Overview:

The proposed study will examine important but under-researched questions about maternity care experiences in the United States. While previous research has focused on psychosocial outcomes such as postpartum depression, this study will directly assess women's patient-provider communication experiences pertaining to their own birth events. This study will also measure women's uncertainty and appraisal of that uncertainty about their births. Finally, this study will evaluate US women's desires for postpartum discussion (also known as "debriefing" or "processing") meetings with providers, the status of which us not currently known. These postpartum discussions, which are radically different from the more traditional, biomedically-focused approach of Western medical practice, are important because they have been shown to facilitate understanding, dialogue, and empowerment by offering informal conversation about a woman's particular birth events early in the postpartum period.

This study will also examine differences in experiences and needs across demographic groups, including race/ethnicity, socioeconomic status, and education level. For example, intertwined with social determinants of health, communication in healthcare settings is at the core of many racial health disparities. Black women, for instance, have historically been, and continue to be, routinely subjected to discrimination in maternity care. Differences in communication experiences will therefore be critically important to explore. To address these issues, I plan to collect quantitative survey data, with the help of Qualtrics Panels, from a diverse and nationally representative sample of 400 women about their perceptions of their recent birth experiences.

Intellectual merit:

The research questions and survey items have been informed by the theoretical foundations of uncertainty management theory (Parrott, Peters, & Traeder, 2012), the principles of shared decision-making in patient-centered care (Epstein & Street, 2011), and previous research about women's postnatal debriefing and support needs (e.g., Baxter, 2019; Baxter, McCourt, & Jarrett, 2014). Women's perceptions of their own knowledge, uncertainty, and roles as decision-makers during birth will not only offer a barometer for how well patient-centered care is being enacted, but will tell us whether certain demographic groups have more or less of a voice during labor and delivery than others.

The line of research that the proposed study will launch presumes that there are communication gaps, needs, and desires to be uncovered among laboring and postpartum women. Supporting evidence for this, however, is currently lacking. The quantitative data in this study will not only provide that evidence, but establish the rationale for more interpretive, qualitative research by providing supporting evidence for that need. Looking forward, there is sufficient theoretical basis upon which to explore solutions to those communication gaps, needs, and desires. Specifically, questions about how shared meaning is constructed among women, healthcare providers, and the larger healthcare system could extend such theoretical approaches as the theory of coordinated management of meaning or symbolic interactionism. It will be key to work alongside women and their providers, observing how they dialogically construct meaning surrounding birth events. Qualitative methodologies, such as video-reflexive ethnography, participant observation, and focus groups will be useful tools to carry this research agenda forward, and aid in developing practices that close an important gap in maternity care for US women.

Broader Impacts:

As researchers in the interdisciplinary field of health communication, we intend for our work to be not only sound, but broadly translational in its utility. The picture that the data reveal in the current study can potentially tell us something larger about other healthcare delivery contexts: What patients need, what they lack, and where there is potential for bridging previously unrecognized communication gaps. It does so by asking about what is and is not discussed, what is and is not understood, and whether a different type of patient-provider interaction is needed.

This study will also add to our knowledge about the roles of race, income, education, and other factors that affect healthcare encounters and outcomes. In particular, at the intersection of a global pandemic and attention to the systematic oppression of people in the United States in the current moment, we see yet again how people of color are disproportionately impacted by the burden of disease- not because of biological or behavioral factors, but because of socially-based etiological factors that must, in turn, be examined from a social standpoint. Although the current study is about childbirth, it is intended to be situated within a continuing conversation about implicit biases and discriminatory communication practices as they exist at all levels of health communication.

Looking forward, this study has the potential to open doors for future research and external funding to address any issues it uncovers. Approaches to maternity care vary greatly by birthing culture, from the more medicalized approach in the US to the more holistic, woman-centered approaches seen in places like Sweden, the Netherlands, and less economically developed countries. Having some of the poorest maternal health outcomes of any developed nation, there is much the US healthcare system can learn from observations of maternity care practices and communication processes in cultures with more favorable birth outcomes. Therefore, future research and funding opportunities in this vein can extend the impact of the

current study. Specifically, ethnographic observation of postnatal birth discussions in a setting where they are regularly employed, with an eye to the communication mechanisms that foster knowledge and empowerment for postpartum women, would be especially useful. From there, we can push forward with the persistent challenge of integrating ideal communication practices into the realities of managed care in the US.

References

Baxter, J. (2019). Postnatal debriefing: Women's need to talk after birth. *British Journal of Midwifery*, *27*(9), 563–571. https://doi.org/10.12968/bjom.2019.27.9.563

Baxter, J. D., McCourt, C., & Jarrett, P. M. (2014). What is current practice in offering debriefing services to post partum women and what are the perceptions of women in accessing these services: A critical review of the literature. *Midwifery*, *30*(2), 194–219. https://doi.org/10.1016/j.midw.2013.12.013

Epstein, R. M., & Street, R. L. (2011). The Values and Value of Patient-Centered Care. *Annals of Family Medicine*, *9*(2), 100–103. https://doi.org/10.1370/afm.1239

Parrott, R., Peters, K. F., & Traeder, T. (2012). Uncertainty Management and Communication Preferences Related to Genetic Relativism Among Families Affected by Down Syndrome, Marfan Syndrome, and Neurofibromatosis. *Health Communication*, *27*(7), 663–671. https://doi.org/10.1080/10410236.2011.629408

Communication during labor and delivery: Examining women's perceptions, needs, and desires

Abstract

This study will examine women's perspectives on their communication experiences, needs, understanding, and desires in the context of labor and delivery. Although women who experience childbirth have a need for explanation and understanding of their labor and delivery experiences, they are often left with gaps in knowledge about what happened during their births. This is an under-researched topic in the United States, where relatively poor birth outcomes and racial disparities mar the maternity care landscape. It is important for healthcare providers to communicate with pregnant, laboring, and postpartum women in a way that offers critical health information about their births. Along the continuum of care, this may also include offering a postpartum birth discussion, or debriefing, wherein women are given the opportunity to ask questions, be heard, and dialogically make sense of birth experiences. But little is known about the utility of these discussions in the United States, and evidence of their efficacy in mitigating adverse mental health outcomes in postpartum women is mixed. This study, therefore, will utilize survey methodology to quantitatively assess women's uncertainty about their births, participation in decision-making, communication with providers, and interest in postpartum debriefing sessions. An online survey will be distributed to a sample of 400 women in the United States who have given birth in the past 12 months. To ensure a representative sample in terms of race, income, education, and geographic location, Qualtrics Panels will be used (if funded) for participant recruitment and survey distribution. Results will be analyzed using SPSS. Descriptive analysis will be used to assess women's overall communication experiences and perceived utility of postpartum discussions. Means comparisons will be used to analyze differences in racial,

socioeconomic, educational, and other demographic variables to better understand how different groups experience patient-provider communication during labor and delivery. This may have implications for understanding the persistent racial disparities in birth outcomes in the United States.

The proposed research study will identify gaps in women's communication and information needs regarding their labor and delivery experiences, as well as gauge interest in further postnatal discussions with their healthcare providers. There is reason to believe that some women experience gaps in understanding about what happened during birth, particularly when their expectations are not met (Baxter, 2007; Lavender & Walkinshaw, 1998; Mercer et al., 2012). In addition, women are not typically asked postnatally how they felt emotionally about their births (Creedy et al., 2000), indicating a missed opportunity to identify women's unresolved emotional and communication needs. Women report that they do feel the need for explanation and understanding of their labor and delivery experiences (Carlgren & Berg, 2008; Thompson & Downe, 2016). While effective caregiver communication during labor and delivery contributes to women's satisfaction and a sense of participation their births (Larkin et al., 2009), a deeper sense of connection to their own particular birth events can be facilitated by offering women informal discussions early in the postpartum period. When given the opportunity to meet with and talk through their birth experiences with a provider, women report on these experiences positively (Freyer & Weaver, 2014). Despite this, these meetings following childbirth are not part of standard practice in the United States, nor are they explicitly recommended as part of optimal postpartum care (ACOG, 2018). Questions remain about whether U.S. women desire opportunities to ask questions, be heard, and make sense of birth experiences with healthcare providers, and how such conversations might function to close an open loop in maternity care.

Background and Specific Aims

While previous research has focused on understanding psychosocial outcomes such as postpartum depression (Meades et al, 2011), social support needs (Negron, 2013), and broad informational needs (Slomiam, 2017), this study will examine women's particular

communication needs within their own labor and delivery events. In addition, existing research about patient-provider communication following childbirth has been mostly conducted outside of the United States (Skibniewski-Woods, 2011), and large-scale US research, such as the Listening to Mothers series of surveys (Declercq et al, 2013; Sakala et al, 2020), has not focused directly on communication and knowledge needs. Those surveys, however, highlight important knowledge gaps, education and racial disparities in maternity care experiences, and overall reticence on the part of pregnant and laboring women in the patient role. Disparities in maternal outcomes across race, income, and education level groups are key indicators of the social determinants of health, wherein systemic factors such as discrimination and unequal access to care lead to disproportionately poor outcomes for certain groups (Scrimshaw & Backes, 2020). Therefore, in addition to measuring overall communication needs and deficits, this study will examine differences across these groups in the United States, where birth outcomes are poor relative to other developed nations (Verbiest et al., 2018) and postpartum debriefing and discussions are not usually offered as part of standard maternity care.

The purpose of this application is to request the funds needed to pursue knowledge that can support larger, external funding goals. Preliminary data will be used to answer the following research questions: (1) What is the status of US women's self-perceived understandings of their own labor and delivery events? (2) How do women perceive the quality of communication with healthcare providers during their labor and delivery events? (3) What level of interest do US women have in postpartum discussion sessions with providers? (4) How do the aforementioned understanding, communication quality, and interest in postpartum discussions vary by race, income, and education level? Answering these questions will fill a significant hole in our

understanding of women's birth experiences, providing opportunities to build innovative solutions with an eye toward overcoming persistent disparities across different groups.

If gaps, needs, and problems do emerge in the currently proposed quantitative study, there is sufficient theoretical basis upon which to qualitatively explore solutions to improve maternal health outcomes in future research using innovative and collaborative approaches, such as video reflexive ethnography. Specifically, questions about how shared meaning is constructed among women, healthcare providers, and the larger healthcare system could extend the theory of coordinated management of meaning (Cronen et al. 1988) as women and providers work together to dialogically construct meaning surrounding birth events. Meaning-making is imbued with both women's subjective interpretations and the objective medical decisions made by providers, helping women achieve an understanding of their birth that is informed and empowering as they navigate future health experiences.

Design and methodology

This study will consist of a survey, constructed and distributed via Qualtrics, designed to assess women's self-perceived understanding of birth events, appraisal of birth-related uncertainty, perceptions of communication with providers, and needs and desires for postpartum discussion. Given the importance of accurate recall for managing future pregnancies (Attanasio et al., 2017), it will be useful to measure women's own levels of personal health information and self-perceived knowledge gaps. Additional items will replicate Baxter's (2019) UK study that addressed similar questions about women's postnatal needs, and examine perceptions of providers' listening, clarity, empathy, and shared decision-making during labor and delivery processes, which are key parts of achieving patient-centered care (Epstein & Street, 2011).

If funded, Qualtrics Panels will be used to recruit a sample of 400 participants from across the United States to ensure geographic, racial, and socioeconomic representativeness. Participants will include women who have given birth at any point in the past 12 months, with details of the birth setting, interventions, support persons, and modes of delivery (vaginal, c-section, etc.) included in the questionnaire because each of these things may impact communication and knowledge of delivery details (Scrimshaw & Backes, 2020). Both descriptive and inferential analysis of women's communication experiences during labor and delivery, differences across groups (regional, racial/ethnic, and socioeconomic status), and predictors of these needs and perceptions of childbirth will be conducted.

Milestones and Timeline

Data collection will commence if and when funding becomes available, ideally in May 2021, and conclude in July 2021. Qualtrics Panels indicates that a 3-4-week timeline is usually sufficient for collecting data. Analysis and writing would take place between July and November 2021, with the goal of producing at least one completed manuscript by the December conference deadline for the International Communication Association.

Resources

Successful completion of this project will require access to Qualtrics to disseminate the survey, funds for the professional recruitment of participants (Qualtrics Panels), and access to analysis software tools including Excel and SPSS. Only the funds for data collection through Qualtrics Panels are requested from the Committee. The risks of attempting data collection on my own, without funding, center primarily around the inability to achieve a robust, representative, high-quality sample in a reasonable amount of time. A diverse sample will help

address persistent questions about disparities – particularly those attributable to racial and ethnic differences – in childbirth.

Future External Funding

This study will provide the rationale for external funding for more ethnographic, qualitative research that explores postpartum debriefing/discussions in places where they are more commonly conducted, such as birth centers. Possible sources of funding include the NIH R03 small grant mechanism for dissemination and implementation research in health; the Robert Wood Johnson Foundation, which would require and support an actionable intervention plan through their Investigator-Initiated Research to Build a Culture of Health; or a Fulbright Scholar Award in a country such as the UK or Netherlands, where I can work with providers who regularly engage in the communication practices of interest and where there are better overall birth outcomes.

Dissemination

Results of this study will be submitted for consideration to the International Communication Association's convention (December 2021 deadline) for presentation in summer 2022. Simultaneously, I will prepare a manuscript for journal submission within the field of health communication (e.g., *Health Communication* or *Patient Education and Counseling*). There are also a variety of obstetrics and gynecology journals for which this research may also be relevant. Improving the knowledge base of patient-provider communication in pregnancy care is a core aspect of my research agenda. I would like to move toward building programs and protocols that incorporate the findings of this line of research into pregnant women's care, helping them become more informed and empowered participants in the US healthcare system across all income, racial/ethnic, and educational groups. In terms of the potential impact on

MTSU, the proposed study could create opportunities for grant funding, scholarship abroad, and undergraduate research projects, as well as highlight the importance of interdisciplinary research and curricula such as that within our new Health Communication concentration.

References

ACOG Committee Opinion (2018). Optimizing Postpartum Care. https://www.acog.org/en/Clinical/Clinical Guidance/Committee Opinion/Articles/2018/05/Optimizing Postpartum Care

Attanasio, L. B., Kozhimannil, K. B., Srinivas, S. K., & Kjerulff, K. H. (2017). Concordance between Women's Self-Reported Reasons for Cesarean Delivery and Hospital Discharge Records. *Women's Health Issues,* 27(3), 329–335. https://doi.org/10.1016/j.whi.2016.12.006

Baxter, J. (2007). Care during the latent phase of labour: Supporting normal birth. *British Journal of Midwifery, 15*(12), 765–767. https://doi.org/10.12968/bjom.2007.15.12.27790

Baxter, J. (2019). Postnatal debriefing: Women's need to talk after birth. *British Journal of Midwifery, 27*(9), 563–571. https://doi.org/10.12968/bjom.2019.27.9.563

Baxter, J. D., McCourt, C., & Jarrett, P. M. (2014). What is current practice in offering debriefing services to post partum women and what are the perceptions of women in accessing these services: A critical review of the literature. *Midwifery, 30*(2), 194–219. https://doi.org/10.1016/j.midw.2013.12.013

Carlgren, I., & Berg, M. (2008). Postpartum consultation: Occurrence, requirements and expectations. *BMC Pregnancy and Childbirth, 8*, 29. https://doi.org/10.1186/1471-2393-8-29

Creedy, D. K., Shochet, I. M., & Horsfall, J. (2000). Childbirth and the Development of Acute Trauma Symptoms: Incidence and Contributing Factors. *Birth, 27*(2), 104–111. https://doi.org/10.1046/j.1523-536x.2000.00104.x

Cronen, V., Chen, V., & Pearce, W. B. (1988). The coordinated management of meaning. *Theories of Intercultural Communication*, 66–98.

Declercq, E. R., Sakala, C., Corry, M. P., Applebaum, S., & Herrlich, A. (2013). Listening to Mothers III: Pregnancy and Birth. New York: Childbirth Connection.

Epstein, R. M., & Street, R. L. (2011). The values and value of patient-centered care. *Annals of Family Medicine, 9,* 100–103. https://doi.org/10.1370/afm.1239

Fryer, J., & Weaver, J. J. (2014). Should a postnatal birth discussion be part of routine midwifery care? *British Journal of Midwifery, 22*(2), 118–123.

Howell, E. A., & Zeitlin, J. (2017). Quality of Care and Disparities in Obstetrics. *Obstetrics and Gynecology Clinics, 44,* 13–25. https://doi.org/10.1016/j.ogc.2016.10.002

Larkin, P., Begley, C. M., & Devane, D. (2009). Women's experiences of labour and birth: An evolutionary concept analysis. *Midwifery*, *25*(2), e49–e59. https://doi.org/10.1016/j.midw.2007.07.010

Meades, R., Pond, C., Ayers, S., & Warren, F. (2011). Postnatal debriefing: Have we thrown the baby out with the bath water? *Behaviour Research and Therapy, 49,* 367–372. https://doi.org/10.1016/j.brat.2011.03.002

Mercer, J., Green-Jervis, C., & Brannigan, C. (2012). The legacy of a self-reported negative birth experience. *British Journal of Midwifery*, *20*(10), 717–723.

Negron, R., Martin, A., Almog, M., Balbierz, A., & Howell, E. A. (2013). Social support during the postpartum period: Mothers' views on needs, expectations, and mobilization of

support. *Maternal and Child Health Journal, 17*, 616–623. https://doi.org/10.1007/s10995-012-1037-4

Sakala, C., Braveman, P., Declercq, E., Marchi, K., Corry, M. P., Heck, K., Shah, M., Turon, J. M., Teleki, S., & Lewis, V. (2020). Listening to Mothers in California Survey, 2018 [Data set]. UNC Dataverse. https://doi.org/10.15139/S3/3KW1DB

Susan C. Scrimshaw & Emily P. Backes. (2020). *Birth Settings in America: Outcomes, Quality, Access, and Choice*. National Academies Press.

Skibniewski-Woods, D. (2011). A review of postnatal debriefing of mothers following traumatic delivery. *Community Practitioner: The Journal of the Community Practitioners' & Health Visitors' Association, 84*(12), 29–32.

Slomian, J., Emonts, P., Erpicum, M., Vigneron, L., Reginster, J. Y., & Bruyère, O. (2017). What should a website dedicated to the postnatal period contain? A Delphi survey among parents and professionals. *Midwifery, 53*, 9–14. https://doi.org/10.1016/j.midw.2017.07.004

Thomson, G., & Downe, S. (2016). Emotions and support needs following a distressing birth: Scoping study with pregnant multigravida women in North-West England. *Midwifery*, *40*, 32–39. https://doi.org/10.1016/j.midw.2016.06.010

Dr. Elizabeth D. Dalton: Biographical Sketch

Dr. Elizabeth ("Betsy") D. Dalton is in her fifth year as an assistant professor in the Communication Studies department at MTSU. Utilizing qualitative, quantitative, and mixed-methods approaches, she examines how human communication about health experiences both reflects and creates reality. Processes of interest include uncertainty management, disclosure, and privacy management. Specifically within patient-provider communication, she has examined disclosure and trust in maternity care, nursing challenges in pain communication, and triadic communication with families. She has also examined predictors of nursing students' likelihood of speaking up when witnessing a medical mistake, the uncertainty management experiences of women who are pregnant following intrauterine loss, and the uncertainty management experiences of the "worried well" during COVID-19. Her experience also includes ethnographic research with pregnant and parenting adolescents in the Appalachian region.

Education

Doctor of Philosophy, Communication & Information. University of Tennessee, Knoxville, 2014.
Master of Science, Mass Communication. Middle Tennessee State University, 2009.
Bachelor of Arts, English. Sewanee: The University of the South, 2004.

Professional Positions

Assistant Professor, Middle Tennessee State University, Communication Studies. (August 2016 - Present).
Lecturer, University of Tennessee, Knoxville, Communication Studies. (May 2014 - May 2016).
Postdoctoral Research Associate, University of Tennessee, Knoxville, Center for Information and Communication Research. (July 2014 - March 2016).

Relevant Scholarship

Sample of Journal Articles (Published)

Dalton, E. D., Gruber, K. G. (2021). Being PAL: Uncertainty and Coping in r/PregnancyAfterLoss. *Health Communication, In press*.

Dalton, E. D., Pjesivac, I., Eldredge, S., Miller, L. (2020). From Vulnerability to Disclosure: A Normative Approach to Understanding Trust in Obstetric and Intrapartum Nurse-Patient Communication. *Health Communication, 2,* 1-14. https://www.tandfonline.com/doi/full/10.1080/10410236.2020.1733225?scroll=top&needAccess=true

Miller, L. E., Eldredge, S. A., **Dalton, E. D.** (2016). "Pain Is What the Patient Says It Is": Nurse--Patient Communication, Information Seeking, and Pain Management. *American Journal of Hospice and Palliative Medicine, 34*(10), 966-976.

Dalton, E. D., Miller, L. (2016). Peers, stereotypes and health communication through the cultural lens of adolescent Appalachian mothers. *Culture, Health, & Sexuality, 18*(2), 115-128.

Dalton, E. D. (2015). The protective effects of adolescent motherhood in South Central Appalachia: salvation from drugs and emptiness. *Journal of Transcultural Nursing, 26*(4), 409-417.

Kelly, S., Eldredge, S. A., **Dalton, E. D.,** Miller, L. E. (2014). Health-information behavior: An initial validity portfolio for active and passive measures. *Communication Research Reports, 31*(2), 171-182.

Under Review

Dalton, E. D., Eldredge, S., Miller, L., Pjesivac, I. "Information-seeking barriers and strategies in maternity care: A framework analysis of nurses' goals, plans, and actions" (Under review, *Journal of Communication in Healthcare*).

Sample of Conference Presentations

Dalton, E. D., Eldredge, S., Miller, L., & Pjesivac, I., Kentucky Conference on Health Communication, "Overcoming the emotional and informational barriers to patient disclosure in pregnancy: Perspectives and strategies of nurses," University of Kentucky; National Cancer Institute and the Office of Behavioral and Social Sciences Research, Lexington, KY (virtual), (April 3, 2020).

Fasano, H., **Dalton, E. D**., & Miller, L. Kentucky Conference on Health Communication, "Speaking up: Predicting interprofessional communication behaviors of nursing students," University of Kentucky; National Cancer Institute and the Office of Behavioral and Social Sciences Research, Lexington, KY (April 2018).

Dalton, E. D., Eldredge, S., Pjesivac, I., & Miller, L. DC Health Communication Conference, "Disclosure, trust, and prenatal care: The trust-attraction hypothesis in obstetric nurse-patient communication," George Mason University's Communication Department and The Center for Health and Risk Communication, Fairfax, VA, United States of America. (March 2018).

Previous FRCAC Award

Dalton, E. D. (Principal), "Disclosure, trust, and prenatal care: The trust-attraction hypothesis in obstetric nurse-patient communication," $7,500.00. (June 2017 - August 2018).

Relevant Memberships and Service Activities

Professional Memberships

National Communication Association (August 2010 – Present)
Southern States Communication Association (March 2014 – Present)

Sample of Service Activities

Health Communication Concentration Committee (MTSU Communication Studies department); Chair: August 2017 – April 2020; Member: May 2020 – Present.
Panel Chair, National Communication Association Annual Conference, "Navigating Conversations about Pregnancy, Postpartum, and Loss," National Communication Association, Baltimore, United States of America. (November 2019).
Panel Chair and respondent, National Communication Association Annual Meeting, "The Maternal Health Crisis in the U.S.: Communicating for Survival," National Communication Association, Baltimore, MD, United States of America. (November 2019).
Reviewer/Referee, National Communication Association Health Communication Division, Washington, DC.
Reviewer/Referee, *Health Communication* (Taylor & Francis)
Ad hoc peer reviewer
Reviewer/Referee, *Qualitative Health Research* (Sage)
Ad hoc peer reviewer
Reviewer/Referee, *Journal of Transcultural Nursing* (Sage)
Ad hoc peer reviewer

March 12, 2021

Dear Reviewers,

Thank you for your feedback, and for the opportunity to revise my FRCAC application materials. I have read carefully through the comments and suggested edits. I am grateful for the encouraging words from the committee, and believe I can successfully address the critiques to make this a stronger proposal.

Reviewer 1:

"Does this include all types for deliveries? C-sections, natural, epidurals, nurse-midwife in the home, etc?...Does prenatal care factor into the outcome?"

The population of interest does include all types of deliveries. New questions have now been added to the questionnaire to capture a variety of aspects of the delivery, including the type (vaginal, planned c-section, emergency c-section), specific interventions for vaginal delivery (e.g., forceps), pain management tools and medications, and labor support people in attendance (including doulas).

Prenatal care does likely impact communication between patients and providers during labor and delivery, which is the outcome of interest here. But my guess is that it is a function of more or less familiarity with the attending caregiver. Therefore, I sought out and borrowed wording from the Listening to Mothers Survey that asks: "Was the person who attended the birth of your baby: *The person or one of the people who took the lead in providing my prenatal care; Someone I met briefly during my prenatal care; Someone I did not meet until the time of labor and birth; Some other person?"* I also included a question about whether the participant had regular prenatal care, and whether that took place in groups, as an individual patient, or both.

Reviewer 2:

"…my broadest recommendation or question is how a quantitative study is going to be used as the basis for a qualitative study in the future."

I agree that using qualitative studies to inform the development of quantitative studies is more common. In communication studies, and in particular health communication, it is not unheard of to start with numbers to identify whether or not a problem exists. In this case, the current study will be used primarily to explore the status of communication quality during labor and delivery to identify whether certain problems, gaps, and desires exist, and to what extent- which, from the literature, we have reason to believe they do. If the quantitative data point to specific needs and issues, then the need to explore this more deeply through qualitative, ethnographic research is warranted. I now highlight this connection on the top of p. 5 of the proposal.

"…theoretical framework…One of the critiques I have of the ways in which people of color and disease are discussed in both the media and in some academic literature could be used to blame the victim/"culture" or biological race. I suggest that Dr. Dalton review some of this work and

perhaps engage it in an effort to both eschew biological explanations for disease etiology and enrich her work."

When examining health inequities, particularly between white and BIPOC populations, I use the public health framework approach of the "social determinants of health." For instance, this includes acknowledgment that the stress of enduring daily racism can better explain Black women's poorer birth outcomes than many biological or behavioral variables. Since my last submission of this proposal, a new book called *Birth Settings in America: Outcomes, Quality, Access, and Choice* has become available which highlights this etiology specifically in maternity care. Because of its specificity in outlining maternity-related social determinants within this public health framework, I have cited it in the proposal on p. 4 (top of page) as a rationale for exploring differences across different demographic groups.

"…I would like to see more attention or mention of whether or not Dr. Dalton is examining the role of midwives and doulas and how variation on different hospital or home birth contexts might be important?"

The survey will ask about birth setting, and additional questions have now been added to capture a variety of aspects of delivery, including the type (vaginal, planned c-section, emergency c-section), specific interventions for vaginal delivery (e.g., forceps), pain management tools and medications, and labor support people in attendance (including doulas). Acknowledgement of the potential impact of these variables on communication and knowledge outcomes is now at the top of p. 6.

Other comments:

"The timeline seems very fast given the challenges with the pandemic?"

The timeline for data collection was estimated by the Qualtrics project managers. For the writing, the potential for spring/early summer data collection will allow me more time to analyze and write the results over the summer months.

"The literature review would be greatly improved by providing more detail and reviewing studies that have been previously conducted."

More literature was added (pp. 3 – 4) to round out the rationale for this study filling a gap in what we know about women's birth experiences.

"The methods could be improved by including other indicators that could meaningfully impact recent child-bearers. These include physical and mental health related indicators that target such characteristics as perceived social/spousal support, anxiety, stress, postpartum depression, etc. By including these indicators, it would be more likely for the PI to identify meaningful associations from her sample."

I did consider these types of indicators when developing this questionnaire, and agree that they play a role in women's overall maternity care experiences, particularly during the postpartum

period. While this study is seeking to gain a picture of the quality of communication and related needs during the labor and delivery and postpartum periods, I hope to have a large enough sample to account for differences in the suggested psychosocial variables, which are not among the potential independent variables of interest (versus the demographic factors described in RQ 4). However, I do ask them to rate on a 1-10 scale their overall delivery experiences from extremely negative to extremely positive.

"An appropriate biosketch is missing that states the qualifications of the PI (e.g. publications, presentations, other aspects of expertise, etc.)."

The biosketch has been revised. It is now in the format of an abbreviated CV, summarizing relevant scholarship, service, and professional associations, as opposed to the narrative description provided in the original submission.

Thank you again for your feedback, and for reviewing this revised submission.

Sincerely,

Betsy Dalton, PhD
Assistant Professor
Department of Communication Studies

Appendix A: Qualtrics Panels Quote

qualtrics.XM

Research Services Quote

Qual2413-0827Birth

333 W River Park Drive
Provo, UT 84604
US

Phone: (801) 374-6682

Fax: (866) 562-9828

08-Mar-2021

Expires after 30 days

Payment Terms Net 30 from invoice

DESCRIPTION

Research Services:	USD 5200
TOTAL AMOUNT DUE TO QUALTRICS	USD 5200

Summary:
- Live in the U.S.
- Female
- Age 18+
- Given birth in the last year

Quotas:
- Education level
- Race
- HHI

What's Included With Current Project Price:
* $8.25 per quality response
* Incentive and Incentive Management
* Speeding screener set at 1/2 of median time
* Can replace bad data (straight-liners or gibberish in open responses)
* Programming of any needed screeners, quotas and redirects
* Soft launch (pause project at 10% of completion so you can review and make minor adjustments to survey)
* Updates on project status (excel spreadsheet of raw data will also be provided at the end of a soft launch and the end of data collection)
* Survey distribution
* Project Manager is there to answer any questions while the survey is out in the field

*Quote assumes no other quotas or screeners. Additional quotas or screeners may affect feasibility and pricing.

Sample Size:	400
Length of Survey:	15 Minutes or less.

Hunter Bagnal hunterb@qualtrics.com (801) 374-6682

Appendix B: IRB Approval

IRB
INSTITUTIONAL REVIEW BOARD
Office of Research Compliance,
010A Sam Ingram Building,
2269 Middle Tennessee Blvd
Murfreesboro, TN 37129

MIDDLE TENNESSEE STATE UNIVERSITY

Human Participant Research Proposal
IRBF004: EXEMPTION REQUEST FORM

"Exempt" Definition:
It is important that seekers of IRB exemption understand that "exempt" does not reflect its literal meaning but those protocols that qualify for "exempt status" are often reviewed by the MTSU Office of Compliance and do not require an annual continuing review. However, the procedure and documents requirement for exempt protocols are mostly same in comparison to those protocols that require more IRB oversight.

What does this form contain?
This new exemption request form contains several newly added features to help researchers to clearly outline their proposal to collect data from living individuals. Although more information is requested from the applicants, the review process is expected to focus on the research and human intervention than on minor issues. This form also contains space for reviewer comments thereby allowing the review process to resemble an informative discussion. The applicant must provide the necessary details for questions in Sections 1-11 (Refer to the following list of contents). The Sections 12 & 13 are for Office Use only.

1. Project Information
2. Investigator Information
3. Exemption Determination
4. Exemption for Research with minors
5. Selection of Research Category
6. Research Methods & Instruments
7. Participant Selection & Recruitment
8. Informed Consent
9. CITI Training
10. Mandatory Documents & Attachments
11. Investigators' Declaration and Assurance
12. *Review (Office Use)*
13. *IRB Action (Office Use)*

Mandatory requirements

- Completed informed consent form - Click
- All of the investigators must complete all required research-specific CITI training modules
- Provide a detailed strategy for avoiding COVID-19 infection if the participants will have direct interaction
- In addition, other documents may be required

Instructions for document submission.

- This application and support documents must be submitted by the faculty member who signs Section 11.2.
- Send all documents as separate files but in a single email to irb_submissions@mtsu.edu
- Submit all IRB forms in their original MS Word format – DO NOT CONVERT TO PDF

Review & Timeline

- Once the OC confirms that the application is complete, a complete review will be completed within 2 weeks
- This form will be sent back to the investigators with reviewers' comments and other instructions
- The review process is iterative and it depends on how swiftly the investigators are able to address all reviewers' concerns.
- Once a final approval has been issued, a "locked" version of this form will be sent to the investigators to be used as a guideline for their study.

1. PROJECT INFORMATION

1.1 **Choose your review type:** ☒ EXEMPT Review

1.2 Enter Project Title

Communication during labor and delivery: Examining women's perceptions, needs, and desires

1.3 Primary Investigator or Principal Investigator (PI) Information:

☒Faculty[4] ☐Staff[4] ☐Graduate[5,6] ☐Undergraduate[5,6] ☐Other[5,6]

Name	Elizabeth Dalton		
Email	elizabeth.dalton@mtsu.edu	Telephone	615-898-2275
Alternate Email	*if PI is a student		
Department/Unit	Communication Studies	College	Liberal Arts
Office Location	Room #201 Building Jones Hall	Box	#200
Contact Address	MANDATORY if Non-MTSU		
CITI Program ID	2955833		

Refer to https://www.mtsu.edu/irb/FAQ/ResponsibilitiesOfPI.php for PI responsibilities.

1.1 Faculty Advisor (FA) NONE

1.4 Investigating Team NONE

Foot Notes:

[4] Faculty PI must complete and sign Sections 11.1 and 11.2

[5] The Student PI must complete Section 11.1 and an MTSU Faculty Advisor/mentor must sign Section 11.2. In addition, the application documents MUST be emailed to irb_submissions@mtsu.edu by the MTSU Faculty who completes Section 10.2 with a statement of approval in the body of the email.

[6] The Students, regardless of their affiliation, MUST complete "Students in Research" module from CITI Program

[7] The faculty advisor or sponsor MUST be an MTSU faculty member.

1.5 Submission Status of this Study:

☒ New Submission[1] ☐ Revision[2] ☐ Previous Protocol ID(s) given to this study[3]

1.6 Research Classification *(select ALL that apply):*

☒ Social/Behavioral/Educational Research ☐ Biomedical Research
☐ Clinical Research ☐ Quality Assurance/Evaluation

1.7 Research Category *(select ALL that apply):*

☒ Faculty/Staff research ☒ FRCAC ☐ URECA ☐ Class Project
☐ Thesis Dissertation ☐ Not for Publication ☒ Publication/Presentation
☐ Other

1.8 Miscellaneous Questions:

Project Questions	Response	Remark(s)
Expected start date	December 1, 2020	Will depend on FRCAC funding cycle and approval
Anticipated completion date The protocol will be closed on this date	December 1, 2022	
Source of funding (Funding agency, number/ID, and expiration date)	n/a	Applying for FRCAC funding

This form also contains space for reviewer comments. Therefore, do not convert this to PDF but instead send the completed form to irb_submissions@mtsu.edu in its original MS Word format.

Review Tracker

Protocol ID	**21-10192q**
Application Date	**08/28/2020**
PreScreen	**08/31/2020**
Revision (if applicable)	**09/01/2020**
Review	**09/03/2020**
Revision (if applicable)	**Not Required**
Exemption Determination	**09/04/2020**

Foot Notes:

[1] Check this box if this is the first time you are submitting this study for IRB review

[2] Check this box if you have already submitted this application to the IRB but you have been asked to make revisions to your application or other documents by the IRB or by the Compliance Staff

[3] Check this box and provide the IRB ID if you are trying to extend a previously approved IRB protocol

2. EXEMPT DETERMINATION QUESTIONAIRE

2.1	**Vulnerable Subjects -** Are the subjects from a vulnerable group, such as, prisoners, seriously ill, cognitively impaired, protected minorities and/or *etc.*?	☐ **Yes** ☒ No
2.2	**Risk to the Subjects -** Does the research involve the collection of behavioral data which, if known outside the research, could reasonably place the subjects at risk for criminal or civil liabilities or be damaging to the individual's financial standing, employability or reputation?	☐ **Yes** ☒ No
2.3	**Sensitive Topics -** Will you be collecting information regarding sensitive topics or personal aspects of a subject's behavior, such as, drug or alcohol use, illegal conduct, sexual behavior, mental health an/or etc.?	☐ **Yes** ☒ No
2.4	**Video/audio -** Will you be audio/video recording participant's response?	☐ **Yes** ☒ No
2.5	**Discomfort(s) to the Subjects -** Will this study expose the subjects to discomfort or stress beyond the levels encountered in daily life?	☐ **Yes** ☒ No
2.6	**Research with Minors -** Does your research involve *collection of data from minors* or *use of data collected previously from minors*? Complete Section 4 if Yes	☐ **Yes** ☒ No

Other than question 3.6, if you answered "YES" to any of the above questions, then t research is DISQUALIFIED from obtaining an exempt designation

3. RESEARCH WITH MINORS

Additional information for data collection from minors and use of data previously collected from minors

If the intended delivery of the educational materials to the minors is not to verify a research question, then this study may qualify for exempt status. The investigating team must *complete the CITI SBR modules "Research with Children"* and *"Research in Public Elementary and Secondary Schools."*

The study involves:	☐ Active participation of minors	Complete 4.1 through 4.4
	☐ Use of data previously collected from minors	Complete 4.1 and 4.2

4.1	Will this study involve activities other than the delivery of education **or the use of data from non-educational activities**? ***If YES, then NOT Exempt***	☒ **Yes** ☐ No
4.2	If answered "NO" for 4.1, then will/did the delivery of education entail(ed) typical curriculum? ***If NO, then this study is NOT Exempt***	☐ Yes ☐ **No**
4.3	The students will be tested to evaluate or assess a research question? ***If YES, then this study is NOT Exempt***	☐ **Yes** ☐ No

Parental Consent Question:

4.4 Will all of the minors do the same activity/activities or will the subjects will be selected from a class using a random sampling scheme?

☐Yes *No further action is necessary if the study passed the other exemption tests*

☐No If the students will be purposefully selected, then study may still qualify for exemption but you must obtain **PARENTAL CONSENT** and administer **the CHILD ASSENT**. Use the forms from the Expedited Review section for both of these processes.

4. RESEARCH CATEGORIES

The Federal Code [45 CFR 46 (46.101)] identifies the activities that fall within the following six categories as exempt. You MUST select the appropriate exemption category that apply to this study.

	Exemption Category - research activities that are exempt from continuing review	
1	Research conducted in established or commonly accepted **educational settings**, involving normal educational practices, such as, (i) research on regular and special education **instructional strategies**, or (ii) research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods	☐
2	Research involving the use of **educational tests** (cognitive diagnostic, aptitude, achievement), **survey procedures, interviews or observation of public behavior**, UNLESS (i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects; AND (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation	☒
3	Research involving the use of **educational tests** (cognitive diagnostic, aptitude, achievement), **survey procedures, interviews or observation of public behavior** that is not exempt in 5.2 of this section if: (i) the human subjects are elected or **appointed public officials or candidates for public office**; OR (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.	☐
4	Research involving the collection or study of **existing data, documents, records** (pathological specimens or diagnostic specimens) if publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects or the data were collected through a different protocol approved by an ethics committee such as the IRB	☐
5	Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate or otherwise examine: (i) **Public benefit or service programs**; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; OR (iv) possible changes in methods or levels of payments for benefits or services under those programs	☐

6	**Taste and food quality evaluation and consumer acceptance studies:** (i) if wholesome foods without additives are consumed, OR (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Services of the US Department of Agriculture	☐
	NONE OF THE ABOVE? – This study may not qualify for exemption.	☐

5. RESEARCH METHODS & INSTRUMENTS

Fill or paste with appropriate text in the editable spaces provided. The ""Review Questions" shown within closed boxes are locked and cannot be edited until a review has been completed.

5.1 Protocol Summary – Use this section to summarize the entire protocol using all the steps presented in this protocol. Provide a step-by-step account all of the procedures and interventions/interactions to be experienced by the participants starting from the recruitment till debriefing. Also include time and resource commitments to the participants. Use subtitles or separate steps using paragraphs.

In this study, I will collect survey data from women in the United States who have given birth in the past 12 months. If funded, I will utlize Qualtrics Panels to obtain a demographically representative sample of about 400 participants. The survey will include both demographic and close-ended Likert-type and yes/no questions about women's perceptions of their understanding of their births, communication with providers, and desire/need for further communication with providers about their births. The survey contains 22 questions with and additional 9 questions pertaining to demographics and birth details. The survey should take about 10-15 minutes to complete. Upon completion of data collection, I will use Excel and SPSS to analyze the data in terms of descriptive understanding of women's needs and experiences, as well as differences between and among different demographic groups.

5.2 Study Description – Describe this study using the outline provided below:

Purpose

Specifically, I am seeking to explore gaps in patient understanding, patient-provider communication, and the need and desire for postpartum discussion with providers.

Background

Previous research has focused on understanding postpartum psychosocial outcomes such as postpartum depression (Meades et al, 2011), social support needs (Negron, 2013), and broad informational needs (Slomiam, 2017). This study, however, will look directly at the women's communication needs about their own birth events with healthcare providers involved their care. In addition, existing research about patient-provider communication following childbirth has been mostly limited to studies outside of the United States (Skibniewski-Woods, 2011), and large-scale US research, such as the Listening to Mothers series of surveys (Declercq et al, 2013; Sakala et al, 2020), have not focused directly on communication and knowledge needs. Those surveys, however, have highlighted important knowledge gaps, education and racial disparities in maternity care experiences, and reticence on the part of pregnant and laboring women in the patient role. The current proposed study will focus on women across the United States, where birth outcomes are poor relative to other developed nations (Verbiest et al, 2018) and postpartum debriefing and discussions are not usually offered as part of standard maternity care. Therefore, it is important to gauge whether US women need or are interested in these types of sessions.

Rationale

Regardless of the type of birth, whether "normal," traumatic, or somewhere in-between, women feel the need for explanation and understanding of their labor and delivery experiences (Carlgren & Berg, 2008; Thompson & Downe, 2016). Research has also identified gaps in women's understanding about what happened during birth (Baxter, 2007; Lavender & Walkinshaw, 1998). In some birthing contexts, such as at birth centers and in European countries, this understanding is facilitated by offering informal discussions of a

woman's particular birth events early in the postpartum period. When given the opportunity to simply meet with and talk through their birth experiences with a provider, women report on these experiences positively (Freyer & Weaver, 2014). Despite this, these meetings following childbirth are not part of standard practice in the United States, nor are they explicitly recommended as part of optimal postpartum care (ACOG, 2018). Questions remain about whether the desire for listening, opportunities to ask questions, and the chance to make sense of birth experiences with healthcare providers exist among women in the U.S., particularly as we seek to understand our alarming disparities in birth outcomes (Howell & Zeitlin, 2017).

Study Design

This study will consist of a survey, constructed and distributed via Qualtrics, designed to assess women's self-perceived understanding of birth events, perceptions of communication with providers, and needs and desires for postpartum discussion. Much of the survey will replicate Baxter's (2019) study conducted in the UK that sought to address similar questions about women's goals and needs in postnatal conversations with midwives. This survey will also examine perceptions of providers' listening, clarity, empathy, and shared decision-making during labor and delivery processes, which are key parts of achieving patient-centered care (Epstein & Street, 2011). Finally, this survey will assess women's self-efficacy in explaining and describing the events and details of their births. Given the importance of accurate recall for managing future pregnancies (Attanasio et al., 2017), it will be useful to capture women's own perspectives on personal health information and self-perceived knowledge gaps.

Other

REVIEW QUESTION A: Is the purpose of this protocol and the associated procedures/interventions clearly described to make a rational decision?
Reviewer Comments:
Investigator Response:

5.3 Data Type – Check all those apply and provide additional information as directed

☐ Existing data *(complete 6.3.6)* ☐ Biospecimen *(complete 6.3.7)* ☐ Educational *(complete 6.3.1-5)*
☒ Social *(complete 6.3.1-5)* ☐ Behavioral *(complete 6.3.1-5)*
☐ Physical interventions ☐ Psychological interventions **THESE ARE DISQUALIFIED**
☐ OTHER(s)

5.3.1 COVID-19 Risk Assessment – Select one of the following

☒ Virtual or online interaction with NO direct physical contact with the participant
☐ **Direct physical interaction with the participant: Complete Section 6.6**

5.3.2 Data Acquisition - Select all that apply

☒ **Survey**[8]
☒ Online Web-based Survey[10] *Insert Weblink for the survey*
Qualtrics Link(s):
https://mtsu.ca1.qualtrics.com/jfe/preview/SV_6DtzkRM6HI1S3SR?Q_SurveyVersionID=current&Q_CHL=preview
Visit https://mtsu.edu/irb/FAQ/OnlineDataCollection.php for more information

☐ **Interview**[8] *Submit interview script/topics*

☐ **Observation**[9]
Explain and describe the instruments

☐ **Focus Group(s)**[9]
Explain and describe the instruments:

☐ **Other**
Explain and describe the instruments

Foot Notes:
[8] *Attach a list of survey/interview questions with the application*
[9] *Describe the instruments to be used in the observational study or to be used during focus groups*
[10] All of the investigators MUST *complete "Internet Based Research" module under CITI SBR course*

6.3.3 **Provide a short description of what is collected in section 6.3.2 above:** Survey data via Qualtrics; includes demographic and Likert-type/yes-no questions about birth experiences

6.3.4 **Explain how the data described in 6.3.2 will be collected:** Using a professional service (Qualtrics Panels- "Services Overview" document attached), survey will be disseminated online using the Qualtrics platform

6.3.5 **Describe how the data collected from 6.3.2 will be analyzed:** Using SPSS, data will be descriptively and inferentially analyzed to identify women's understanding, needs, and desires related to communication in labor and delivery setting; Will also examine differences between and across demographic groups.

6.3.6 ***Existing Data – OTHER THAN BIOSPECIMEN***

- *Definition:* "Existing Data" corresponds to the generalizable information generated or collected from living individuals using an approved IRB protocol. If the data were already collected without an IRB protocol, then IRB approval will not be granted.
- *Data Release:* If the existing data are not publicly available, a **Data Release Certification** may be needed from the original owner of the data in order to obtain IRB approval

6.3.7 ***Biospecimen collected through a previously approved IRB protocol***

REVIEW QUESTION B: Is the data acquisition, usage and analysis clearly explained?
Reviewer Comments: Yes
Investigator Response:

6.4 Research Site(s) - Where will the research be conducted?

☐ MTSU – Department(s)/Building(s)
☐ Public Place(s)
☒ OTHER[12] Online

[12] *Permission letter(s) from non-MTSU organizations must be provided as a scanned PDF of a message written on an official letter head signed by an official from the organization who has such authority. Forwarded emails, text messages and other non-verifiable formats will NOT be accepted.*

6.5 What are the risks for the participants? – Describe in detail how this proposed study presents no more than minimal risk[13] to the participants.

Women will be asked to respond to closed-ended prompts about their most recently labor and delivery experiences. They will not be required to disclose any personal or sensitive information, which minimizes the risk of harm or discomfort posed by this questionnaire. If a participant's recent birth was a negative experience, she may experience some discomfort reflecting on that experience. However, she may withdraw her participation or exit the survey at any time

[13] *"Minimal risk" describes the probability and magnitude of harm or potential discomfort anticipated in the research are not greater than those ordinarily encountered in daily life. Also note that research that involves more than minimal risk will disqualify this study from exemption.*

6.6 If the participants will direct interactions with other participants or with the investigators, then complete this section to describe how this protocol will address the risk due to COVID-19. Describe in detail

Please provide the information requested in the following items:

REVIEW QUESTION C: If risks are necessary, are they minimized to an extent such that the participants are only exposed to the same amount of risk they would experience in their normal life?
Reviewer Comments: Yes
Investigator Response:

6.6 **What are the benefits of this study?**

This study will provide a quantifiable look at previously unanswered questions about women's communicative experiences during labor and delivery. The women participating will be indirectly benefitted by the knowledge this study contributes to healthcare practice.

REVIEW QUESTION D: Does this study result in benefits that outweigh the potential risks?
Reviewer Comments: A compensation of $8.25 is not a valid benefit as defined by HHS. Please revise this with the actual benefit to the participant that she may receive only in the context of this research
Investigator Response: I removed the statement about the compensation. Please let me know if there is more I should add. This has been removed from the benefits section of the informed consent statement as well.

7 PARTICIPANT INFORMATION

7.6 **Research Participant Recruitment –** Describe how you will recruit the participants (recruitment materials MUST be submitted with this form), indicate whether the participants are 18 years of age or older, estimate the approximate number of research participants and describe inclusion/exclusion criteria used in selecting the participants.

7.6.1 ***Recruitment Tool(s) – Visit*** *https://mtsu.edu/irb/FAQ/Recruitment.php*

☐Flyer

☐Word of mouth[14] ☐Email[14] ☐Telephone[14] ☐Regular Mail[14] (Submit sample)

[14]Send the recruitment transcript as a separate file for IRB review. If contacting the participants by email or telephone or regular mail, explain how you originally obtained their contact information.

☐Web posting – Explain how the initial contact will be made

☐Social media – EXPLAIN how the initial contact will be made

☒OTHER Professional panel recruitment

7.6.2 **Describe the recruitment strategy including the recruitment steps to be followed using the recruitment tools stated above:** Qualtrics Panels will recruit, pay, and collect responses from the target population of interest (see attached "Online Sample Project Flow"). Data and responses will then be sent to me for analysis.

7.7 **Participant Description – Complete this section for all types of research including analysis of existing data** (if previously collected data are used, then describe the source from whom the data were originally collected).

7.7.1 Participants' Age	18+
7.7.2 Participant Description	Females who have given birth in the past 12 months
7.7.3 Sample Size	400
7.7.4 Inclusion Criteria	Females, at least 18 years old, minimum gravida 1
7.7.5 Exclusion Criteria	Under 18 years old, nulliparous
7.7.6 Compensation	$8.25

All recruitment materials must be submitted for IRB approval, including transcripts of personal correspondences. If the participants are to be drawn from an institution or an organization that has the authority to allow its members to participate in human subject research, then proper approval notifications from that institution MUST be submitted with this application

7.8 **Recruitment of participants through the Psychology Research Pool:**
Visit http://capone.mtsu.edu/wlangsto/ResearchPoolPage.html for further information**.**

REVIEW QUESTION E: Did you find the recruitment practice to be proper?

Reviewer Comments: yes
Investigator Response:

REVIEW QUESTION F: Does the proposed inducement sound reasonable without conflicts of interest or coercion?
Reviewer Comments: Please submit qualtrics panel additional information page. Refer to the IRB forms page of www.mtsu.edu/irb
Investigator Response: This has been completed and is attached.

7.9 **Confidentiality –** Describe in detail how you propose to protect the confidentiality of the information obtained from the participants

No personally identifiable information will be collected from participants.

7.10 **Data Storage -** Where will the data/records relating to the human participants be stored?

Data will be collected and stored on the Qualtrics servers. Their Security Statement (https://www.qualtrics.com/security-statement/) says that these servers "are protected by high-end firewall systems…Access to systems is restricted to specific individuals who have a need-to-know this information and who are bound by confidentiality obligations." Once downloaded, data will be stored only on the password-protected MTSU computer of the PI.

The data and records must be stored by the PI (Faculty advisor if the PI is a student) for at least THREE years after the study has been completed.

REVIEW QUESTION G: Has/Have the researcher(s) done everything possible to protect the participants' anonymity and confidentiality?
Reviewer Comments: Yes
Investigator Response:

8 INFORMED CONSENT

Investigators must remember that the consent process is like a conversation; it is not merely a document. Therefore, this process must be one of the center theme of your protocol in addition to protecting the autonomy and confidentiality of the subjects. The investigators are required to fully inform the participants on all of the activities to be carried out in the study and they must obtain consent from the latter prior to data collection. An informed consent document can be obtained from the MTSU IRB website. **Respond to these questions after completing the** MTSU-approved informed consent template**:**

8.1 Who will obtain informed consent? (Full Name(s)) — Elizabeth Dalton via Qualtrics

8.2 How will the consent be obtained? (Describe how consent will be administered and obtained) — Informed consent will be a statement to which participants agree on the first page of the survey by clicking "agree" or "next."

8.3 What language(s) is the text? — English

8.4 Where will the consent be obtained? — Online

REVIEW QUESTION H: Is there enough evidence that the subjects are adequately informed and the autonomy of the participants respected?
Reviewer Comments: Yes - A revised IC has been submitted
Investigator Response:

REVIEW QUESTION I: Are the informed consent processes/documents fair and appropriate?
Reviewer Comments: Yes
Investigator Response: I am attaching a revised version with additional info requested by the Qualtrics Panels form.

9 CITI TRAINING

This application WILL NOT be reviewed if the training for all of the investigators is incomplete

- The entire investigating team must complete "Social and Behavioral Research" basic training module
- Students must also complete "Students in Research" module in addition
- Study-specific and participant-specific modules/training must also be completed
- Click here **or visit** http://www.mtsu.edu/irb/requirements.php **to learn more**

The following CITI course(s) and modules are mandatory. Review your CITI training certificate and check boxes for all those modules that have been completed by the entire research team.

☒ Social & Behavioral Research (SBR)	
Modules for All Researchers	Modules required based on researcher status and the study
☒ Belmont Report and CITI … (ID: 1127) ☒ History and Ethical Principles - SBE (ID: 490) ☒ Defining Research ….. - SBE (ID: 491) ☒ The Federal Regulations - SBE (ID: 502) ☒ Assessing Risk - SBE (ID: 503) ☒ Informed Consent - SBE (ID: 504) ☒ Privacy and Confidentiality - SBE (ID: 505) ☒ Conflicts of Interest in …. (ID: 488) ☒ MTSU Module DEMO (ID 1073)	☐ Students in Research (ID 1321) **MANDATORY FOR STUDENTS** ☐ Research with Prisoners – SBE (ID: 506) ☐ Research with children – SBE (ID 507) ☐ Research in Public ….. Schools – SBE (ID 508) ☐ International Research – SBE (ID 509) ☐ International Studies (ID 971) ☐ Internet-based research – SBE (ID 510) ☐ Research and HIPAA …. (ID 14) ☐ Research on Workers/Employees (ID 483) ☐ Hot Topics (ID 487) ☐ IRB Member module (ID 816) ☐ IRB Administrators …. (ID 13813)

REVIEW QUESTION J: Are the reseachers' experience/qualification/training adequate?
Reviewer Comments: Yes
Investigator Response:

10 **ATTACHMENTS AND ENCLOSURES**

Documents or Websites Included in this IRB submission:

☒ Informed Consent form ☒ Surveys/questioners/interview scripts

☐ Recruitment materials and transcripts ☐ Official Permission Letter(s)

☐ Prescreening/debriefing materials ☒ CITI certificates

☒ OTHER(S), Specify: Qualtrics Panels Research Services Quote, Online Sample Project Flow, and Services Overview

☐ Online link(s):

Separate the links by ";" for materials to be reviewed (video clips, literature data and etc.)

11 DECLARATION

PI Status:

☐ Student – Complete 11.1 and have faculty advisor/sponsor must fill 11.2
☒ Faculty/Staff – Complete 11.1 AND 11.2

11.1 Primary Investigator's Assurance

I, **Elizabeth Dalton**, hereby certify that

	Indicate acceptance by entering initials
1. As the PI of this study, I assure that this application packet has been fully completed by providing all essential and required information.	EDD
2. The information provided for this exemption request is accurate to the best of my knowledge.	EDD
3. All of the investigators have completed all research-specific CITI training; I will inform the IRB immediately if training deficiencies should occur.	EDD
4. Email addresses and contact information for all investigators are given.	EDD
5. Surveys, questionnaires, tests, interview forms etc. have been included.	EDD
6. Recruitment materials (OR/and) signup information for using Psychology research pool is completed *(Enter N/A if not applicable).*	N/A
7. A filled informed consent form is attached.	EDD
8. PDF scan of all signed permission letters for researching at outside institutions (e.g., schools), is provided on official letterhead (Enter N/A if not applicable).	N/A
9. Once this protocol has been approved,	
• I will make every effort to protect the safety and welfare of the participants. I will inform the IRB immediately of any adverse events to the participants.	EDD
• Any deviations from the proposed methods will be reported immediately and changes will be implemented only after IRB approval.	EDD
• I will submit a status report of this study if directed by the IRB.	EDD
• I am aware of potential liabilities and sanctions for failure to adhere to my proposed protocol from IRB and non-IRB entities within MTSU and I agree to comply with those requirements.	EDD
• I assure that the data collected during this study and other records will be stored in a secure place within MTSU, such as the office of an MTSU faculty member. I also assure that the records will be stored for at least three years after the active data collection has been ceased.	EDD

PI[14] Elizabeth Dortch Dalton Date: 08/31/2020

[14]Student PIs must complete this section using their MTSU FSA account

11.2 Faculty Investigator's Assurance

This section must be completed by an MTSU faculty member regardless if the PI is a student or not. An MTSU faculty member must read and endorse this section if the applicant is a student. Preferably use your MTSU FSA account when completing this section. If using a home computer, please ensure that you use a licensed version of MS Office for capturing the identity of the signee. Please visit the Faculty Information page http://www.mtsu.edu/irb/FAQ/Faculty.php before signing off this form.

I, **Elizabeth Dalton**, hereby certify that

Indicate acceptance by entering initials

1. This project will be carried out under my direct supervision EDD
2. The investigators are competent and professional to work with human subjects and they comply with all of the provision required for the approval of this protocol EDD
3. I have read this application thoroughly and I attest to its scientific merit. EDD
4. I am fully aware of the activities to be performed under this exemption request. EDD
5. All of the investigators, including myself, have completed all research-specific CITI training; I will inform training deficiencies to the IRB immediately. EDD
6. Once this protocol has been approved,
   - I will report any significant or adverse events related to this study to the IRB within 72 hours of when I become aware of such incidents. I will also report breaches, such as, negligence or compromise to participant confidentiality or study-related injuries/discomforts to the participant. EDD
   - I take full responsibility to review any future changes or alterations to this study before a formal request is submitted to the IRB. Any deviations from the proposed methods will be reported immediately and changes will be implemented only after IRB approval EDD
   - I am aware of potential liabilities and sanctions for failure to adhere to my proposed protocol from IRB and non-IRB entities within MTSU and I agree to comply with those requirements[16] EDD
   - I assure that the data collected during this study and other records will be stored in a secure place in my Office or in my Department Office. I also assure that the records will be stored for at least three years after the active data collection has been ceased. EDD
   - I agree to meet with the investigators on a regular basis to monitor the study progress and compliance. I will retain records of such meetings, like email transactions and other verifiable communication records. I will also document specific conversations that would entail the welfare of the participants and other courses of actions EDD

Faculty[15] Elizabeth Dortch Dalton Date: 08/31/2020

[15]Preferably complete this section using using your MTSU FSA account

[16]Faculty Sponsor Responsibilities - http://www.mtsu.edu/irb/FAQ/Faculty.php

INSTRUCTIONS FOR SUBMISSION:

- This application and support documents must be submitted by the faculty member who signed Section 11.2.
- Send all documents as separate files but in a single email to irb_submissions@mtsu.edu
- If multiple emails had to be sent due to memory insufficiency, then provide a proper explanation in each email
- Submit all IRB forms in their original MS Word format – DO NOT CONVERT TO PDF

The REVIEW STEPS

- The Office of Compliance (OC) will issue an IRB ID if the submission is determined to be complete
- If the application is incomplete, then the IRB request will be returned with no action
- Once the OC confirms that the application is complete, a reviewer will inspect the application packet and will enter any comments or request for additional information in the appropriate space provided within this form

- This form will be sent back to the investigators with reviewers' comments
- The investigators will receive any review comments, request for clarifications or recommended revisions along with other concerns. The review process is iterative and it depends on how swiftly the investigators are able to address all reviewers' concerns.
- Once a final approval has been issued, a "locked" version of this form will be sent to the investigators to be used as a guideline for their study.

12. REVIEWER SECTION
(Office Use Only)

Exempt Pre-Review Checklist	Y	N	N/A	Reviewer Comments
Application is complete	☐	☐	☐	
Informed consent is complete	☐	☐		
Recruitment/Debriefing is provided	☐	☐	☐	
Link for web-based research – TRAINING REQD	☐	☐	☐	
CITI Training Complete (PI, FA, Co-Investigators)	☐	☐	☐	
Application Appendices	☐	☐	☐	
Faculty Endorsement	☐	☐	☐	
Off-site Permission Letters	☐	☐	☐	
Research Instruments and Tools (i.e. Surveys)	☐	☐	☐	
Grant Information/Source of Funding Provided	☐	☐	☐	
Participant Pool	☐	☐	☐	
Sample Size	☐	☐	☐	
Restrictions	☐	☐	☐	

13. IRB ACTION

Review Summary:	**Yes**	**No**
a. Is the purpose of this protocol clear?	☐	☐
b. Did you find the recruitment practice to be proper?	☐	☐
c. Does the proposed inducement sound reasonable?	☐	☐
d. Are the researchers' experience adequate?	☐	☐
e. Is there enough evidence that the subjects are adequately informed?	☐	☐
f. Are the informed consent process/documents appropriate?	☐	☐
g. Will the researchers protect the participants' confidentiality?	☐	☐
h. If risks are necessary, are the minimized to the maximum extent?	☐	☐
i. Does this study result in benefits that outweigh the potential risks?	☐	☐
j. Did the researcher(s) clearly explain the data usage?	☐	☐

Applicability:
Choose the criteria for IRB exemption: *(2) Educational Tests Qualtrics Survey*

Recommendation:

Level of Risk:	☒ Lower than Minimal	☐ Greater than Minimal
Exemption Decision	☒ Exempt	☐ **Revise and Resubmit**
	☐ Defer (Expedited/Full)	☐ Not a "research"

Moses Prabu — 09/04/2020
(Reviewer's OC ID) — (Date of Determination)