about their illness during their participation in clinical research trials, participants are gaining
insight into themselves and their disorder and gaining self-esteem. Learning about schizophrenia appears to be significantly important to this low-income population, a finding distinctive to this low SES group. This aspect is seen in the literature but emerges in this study as distinctly meaningful in this particular sample, possibly due not only to low levels of education, but the inadequate standard level of health care received by this low-income group generally in which a majority of the participants in this study report they are not adequately educated about their diagnoses.

Another area of importance to participants includes debriefing, a key area of concern to participants who wish to remain active and informed when it comes to their health care decisions. Research findings indicate that participants’ value and support their own autonomy tenaciously however, authentic choice when it comes to informed consent is often shaped by other underlying factors. Factors such as past experiences may color an individuals’ own risk/benefit assessments and influence relationships of trust such as the relationship between healthcare providers and patients within the context of a hegemonic biomedical model.

Trust, as is discussed throughout the catalogue of literature on research participation, was found to be significant in this research study. Trust was an underlying value present and reported by every participant in this sample, further demonstrating its importance as a motivation for research participation. Trust built between participants and research staff over time was also seen amongst the data, as hypothesized however trust as a factor shaping decision-making was not foreseen and presented as a major finding in this study. This study uncovered various differences when it came to informed consent experiences, including a significant portion of participants who reported they made their decisions to participate before reading the informed consent form. Trust again appeared as an overarching theme amongst the data, influencing both decision-
making and perceptions of the clinical research staff at the clinic. These findings have implications for how informed consent is conducted and how recruitment is navigated, as trusted healthcare providers could be further utilized to recruit interested possible participants. In order to promote genuine understanding when it comes to informed consent, meaningful and educationally appropriate communication is essential.

Though this research did not specifically target African American participants, ninety percent of the sample identified as African American/Black, distinctly characterizing this group not only as low-income but also as minority. The general underrepresentation of minority populations in clinical research can be informed by the findings in this study. The results of this research have implications for clinical trial recruitment of African Americans as the perspectives, insights, and motivations of this population when it comes to participation in biomedical research trials are highlighted within this ethnography. The larger representation of African American males in particular this sample also directly counters what is known in the literature regarding African American males being the least likely to participate in research and sheds light on their experiences and incentives (Byrd et al. 2011: 480, Shavers-Hornaday et al. 1997).

Conclusions regarding trust factor highly when coupled with what is known in the literature regarding African Americans and distrust when it comes to research participation, as lack of trust is one of the leading reasons for non-participation (Byrd et al. 2011: 480). Though not previously hypothesized, the findings here within can be used to help mitigate the lack of inclusion of minority groups in biomedical research through purposeful and meaningful recruitment tactics incorporating opportunities to cultivate trust, learning about schizophrenia, community partnership, and friendship with this underserved population. Focusing on physician recommendation in regards to clinical trial recruitment and awareness when it comes to reducing
stigmatizing attitudes can be beneficial in this group (Ford et al 2013: 30, Carpenter-Song et al. 2010: 224).
Research Questions Summary

What motivates this low-income population’s participation in clinical research trials? While financial incentives do remain important to participants, they are not solely the motivation for involvement in clinical research trials amongst this low-income population. Participants identified other areas and motivating factors for their participation such as helping people, helping themselves, access to medicine which can decrease or eradicate symptoms, and the opportunity to learn and understand more about their illness and therefore themselves. The ability to interact and be around others also motivates this population’s participation in clinical trials.

How have participants experienced their participation in clinical research trials? Participants are using clinical trials as source of social and psychosocial support and source of close continued care. A “care system” and a “one-stop-shop.” Many expressed that schizophrenia, in their experience with the illness, had caused them to isolate themselves and makes it hard to communicate with others for reasons such as fear, paranoia, and stigma. Many participants cited one of the major advantages of participation in clinical trials was the opportunity to communicate and be listened to. Many feel genuine concern on the part of the staff, can speak to them openly, and feel like they are treated with respect and as a “normal person” not merely as a person with a disease. Some participants conceptualize their relationship with staff at InSite Clinical Research as friendship or even family.

Participation also gives participants a reason to get out of the house and feel engaged in life, a feeling of “joining in” while involved. Participants voiced that coming to the clinic helped their social skills improve and participation improves their self-esteem. Many do not discuss their illness with anyone else. There is a general attitude that the illness has changed them and they are “different” than before, clinical trials were explained as a means to understand themselves better and described by one participant as a way to “get back to me.” There is a general sense of independence participants expressed from participating in research and a sense that participating keeps them accountable and helps them to achieve their goals. The size of the staff and clinic was mentioned as an added benefit as compared to other places that conduct research, InSite Clinical Research was described as being “close-knit.”

What are the attitudes, values, and beliefs held by this population in regards to clinical research involving schizophrenia? Participating in research in order to help others is major theme found in these interviews, confirming the literature that states altruism as a leading motivating factor. Helping themselves is also a key motivation for participants. The interviews and surveys show that debriefing remains extremely important to participants and every participant interviewed reported that they placed trust in the staff and doctor at InSite Clinical Research. Overall participant feedback is positive.

What do participants hope to accomplish by participating in clinical trials? Participants are learning more about their illness and also finding out other information about their health that they claim they may have not otherwise (examples include finding out that they were a fast metabolizer of drugs, had dangerous blood sugar levels, having a heart murmur and other heart issues discovered via ECG).
How does this population perceive its autonomy? Participants in this sample strongly supported their own autonomy. Participants expressed the viewpoint that they are able to make decisions but many voiced that it was reasonable to want other family members involved at severely acute times during their illness or times when they were unstable on medications.

When do they decide to become involved with research? Participants’ decisions to take part in biomedical research is shaped by underlying factors. Many participants chose to be in trials based on the recommendation of their doctor or health care provider or another trusted person in their life (most commonly a group or boarding home manager) while others were referred through word of mouth by friends or family or through recruitment and/or advertising. The data showed that many of the participants in this sample made up their mind before they read the informed consent form, based on trust in their provider or their own assessment of benefit to them or a combination of both, which has implications for how informed consent is conducted.

How is informed consent being understood? Based on these data, it doesn't seem to have a defining impact as a process to many of the participants in this sample. Though participants in this sample generally understood the purpose of clinical trials, including the potential risks and benefits, and the voluntary aspects, some reported difficulties understanding research language and terms. Participants need to be consented in a culturally, linguistically, and educationally appropriate way to ensure meaning in context.
1. Recommendations

*Recommendations to Informed Consent Procedures*

Updated guidance from the Federal Drug Administration (FDA) mandates the informed consent process move beyond the document and “be the basis for a meaningful exchange between the investigator and the subject” (Gearheart 2014). While InSite Clinical Research’s standard operating procedure (SOP) regarding informed consent meets industry standards, additional language relating to meaning and comprehension in context at every interaction is recommended to be added to the SOP. The results of this research reinforce this FDA update and accentuate the need for emphasis on meaning when it comes to genuine understanding and explanation to clinical trial participants.

These research findings demonstrate the necessity for informed consent language and communication to be understandable at a participants’ educational level. The new FDA guidance “encourages options to text-only consent forms…presenting information as graphs, tables, or diagrams instead of written explanations,” opening up the possibility for diverse and personally tailored methods of documenting informed consent understanding (Gearheart 2014). In addition to these suggestions, after conducting this ethnography, the following recommendations are given:

- To encourage further checks on comprehension for understanding and meaning not only at the time of initial informed consent but at all subsequent visits, as based on these data and previous literature (Stone et al. 2004).

- The need to clarify most research terms in a culturally, linguistically, and educationally appropriate way. Terms such as placebo, double-blind, allocation, and adverse event, for example.
• Increase education to further general knowledge and awareness of the purpose of clinical research trials, not only for individual participants but also amongst the general public. This could be accomplished through additional community outreach or attendance at public events or support groups to spread information and awareness. As per previous research, willingness to participate in biomedical research is related to knowledge about research and its purposes (Kaminsky et al. 2003: 282, Ford et al. 2013: 30).

• Increase individual education about schizophrenia, a direct need for participants utilizing clinical research trials as a source of information.

• The opportunity exists to further improve and enhance debriefing communication practices both during research participation and after a clinical trial is completed. This could include additional correspondence informing and updating the participant regarding the approval of an investigational product. This will include the participants throughout the process, address their valued needs, and may also impact participant retention as it would assist in maintaining communication after clinical trial participation.

• When it comes to diminished capacity for decision-making, as is often a concern when conducting research amongst those with schizophrenia, the use of the UBACC is recommended at InSite Clinical Research.
  
  o The UBACC is a practical validated instrument that takes less than five minutes to administer and assesses decision-making capacity (Jeste et al. 2007: 966).
  
  o The ten questions included within the UBACC are: “What is the purpose of the study that was just described to you?, What make you want to consider participating in this study?, Do you believe this is primarily research or primarily treatment?, Do you have to be in this study if you do not want to participate?, If
you withdraw from this study, will you still be able to receive regular treatment?,
If you participate in this study, what are some of the things that you will be asked
to do?, Please describe some of the risks or discomforts that people may
experience if they participate in this study (Please describe the two serious risks
associated with the study), Please describe some of the possible benefits of this
study, Is it possible that being in this study will not have any benefit for you?,
Who will pay for your medical care if you are injured as a direct result of
participating in this study” (Jeste et al 2007: 968).

Recommendations for Recruitment and Retention of Research Participants

Recruitment and retention of these essential stakeholders is vital for research. Participant
retention throughout a clinical trial helps to improve the quality of data and ensures close
continued care for the participant during their enrollment in the study. Feedback from
participants in this study provide the basis for the following recommendations:

• As per participant feedback, the research clinic should offer more nutritious food to
research participants to mitigate the distressing effects of fasting that is required for
blood work.

• The inclusion of a phone hotline at the research clinic outside of normal business
hours for participants. This could meet the psychosocial support and communication
needs of participants outside of the clinic.

• Increased focus on in-person field recruitment, which appears to be one of the most
useful forms of recruiting in this low-income schizophrenic population.

• Increased emphasis on utilizing all health care providers (Nurse Practitioners,
Physician Assistants, and Counselors at the clinic) to inform potential participants
about clinical trial opportunities in order to boost participant enrollment, as based on findings related to trust. Despite being located in the same building, the research clinic and private practice clinic cultures differ widely. Further integrating a research perspective and engaging others in the promotion of research could aid in recruitment, increase education about research, and create a culture of trust encompassing both services, ensuring a comprehensive care model within these health settings.

- Based on the literature review findings and participant reported experiences in this sample, an increase in partnership, advertising, and recruitment within churches and other trusted groups in the community could be beneficial in aiding recruitment. This would provide the opportunity to help bridge psychosocial support networks.
- Increasing engagement and partnerships with other health care providers and clinics in the community could also aid in this regard, given findings surrounding trust in healthcare providers.

These recommendations, while pertinent for InSite Clinical Research may prove applicable at other research facilities as well.

2. Deliverables

The results of this research were delivered to the client in the form of a PowerPoint presentation that included a summary of relevant findings and recommendations to company procedures and policies, namely the informed consent process and participant recruitment and retention practices. The student investigator presented these findings to Dr. Shiwach and the staff of InSite Clinical Research during a monthly staff meeting. The client also received a copy of this written report. These deliverables were intended to be valuable to the client in several ways.
First, to allow for in-depth understandings of the community served and second, to use these understandings to inform future practices. This information was primarily intended to be used internally by InSite Clinical Research, the extrapolation of an advertising flyer with study results including feedback from participants has also been proposed to the marketing/recruitment department in order to disseminate information in the community. Participant feedback will be used as testimonials on the company website, where a copy of this report will also be available.

3. Personal Reflection and Future Research

This research provided me the opportunity to apply the culmination of knowledge and anthropological skills I have acquired so far and fully enter into a community of practitioners. This ethnography was useful in allowing me insight and experience with planning, conducting, managing, analyzing, and presenting research while negotiating my identity as an anthropologist. I appreciated the opportunity to work directly with this population and I am grateful to have been able to inform the company I work for in the process. The ability to use qualitative research to support new approaches that can be implemented into research practices and provide holistic valuable insight and understandings in a biomedically-dominated field was exciting and pioneered the way for future use of ethnographic methods. Participants’ openness, willingness to talk with me, and deep insight they shared made this new experience enjoyable and rewarding and invigorated me as I worked in the field.

During the course of these interviews many respondents opened up and shared with me their beliefs as to what caused their schizophrenia, this included drug use, religion, grief, and many other reasons participants found meaningful. They also shared how they treat their illnesses outside the context of the clinic. In the future, I am interested in conducting research with this population again, focusing on explanatory and cultural models of disease and “sufferer
experiences” (Singer and Baer 2012: 106). Exploring participants own ideologies regarding the cause of their disease and how they treat their illness in the context of their lives, could help gain insight into or guide treatment interventions and bridge gaps in communication between healthcare providers and patients. I see the opportunity to become an advocate for this community, bringing their perspectives, the realities of their experiences, and viewpoints to important conversations.

Interviews with clinical trial participants with different, less chronic, diagnoses would also be interesting to study in order to gauge if there are differences in values, motivations, beliefs, and influences between diverse groups, specifically when it comes to debriefing, as it was found to be of central importance to all of the participants in this specific sample. I would also like to build upon the research finding that showed some participants reported clinical trials helped to improve self-esteem. Exploring the relationship between this and stigma when it comes to schizophrenic populations would also be fascinating to investigate.
Semi-Structured Interview Guide

1. How did you first learn about clinical research trials?
2. How did you hear about this research site (InSite Clinical Research)?
3. Tell me about what made you decide to find out more information?
4. Describe for me when you made the choice to be a part of the study and the major reason or reasons behind that decision. Where were you when you made the decision to definitely participate? Did you have any expectations about how your experience would be or what would happen? What did you hope would happen? Were you worried about participating?
5. Do you think other people in your life (ie: caregivers or family members) should be involved in your decision to participate?
6. Some people think that those with serious mental illnesses, like schizophrenia, are not capable of making decisions about participating in clinical research trials by themselves or worry that they may not fully understand what they are consenting to or that they may feel pressure from others (like doctors or staff) to participate. Other people think that those with serious mental illnesses, like schizophrenia, are fully capable of making decisions by themselves based on the information they are presented with and they understand the risks and benefits of participating in a clinical trial. How do you feel about that? How would you respond to either side of the argument?
7. Have you ever said “no” to participation in a clinical trial? Why or why not? Have you ever discontinued a trial voluntarily? If so, what were the reasons behind discontinuing? What would happen if you discontinued in a trial?
8. Okay, now I would like to ask you about your experience(s) with clinical trials at InSite Clinical Research. Can you tell me about the last trial you participated in?
9. Did you sign a consent form? Tell me about what that was like. Did you ever discuss the study with any other people not at InSite Clinical Research (NOT the study doctor or staff but your personal doctor, family, or caregiver(s)) before you signed the informed consent form?
10. What are the benefits for you participating in a study for you? In general?
11. What are the disadvantages to participating in a study for you? In general?
12. What was your experience with the doctor and staff like? Did you trust what they were telling you? Describe the relationship/interaction for me.
13. What qualities do you think a doctor and staff running a clinical trial for schizophrenia should have?
14. How do you feel about the treatment you received at InSite Clinical Research? Was there anything that made your experience better or made your experience worse?
15. In your own words, what does participating in research do for you? What do you think you “get out” of participating in clinical research trials? Please elaborate.
16. What do you think the purpose of clinical research trials is in general?
17. How important is knowing the results of clinical trials you participate in to you? What about knowing the results of any tests done during a clinical trial?
18. What would you tell others about participating in clinical research trials?
19. Can you tell me any reasons or situations in which people with schizophrenia should not participate in clinical research?
20. Is there anything you would change about your research experience or the way clinical trials are conducted at InSite Clinical Research?

21. Okay, now I would like to ask you more about your illness. Can you tell me more about your schizophrenia? What does it do to you? How do you feel it coming on? What do you do then? (If see a doctor, then ask)- Which doctor do you see? How do you decide which doctor? Do you do anything else?

22. How has your schizophrenia affected you? How has it affected others in your life (ie. Family, significant others, friends)? Has it caused you any problems? What do you worry most about your schizophrenia?

23. What do you think brought on your schizophrenia? Is there anything you can do to manage it? What can doctors do? How severe is it, in your opinion?
APPENDIX B

IRB APPROVED SURVEY INSTRUMENT
Survey Instrument

Please do NOT provide your name. All information you provide will be kept confidential.

1. What is your age?
   
2. What is your gender? (Please circle one)
   Male / Female

3. With which race/ethnicity do you identify? (Please select from below)
   a. Asian/Pacific Islander
   b. African American/Black
   c. White/Caucasian/Non-Hispanic
   d. Hispanic/Latino
   e. Native American
   f. Other
      Please describe: ________________________
   g. More than one race/ethnicity
      Please describe: ________________________

4. What is highest level of education that you have completed? (Please select from below)
   a. No formal school
   b. Less than 8th grade
   c. Some high school, no diploma
   d. High school graduate
   e. Some college, no diploma
   f. Trade or technical school
   g. Associates degree
   h. Bachelors degree
   i. Masters degree
   j. Professional degree
   k. Doctorate degree

5. What is your current occupational status? (Please select from below)
   a. I am employed full time
   b. I am employed part time
   c. I am unemployed
   d. I am disabled/unable to work
   e. I am retired
   f. I am a student
6. How many clinical research trials have you participated in the **past 12 months**?  
   (Include those at InSite Clinical Research and any other research facility).  
   __________

7. How many clinical research trials have you participated in over the course of **your lifetime**?  
   (Include those at InSite Clinical Research and any other research facility)
   __________

*For the following questions, please indicate if and how much you agree with the following statements based on your experiences with clinical research at this site:*

8. Overall, I feel like I have personally benefited from my participation in clinical research.  
   a. Strongly agree  
   b. Agree  
   c. Neither agree nor disagree  
   d. Disagree  
   e. Strongly disagree

If you answered “neither agree nor disagree”, “disagree” or “strongly disagree” to question 8 above please explain why in your own words:

_____________________________________________________________________________________
_____________________________________________________________________________________  
_____________________________________________________________________________________  
_____________________________________________________________________________________  
_____________________________________________________________________________________  

9. People with schizophrenia should participate in clinical research trials.  
   a. Strongly agree  
   b. Agree  
   c. Neither agree nor disagree  
   d. Disagree  
   e. Strongly disagree

10. I understand more about my condition and myself since participating in clinical research.  
    a. Strongly agree  
    b. Agree  
    c. Neither agree nor disagree  
    d. Disagree  
    e. Strongly disagree
11. Participation in clinical research is beneficial to society.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree

12. I am satisfied with the amount of information given to me about my health during participation in a clinical research trial at this site.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree

13. I trust the doctor and the staff I work with at InSite Clinical Research.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree

14. The doctor and staff at InSite Clinical Research care about my health.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree

15. The staff and doctor I work with at InSite Clinical Research really listen to me.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree

16. Overall, I am satisfied with my clinical research experience here at InSite Clinical Research.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree

17. I worry about the risks of clinical research trials (includes procedures and study medication).
a. Strongly agree  
b. Agree  
c. Neither agree nor disagree  
d. Disagree  
e. Strongly disagree

18. Clinical research about schizophrenia is very important.  
a. Strongly agree  
b. Agree  
c. Neither agree nor disagree  
d. Disagree  
e. Strongly disagree

19. Clinical research participation is helpful to science.  
a. Strongly agree  
b. Agree  
c. Neither agree nor disagree  
d. Disagree  
e. Strongly disagree

20. Knowing about the results of the clinical research trial or trials I participate in is important to me.  
a. Strongly agree  
b. Agree  
c. Neither agree nor disagree  
d. Disagree  
e. Strongly disagree

If you have any further comments about your experience with clinical research trials at InSite Clinical Research or suggestions for how the conduct of clinical research could be improved, please use the space below.

______________________________________________________________________  
______________________________________________________________________  
______________________________________________________________________  
______________________________________________________________________  
______________________________________________________________________  
______________________________________________________________________  

Thank you for participating in this survey!
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