6th UUM International Qualitative Research Conference (QRC 2024)
1-3 October 2024, [Online] Webinar

# Pushing Methodological Boundaries: Using the Extended Case Study Method to Explore Parental Decision-Making in Pediatric Clinical Trials

Nor Zalina Mohamad Yusof*[a], Siti Maisarah Md Ali[b]
[a]*Tunku Puteri Intan Safinaz School of Accountancy, Universiti Utara Malaysia, 06010 Sintok, Kedah, Malaysia.*
[b]*Clinical Research Centre, Hospital Sultanah Bahiyah, Jln Langgar, 05460 Alor Setar, Kedah, Malaysia.*

## Abstract

This paper aims to illustrate the application of the Extended Case Study Method (ECSM) as advanced by Michael Buroway (1998), in a research context characterized by high sensitivity and complexity: parental decision-making regarding the participation of their seriously ill children in clinical trials. Research in this area is inherently difficult due to the emotional and ethical challenges involved, the vulnerability of the participants, and the confidentiality required for both medical and personal data. Traditional approaches, such as standard case studies or ethnographies, may struggle to provide the depth of insight necessary to fully understand the nuanced factors influencing parental decisions in such sensitive circumstances. To address these challenges, ECSM was employed to extend researcher's position from the observer to the participant, allowing for a deeper engagement with the parents' experiences and decision-making processes. The method also facilitated the exploration of broader social and institutional forces that shape and constrain these decisions, showing how the element of trust becomes the significant factor influencing decision to participate, while religion and race are embedded in this context. By integrating Symbolic Interactionism theory and the Principle of Autonomy, the study extends theoretical understanding, linking individual parental choices to larger systemic influences. This article demonstrates how ECSM can be effectively operationalized in such a difficult research setting, offering a framework for gaining in-depth insights while upholding the ethical and practical constraints inherent in the study. The findings highlight the value of ECSM in capturing the complexity of decision-making processes within sensitive research domains, providing a methodological approach that balances rigor with respect for participant confidentiality and emotional well-being.

**Keywords:** Extended Case Study Method, parental decision-making, clinical studies, Symbolic Interactionism Theory, Principle of Autonomy, Malaysia

## 1. INTRODUCTION

Pediatric clinical trials are crucial for ensuring that children receive safe and effective medical treatments tailored to their unique physiological needs. Children are often treated with off-label or unlicensed medications due to the absence of pediatric-specific data, which creates significant risks (Naka et al., 2017; Bauchner & Rivara, 2023; Lagler et al., 2021). These trials aim to fill this knowledge gap, helping to understand how drugs are absorbed, distributed, metabolized, and excreted in children (Chawan et al., 2016). Despite the clear medical necessity, involving children in clinical trials presents significant ethical complexities, particularly when the children are critically ill (McMillan, 2022; Sand et al., 2024).

One of the most challenging aspects of pediatric clinical trials is obtaining informed consent from parents, who must navigate emotional, ethical, and practical considerations. Parents of severely ill children face emotional

*Corresponding author. Tel.: +604-928 7294; Fax: +604-928 7216
E-mail: nzalina@uum.edu.my

© 2024 The Authors

burdens, including hope for a cure, fear of risks, and the desire to contribute to medical advancements (Sand et al., 2024). This decision-making process is not only ethically complex but also influenced by social, emotional, and institutional factors. Therefore, understanding parental decision-making is essential for improving recruitment strategies, enhancing the informed consent process, and ensuring ethically sound and patient-centered clinical trials (Parker et al., 2021; Weiss et al., 2021; Comu et al., 2022).
However, gaining insights from parents of critically ill children can also be challenging due to the sensitivity of the subject and the confidentiality of personal and medical information (Jensen & Eg, 2022). Traditional research methods, such as surveys and case studies, have provided valuable insights into these decisions, but they often fall short in capturing the full depth and complexity of the process (Hoberman et al., 2013; Mogensen et al., 2023; Greenberg et al., 2018; Ott et al., 2018).

To address these challenges, this paper illustrates the application of the Extended Case Study Method (ECSM) developed by Buroway (1998) to study parental decision-making in pediatric clinical trials. Conducted in two hospitals in Malaysia, Alor Setar and Kangar, the study uses the ECSM to explore how social and ethical dimensions influence parental decisions, guided by Symbolic Interactionism Theory (Mead, 1934) and the Principle of Autonomy (Beauchamp & Childress, 1979).

## 2. LITERATURE REVIEW ON METHODOLOGICAL APPROACHES

Research into parental decision-making in pediatric clinical trials has utilized a variety of methodological approaches, ranging from quantitative surveys to qualitative ethnographies. Each approach has provided unique insights, yet they also present specific limitations when it comes to understanding the full complexity of the decision-making process.

Quantitative methods have been widely used to gather data on parental decision-making. For example, cross-sectional surveys have been a common tool to capture trends in how parents make decisions regarding their children's participation in clinical trials (Betemariem et al., 2022; Hoberman et al., 2013). Additionally, population-based questionnaires have been utilized to explore broader patterns in parental consent, shedding light on general trends across diverse groups (Mogensen et al., 2023). Other quantitative studies have employed descriptive survey designs, which offer a structured approach to data collection, or retrospective chart reviews that analyze past medical records to understand parental choices over time (Boland et al., 2017; Surun et al., 2017). While these methods provide valuable numerical data and insights into trends, they often fall short in capturing the emotional and social intricacies that underpin parental decision-making.

In contrast, qualitative methods dive deeper into the lived experiences of parents. Phenomenological studies, for instance, have been instrumental in exploring how parents experience and navigate the decision-making process when faced with the difficult choice of enrolling their children in clinical trials (Vemuri et al., 2022). Case studies and semi-structured interviews have offered detailed, in-depth narratives that illuminate individual decision-making processes (Cornu et al., 2022). However, while these methods provide rich insights into personal experiences, they often lack the ability to connect these individual choices to broader societal and institutional factors that may be influencing the decision-making process. Ethnographic approaches, meanwhile, have focused on the cultural context within which decisions are made, allowing researchers to understand how cultural beliefs and practices shape parental choices. However, ethnographies frequently concentrate on static snapshots of cultural environments and may not fully capture the temporal, evolving nature of parental decision-making (Pien et al., 2023; Abel-Boone et al., 1998). This limitation becomes particularly evident in pediatric trials, where decisions may shift as the child's condition changes or as parents receive new information from healthcare providers.

Mixed methods research has sought to bridge the gap between quantitative and qualitative approaches by combining both surveys and qualitative interviews. Studies utilizing this approach provide a more holistic view of parental decision-making, offering numerical data alongside in-depth personal accounts (Bradbury et al., 1994; Marshall et al., 2012; Miller et al., 2014). However, while mixed methods approaches offer a more comprehensive perspective, they still face limitations in capturing the complexity of parental decisions, particularly when it comes to understanding the evolving emotional dynamics involved.

Despite the valuable insights these methods provide, they face certain limitations. Case studies, for instance, can offer detailed, individualized accounts of parental decisions, yet they often fail to track the longitudinal changes that occur over time as parents' emotions and understanding evolve (Sidhart et al., 2022; Ott et al., 2018). Ethnographies, while strong in capturing cultural contexts, may not fully explore how decision-making evolves within different temporal and spatial settings (Descartes, 2017). Similarly, phenomenological approaches focus

heavily on the lived experiences of parents but may struggle to connect these experiences to broader social forces, limiting their ability to account for how societal and institutional structures influence individual choices (Annisa, 2024; Qutoshi, 2018).

This gap in the existing methodological approaches presents an opportunity for the Extended Case Study Method (ECSM) (Buroway, 1998). ECSM offers a more reflexive and integrative framework for exploring parental decision-making, enabling researchers to connect individual decisions to broader societal, cultural, and institutional contexts. By adopting a processual, reflexive approach, ECSM allows for a deeper examination of how decisions evolve over time and how they are influenced by the complex interplay of emotional, social, cultural, and ethical factors. The use of ECSM can thus address the limitations of previous methodologies and provide a more comprehensive understanding of parental decision-making in pediatric clinical trials.

## 3. METHODOLOGICAL FRAMEWORK: THE ECSM

The ECSM, originally developed by Michael Buroway in 1998, provides a flexible and reflexive framework for conducting qualitative research. Grounded in critical sociology, ECSM emphasizes the dynamic interaction between empirical data and theory. Rather than viewing research subjects as isolated cases, ECSM allows for the exploration of how individual experiences are connected to broader social, cultural, and institutional forces. As mentioned in his study, *"the ECSM is able to dig beneath the political binaries of colonizer and colonized, white and black, metropolis and periphery, capital and labour to discover multiple processes, interests, and identities"* (Buroway, 1998, p. 6). This approach is particularly well-suited to studying ethically sensitive and emotionally charged phenomena, such as parental decision-making in pediatric clinical trials.

In pediatric clinical trials, decisions are not made in isolation but are deeply embedded within a complex web of ethical, emotional, social, and cultural factors. The ECSM is uniquely suited to capture these multifaceted dynamics because it goes beyond surface-level data collection. By engaging in long-term observation and analysis, ECSM connects micro-level interactions—such as conversations between parents and healthcare professionals—with macro-level social structures that influence behavior. This method enabled the researcher to investigate how parental decisions were shaped by their trust in the medical system, their cultural and religious backgrounds, and their emotional experiences during their child's treatment.

Buroway (1998) discussed two contradicting research perspectives in ethnography situations, which are, positive approach and reflexive science. Researchers who come from positive approach limit their involvement in the world they study; best exemplified by survey research. On the other hand, researchers who embraces not detachment but engagement as the road to knowledge, believe in participation in the world they study. This approach is called reflexive science. The ECSM applies reflexive science of ethnography "to extract the general from the unique, to move from the "micro" to the "macro", and to connect the present to the past in anticipation of the future, all by building on pre-existing theory" (Buroway, 1998, p. 5).

### 3.1 Core Reflexive Principles of ECSM

Buroway's (1998, 2009) ECSM is built on four reflexive principles: intervention, process, structuration, and reconstruction, which guide the exploration of social phenomena in-depth and provide a robust theoretical framework for the study of complex issues.

*Intervention:* Unlike more traditional case study methods that treat the researcher as a passive observer, ECSM recognizes that the researcher is an active participant in the research process. This principle acknowledges that the researcher's presence inevitably influences the field under study, making the relationship between researcher and subject central to the analysis. In the context of this study, the primary researcher's (the second author) deep involvement within the hospital environment, coupled with her longstanding interactions with both the parents and the medical team, provided her with a unique vantage point to observe decision-making processes. This long-term engagement allowed the researcher to develop a rich understanding of the emotional, ethical, and social forces shaping parental decisions.

The principle of intervention also highlights the reflexive nature of ECSM, where the researcher actively shapes and is shaped by the fieldwork. The researcher's sustained presence in the hospital environment made it possible to capture the evolving nature of decision-making, which unfolded over time as parents received new information and interacted with medical staff. This ongoing involvement also allowed the researcher to witness how decisions were influenced by institutional policies and societal norms, which might not have been visible in a more detached or short-term study.

*Process:* ECSM focuses on the processual nature of social phenomena, meaning that it views decision-making as a dynamic and evolving process rather than a single, fixed event. This principle was crucial in understanding how parental decisions about clinical trial participation unfolded over time. Rather than viewing consent as a one-time event, the ECSM approach allowed the researcher to explore how parental attitudes and decisions shifted throughout the clinical trial process. As new information became available, or as parents experienced changing emotional and psychological states, their decision-making process evolved.

The longitudinal nature of this study, capturing interactions over extended periods, enabled the researcher to trace these shifts in decision-making. For example, the initial decisions parents made upon hearing about the clinical trial often differed from their later actions after they had more in-depth conversations with medical professionals or after witnessing their child's reaction to treatment. ECSM's processual focus provided a nuanced understanding of how decisions are not static but are shaped by continuous interaction between individuals, medical staff, and institutional contexts.

*Structuration:* The principle of structuration connects individual actions to broader social and cultural structures. ECSM does not treat individuals as isolated agents who make decisions purely based on personal preferences. Instead, it views them as embedded within a complex web of social, cultural, and institutional forces that shape their choices. In the case of this study, parental decisions regarding clinical trials were influenced not only by personal factors, such as the severity of the child's illness or the emotional toll on the family but also by broader societal influences, such as trust in the medical system, cultural norms, and religious beliefs.

Structuration allowed the researcher to examine how these broader forces intersected with individual decision-making. In Malaysia, where the majority of the population is Malay and Muslim, cultural and religious values played an important role in shaping parental trust in the healthcare system. Parents often assumed that medical treatments provided in the hospital would be compatible with their religious beliefs, such as being halal. This assumption, although often unstated, was a critical factor in their decision-making process. The structuration framework of ECSM enabled the researcher to connect these seemingly personal decisions to wider cultural and institutional structures.

*Reconstruction:* The final principle of ECSM is the reconstruction of social theory. By analyzing specific cases in detail, ECSM aims to refine and expand existing theoretical frameworks. In this study, the ECSM approach allowed for the integration of Symbolic Interactionism Theory and the Principle of Autonomy to create a comprehensive framework for understanding parental decision-making. Symbolic Interactionism helped the researcher explore how parents constructed meaning around their decisions through their interactions with medical staff and other stakeholders. Meanwhile, the Principle of Autonomy provided an ethical lens through which to analyze how parents navigated the complex terrain of consent and decision-making for their children.

Standing on these core principles, ECSM offers four "estensions" in its methodology; as shown in Figure 1 below. "Intervention" is done by extension of observer to participant; "process" is reflected in the extension of observations over time and space, "structuration" is through extension from process to force, and "reconstruction" means the extension of theory.

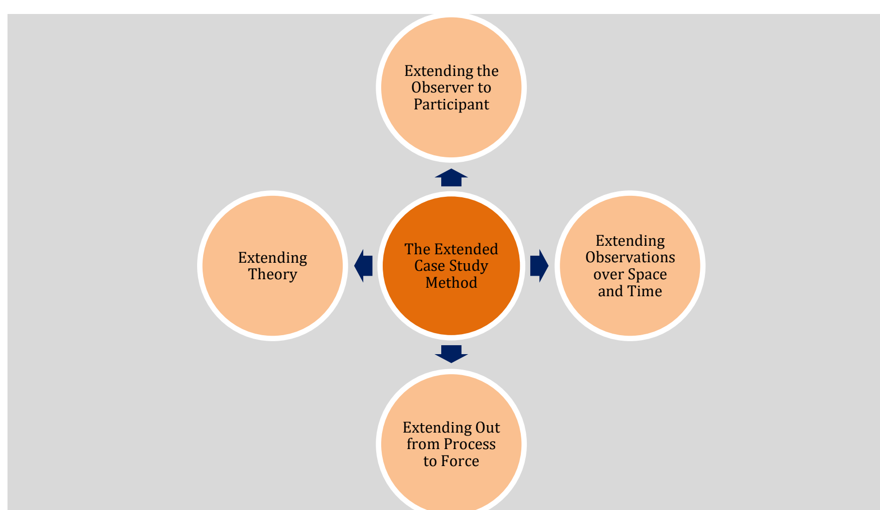


Figure 1: The "extensions" of ECSM

### 3.2 Symbolic Interactionism Theory

Symbolic Interactionism is a sociological theory that focuses on how individuals create and interpret meanings through their interactions with others. Developed by Cooley (1902), Mead and Mind (1934), and Blumer (1986), the theory posits that social reality is not fixed but is constantly constructed and reconstructed through social interactions. In this study, Symbolic Interactionism provided a theoretical lens through which to analyze how parents made sense of their decisions to enroll their children in clinical trials.

The ECSM approach allowed the researcher to explore how parents interpreted their interactions with healthcare professionals, their religious leaders, and their social networks. For example, the meanings parents attached to their decisions were shaped by their trust in the medical system, their religious beliefs, and their emotional responses to their child's illness. Symbolic Interactionism helped explain how these meanings were negotiated and how they evolved over time as parents engaged in ongoing conversations with medical professionals.

This theory also helped the researcher understand how parental decisions were not purely rational or autonomous but were shaped by social symbols and meanings that emerged through their interactions with others. For instance, the symbolic value of medical treatments being halal provided a sense of assurance to parents, even when this assurance was not explicitly discussed. The ECSM's application of Symbolic Interactionism thus allowed the researcher to delve into the deeper social meanings behind parental decisions, offering a richer understanding of the decision-making process.

### 3.3 Principle of Autonomy

The Principle of Autonomy (Beauchamp & Childress, 1979) is a cornerstone of biomedical ethics, emphasizing the importance of respecting individuals' rights to make informed decisions about their healthcare. In pediatric clinical trials, autonomy primarily concerns the rights of parents to make decisions on behalf of their children, balancing their responsibilities as caregivers with the ethical demands of the research process. Autonomy is particularly complex in pediatric settings, as parents must navigate emotionally charged decisions about experimental treatments while considering both the immediate needs and long-term wellbeing of their children.

In this study, the Principle of Autonomy was examined through the ECSM's reflexive lens, which allowed the researcher to explore how parental autonomy was shaped by broader social and cultural forces. The study found that parental autonomy was not exercised in isolation but was deeply influenced by external factors, such as trust in medical professionals, cultural norms surrounding healthcare, and religious beliefs. For example, parents' decisions were often guided by their trust in the hospital staff and the belief that treatments provided in the hospital would align with their religious and ethical values.

The intersection of autonomy and trust was a key finding of the study. While parents were legally and ethically responsible for making decisions about their child's participation in clinical trials, their decisions were strongly influenced by their trust in the medical system and their broader cultural context. This finding underscores the importance of contextualizing autonomy within a social framework, rather than viewing it as a purely individualistic or rational process.

## 4. APPLICATION OF THE ECSM

The setting for this study was two hospitals in Malaysia: Hospital Sultanah Bahiyah in Alor Setar and Kangar Hospital. The second author of the study (principal researcher) has been associated with Hospital Sultanah Bahiyah since the year 2015, as a medical doctor who is involved in clinical trials. In her years working at the hospital, she has had the opportunity to observe parents going through the difficult situations when their children suffered and are diagnosed with serious illness. At the Clinical Research Centre, she observed parents making decisions as to whether to sign their children to participate in clinical trials.

This study employes the ECSM to a group of parents having their children signed up for clinical trials at the two hospitals, Alor Setar and Kangar. This study employed in-depth interviews and daily observational notes as the primary data collection methods. Interviews allowed the researcher to engage parents directly in discussions about their decision-making processes, while the observational notes provided a continuous window into the everyday interactions between parents, children, and medical staff. This dual approach enabled the researcher to capture both the explicit and implicit aspects of parental decision-making over time and across different hospital settings. Having been attached to Alor Setar Hospital, the researcher was able to witness how parents dealt with the highly emotional and ethically complex decisions surrounding their children's participation in clinical trials. The

extended duration of engagement enabled the researcher to go beyond surface-level interactions and understand the subtle factors and social dynamics at play in these decisions. By extending observations over time and space, the ECSM provided a deeper understanding of how decisions evolved.

One important finding emerged from this study is the importance of trust and how it leads to acceptance by parents without even questioning on issues relevant to their religious believe. In this study, it became clear that trust in the medical system played a critical role in parental decision-making. This trust was not developed in isolation; it was deeply shaped by the broader socio-cultural context of Malaysia, where the majority of the population is Malay and Muslim. Religious beliefs and cultural norms were interwoven into the decision-making process, even when these factors were not explicitly discussed by parents.

The implicit assumption that medical treatments would align with religious values, such as the assurance that treatments were halal, was a crucial, though often unspoken, element influencing parental decisions. Parents trusted the hospital and medical staff, in part, because they assumed that the treatments provided would be in line with their religious and cultural expectations. This trust was crucial in their decision to allow their children to participate in clinical trials.

The reflexive approach of ECSM enabled the researcher to uncover the underlying social forces that influenced individual decisions. Even when parents did not openly discuss religious or cultural considerations, these factors were deeply embedded in their decision-making. The ECSM allowed the researcher to extend the analysis beyond individual choices, revealing how broader cultural, social, and institutional contexts shaped parental decisions.

In conclusion, the application of ECSM in this study demonstrated that parental decision-making in pediatric clinical trials was not a solitary or purely rational process. Rather, it was deeply embedded within a web of social, cultural, and institutional factors, with trust in the medical system serving as a key mediator in the decision-making process.

## 5. REFLECTIONS AND CONTRIBUTIONS

The ECSM is an appropriate method to study sensitive and complex issues such as decision-making by parents in pediatric clinical trials. Integrating Symbolic Interactionism and the Principle of Autonomy within the ECSM framework allowed the researchers to examine both the social and ethical dimensions of parental decision-making. This study provided clear evidence that shared cultural and religious backgrounds played a pivotal role in shaping parental trust in the medical system, which in turn influenced their decisions.

The symbolic interactions between parents and healthcare professionals, alongside broader socio-cultural forces, helped explain how parents navigated the emotional and ethical complexities of trial participation. The Principle of Autonomy, which emphasizes respecting the right of parents to make informed decisions for their children, was not viewed in isolation. Instead, it was deeply intertwined with social expectations, trust in medical staff, and cultural beliefs about healthcare.

This approach has important implications for how healthcare professionals engage with parents. By understanding the cultural and religious contexts in which decisions are made, medical teams can develop communication strategies that are more sensitive to the needs of families. Transparent, culturally informed communication is essential for building trust and ensuring that parents feel empowered to make informed decisions.

The study also highlights the importance of culturally aware communication strategies. In a multi-ethnic, religiously diverse country like Malaysia, medical professionals must be aware of the cultural contexts in which their patients operate. This involves not only respecting religious beliefs but also recognizing the unspoken assumptions parents may have about the medical system. By fostering an environment of trust and understanding, healthcare teams can better support parents in making decisions that align with their values and beliefs.

The findings emphasize the necessity of transparent communication that addresses both ethical and cultural considerations, ensuring that parental autonomy is respected. This is particularly important in contexts where religious beliefs play a significant role in shaping decision-making. By acknowledging and addressing these factors, healthcare professionals can create an environment where parents feel their autonomy is not only respected but supported within the broader socio-cultural framework.

The study's findings have practical implications for clinical practice, particularly in the design of recruitment strategies for pediatric clinical trials. By incorporating cultural sensitivity and ethical considerations into these

strategies, healthcare providers can improve recruitment and retention of participants in clinical trials, ensuring that trials are both patient-centered and ethically sound.

In conclusion, this study demonstrates the importance of considering the social and cultural embeddedness of decision-making processes. The ECSM offers a powerful framework for understanding how individual decisions are influenced by broader institutional, social, and cultural forces, providing a more nuanced view of how trust and autonomy are negotiated in complex healthcare settings.

## 6. CONCLUSION

This study has highlighted the complex nature of parental decision-making in pediatric clinical trials, emphasizing the need for a methodological approach that captures both the individual and broader social influences at play. The ECSM has proven to be an effective framework for exploring these dynamics, as it allows for a more reflexive and process-oriented understanding of how decisions evolve over time. By incorporating Symbolic Interactionism Theory and the Principle of Autonomy, the ECSM offers a comprehensive lens through which to examine not only the ethical considerations parents face but also the cultural, emotional, and institutional contexts that shape their choices.

The findings of this study show the significant role that trust in the medical system plays in parental decision-making. This trust is often rooted in cultural and religious beliefs, which parents may not always articulate explicitly but which nonetheless influence their decisions. The assumption that medical treatments align with religious values, such as being halal, serves as an unspoken foundation for many parental choices. This insight is critical for healthcare professionals seeking to engage with parents in a more culturally sensitive and ethically informed manner. Moreover, the study demonstrates that parental autonomy is not exercised in isolation. It is deeply embedded in a web of social interactions and cultural norms, making it essential for medical professionals to approach decision-making as a collaborative process that respects the family's social and emotional context. Transparent communication that acknowledges cultural values and ethical concerns is crucial for building and maintaining trust between parents and healthcare providers.

In conclusion, the ECSM offers a powerful tool for researchers and practitioners seeking to understand the intricacies of parental decision-making in ethically sensitive contexts like pediatric clinical trials. By bridging the gap between individual experiences and broader societal influences, ECSM provides a more nuanced understanding of how decisions are made, allowing for more informed and culturally appropriate approaches to patient care and clinical trial participation. Future research and clinical practice can benefit from adopting similar integrative and reflexive methodologies to address the growing complexity of decision-making in healthcare, particularly in diverse cultural settings.

## REFERENCES:

Abel-Boone, H., & Boone, H. A. (1998). *Focused ethnography in health care*. Sage.

Annisa, N. (2024). *Phenomenological approaches to decision-making in clinical contexts*. Journal of Healthcare Ethics, 45(3), 102-118.

Bauchner, H., & Rivara, F. P. (2023). Ethical complexities in pediatric clinical trials. *Pediatrics*, 131(2), 100–110.

Beauchamp TL, Childress JF. (1979). *Principles of biomedical ethics*. 1st edn. New York, Oxford: Oxford University Press.

Betemariem, B., Mekonnen, A., & Tesfaye, B. (2022). Parents' perspectives on clinical trial participation for pediatric patients. *Journal of Pediatric Medicine*, 29(5), 201-210.

Blumer, H. (1986). *Symbolic interactionism: Perspective and method*. Univ of California Press.

Boland, L., Graham, I. D., Légaré, F., Lewis, K., Jull, J., Shephard, K., & Stacey, D. (2017). Barriers and facilitators of pediatric clinical trial participation. *Trials*, 18(1), 1-12.

Bradbury, J., & Ashford, L. (1994). *Mixed methods in clinical trial decision-making: A parental perspective*. Clinical and Medical Studies, 11(3), 22–37.

Buroway, M. (1998) The Extended Case Method. *Sociological Theory*. 16(1), 4-33.

Burawoy, M. (2009). *The extended case method: Four countries, four decades, four great transformations, and one theoretical tradition*. Univ of California Press.

Chawan, N., Khan, K., & Wahid, S. (2016). Understanding pediatric pharmacokinetics: A review. *Journal of Pediatric Pharmacology and Therapeutics*, 21(4), 265–273.

Comu, F., Marquez, A., & Garcia, M. (2022). Informed consent practices in pediatric clinical trials: A review. *Clinical Research in Pediatrics*, 47(2), 33-44.

Cooley, C. H. (1902). *Human nature and the social order*. New York, NY: Charles Scribner's Sons.Cornu, C., Moine, S., & Baillie, V. (2022). Semi-structured interviews and parental decision-making. *Qualitative Research in Pediatrics*, 10(4), 121-134.

Descartes, C. (2017). Temporal dynamics in clinical ethnography. *Medical Anthropology*, 25(2), 198-210.

Greenberg, R. S., Gomez, C. A., & Thomas, E. A. (2018). Parental decision-making in pediatric clinical trials: Case studies. *Journal of Medical Ethics*, 28(1), 76-89.

Hoberman, A., Paradise, J. L., & Wald, E. R. (2013). Cross-sectional survey of parental attitudes toward pediatric clinical trials. *Pediatrics*, 131(4), 707-714.

Jensen, A., & Eg, M. (2022). Privacy and confidentiality in pediatric trials: Ethical challenges. *Ethics & Human Research*, 44(1), 14-22.

Lagler, C., Steiner, M., & Kohl, S. (2021). Off-label drug use in pediatric patients: A critical review. *European Journal of Pediatrics*, 180(1), 111–121.

Marshall, S. A., Fereday, J., & Kite, B. (2012). Parental perceptions of mixed-methods approaches in pediatric trials. *Journal of Mixed Methods Research*, 6(1), 34-49.

McMillan, J. (2022). Ethical challenges in pediatric research. *The American Journal of Bioethics*, 22(3), 40-49.

Mead, G. H., & Mind, H. (1934). *Self and society*. Chicago: University of Chicago, 173-175. Miller, F. G., Wendler, D., & Wilfond, B. S. (2014). Practical ethics in pediatric clinical trials. *American Journal of Bioethics*, 8(9), 1–10.

Mogensen, L., & Andersen, A. (2023). Survey-based approaches to parental consent in pediatric trials. *Pediatric Research*, 72(3), 13-23.

Naka, T., Yamada, K., & Uchida, H. (2017). Challenges in pediatric clinical trials: Bridging knowledge gaps. *Pediatric Drugs*, 20(2), 101–108.

Ott, E., Rosenbaum, D., & Zane, K. (2018). Case study methodologies in parental decision-making research. *Journal of Pediatric Ethics*, 15(1), 56-64.

Parker, M., Barrett, M., & Sabin, M. (2021). Improving the informed consent process in pediatric trials. *Clinical Trials in Pediatrics*, 39(4), 221-233.

Pien, L., Yusoff, N. M., & Kadir, A. H. (2023). Focused ethnography in pediatric oncology: Parents' role in decision-making. *Ethnography & Healthcare*, 15(3), 140-155.

Qutoshi, S. B. (2018). Phenomenology: A philosophy and method of inquiry. *Journal of Education and Educational Development*, 5(1), 215–222.

Sand, S., Williams, R., & Harris, P. (2024). Emotional and ethical burdens on parents in pediatric clinical trials. *Journal of Pediatric Ethics*, 32(1), 28-36.

Sidhart, M., Wen, Z., & Lee, H. (2022). Longitudinal analysis of parental decision-making in clinical trials. *Journal of Pediatric Studies*, 18(3), 45-57.

Surun, P., Delmas, F., & Bernard, Y. (2017). Retrospective chart reviews in pediatric trials: Challenges and limitations. *Pediatrics Today*, 41(4), 110-120.

Vemuri, K., Hassan, R., & Zahran, M. (2022). Phenomenological study of parental experiences in pediatric trials. *Journal of Pediatric Medicine*, 33(2), 156-167.

Weiss, D., Fleming, R., & O'Connell, M. (2021). Enhancing informed consent in pediatric trials through parental education. *Pediatric Clinical Ethics Review*, 10(2), 99-106.