NCT02812017: Thirty Million Words- Well Baby Initiative (TMW-WB)

PROTOCOL TITLE: Thirty Million Words- Well Baby Initiative (TMW-WB)

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Thirty Million Words: Well Baby Initiative IRB
Protocol Narrative

Introduction

The Thirty Million Words Well Baby Initiative (*TMW-WB*) is a public health intervention that aims to impact parents' beliefs about their role is in creating a stimulating and enriching language environment for their baby. This comparative study of will evaluate the effectiveness of promoting critical language and cognitive development in infants of low-SES English- and Spanish-speaking parents. *TMW-WB* will target infants zero to six months and their parents during routine Well Baby pediatric visits at one week, one month, two months, four months, six months, and a final nine month follow-up. Developed in both English and Spanish, *TMW-WB* will integrate education and technology into a scalable multimedia platform. This educational intervention will impact maternal awareness and knowledge about the importance of children's early language environment.

Theoretical Background

The Well Baby Initiative is both an extension and a focused adaptation of the larger *Thirty Million Words* Initiative (TMW®). *TMW-WB* is grounded in three main bodies of literature and research. The first is research on early childhood language acquisition, child development, and child behavior. The foundation of our evidence-based curriculums derives from the differences found in children's language environments, which largely depend on socio-economic status (Hart and Risley 1995). Second is research on maternal health education and health literacy, specifically on prenatal, perinatal and postpartum education. Third is research and data on the impact of bilingual language environments on early childhood language development. Additionally, this project addresses a high priority topic for both patients and health care providers that has long-term implications for educational and health trajectories for low-SES children. In regards to making informed decisions about their children's language and cognitive development, research has shown that a gap exists between the anticipatory guidance parents want to receive, and the guidance that is provided by practitioners and parent-focused interventions. Therefore, *TMW-WB* aims to increase parental knowledge of early childhood language development and to identify the most effective way to provide consistent anticipatory guidance to caretakers. We aim to bring these bodies of research together to craft a public health intervention using existing initiatives while also adding an important educational component.

Importance of Language Acquisition on Cognitive Development:

A child's early language exposure is pivotal in language development and in ultimate educational and intellectual achievement (Bruner, 1981; Chapman, 2000; Gallaway & Richards, 1994; Hart & Risley, 1995; Huttenlocher, Haight, Bryk, Selzer, & Lyons, 1991; Rowe, 2008). Hart and Risley's landmark study demonstrated the tremendous impact of a child's early language milieu on future learning by revealing a significant correlation between the number of words a child is exposed to between ages 0-3 and his or her ultimate IQ and academic success (Hart & Risley, 1992; 1995). Their findings were both significant and alarming, demonstrating the critical and time-sensitive role that early language exposure plays in a child's life.

The concern for children born into poverty is the overwhelming inequity in their early language experience. Hart and Risley's study revealed a steep socioeconomic gradient in early exposure to words and language. At the end of their third year, children from high socioeconomic status (SES) families heard approximately *forty-five million* words; children from economically impoverished backgrounds heard only approximately *thirteen million*. Hart and Risley found that

more parental talk equated to faster vocabulary growth and higher IQ test scores at three years and older. Their follow-up with these children at 9-10 years of age confirmed that preschool/school interventions came too late to alter these trajectories; the reverberations of early linguistic shortfall were likely to follow these children throughout their lives.

However, the challenges these children face is not unalterable. It is neither genetics nor a lack of potential that lie at the heart of this inequity, but rather parental knowledge. In 2008, Rowe demonstrated that the relationship between socioeconomic status and parental communication ability is mediated by parental knowledge (Rowe 2008). Other studies have corroborated these findings, demonstrating that the effect of socioeconomic status on a child's vocabulary was primarily dictated by maternal speech (Hoff 2003). Encouragingly, studies have also demonstrated that a well-planned, parent-directed language intervention in low-income populations may positively affect parental speech behaviors by increasing the use of facilitative language with their children (Oneil-Pirozzi, 2009).

Additionally, in families where neither parent has native English proficiency, parents may choose to speak English with their children to aid their transition into an English-speaking school system. However, research reveals that native language input is more supportive of language and cognitive development than nonnative language input. (Place & Hoff, 2011; Winsler et al., 2014) This strongly suggests that both quantity and quality of input matters for successful early child language development. Additionally, native input is critical since native proficiency in one language facilitates the acquisition of another language (Oller & Eilers, 2002).

Addressing the Gap in Anticipatory Guidance

Even though parent knowledge of child development has been shown to mediate language outcomes for low-SES children, parents report that early learning topics and discussions of developmental issues are information they desire but do not receive during pediatric visits (Dungy, 2000; Young, Davis , Schoen, & Parker, 1998). Patients' unmet needs include psychosocial concerns for children, and guidance in understanding how children grow and develop (Hickson, Altemeier, & O'Connor, 1983; McCune, Richardson, & Powell, 1984; Young et al., 1998).

Practitioners agree about the need for anticipatory guidance, but report multiple barriers and wide variability in their use of screening tools (Sand et al., 2005). In a review conducted by Piotrowski, Talavera, and Mayer (2009), health care providers cited time constraints, limited staff, and lack of knowledge and resources for specific recommendations and preventative care (Kogan et al., 2004; Piotrowski et al., 2009). Similarly, Coker's and colleagues' (2013) systematic review revealed that the need for research on effective anticipatory guidance methods and redesign of patient-centered strategies to improve Well Baby care has been identified as a priority among health care providers (Chien et al., 2006; Coker et al., 2013).

The proposed study is designed to fill this gap in anticipatory guidance from birth to six months of age by providing parents with the information they seek regarding childhood development. It aims to determine the most effective and scalable way to improve healthcare delivery and increase parent knowledge, child language outcomes, and parent-child interaction.

A Participatory Model of Educational Intervention:

The *TMW-WB* educational intervention is currently being designed and planned with iterative participation and feedback from the audience we seek to have an impact on. Exploratory and formative qualitative research informs the intervention, drawing insights from mothers in immediate post-partum, parents, and healthcare providers. Our intervention is being developed

with focus groups and individual interviews with mothers and parents, consultation with medical professionals (RNs, OB GYNs, Pediatricians), and visits to community health centers and in Chicago to understand the feasibility of implementation during recommended well baby visits.

While the earlier TMW intervention was developed for toddlers, the *TMW-WB* intervention will be tailored for parents of newborns and infants. The advantage of *TMW-WB* is the employment of multiple touch points to disseminate information to parents, allowing for a continuous flow of information. The utilization of the recommended well baby visits as a platform for the TMW educational intervention ensures that parents receive information that parallels their baby's present developmental stage rather than being predictive of future behaviors. The curriculum will include messages and strategies specifically for children from birth to six months of age with a focus on preverbal communication and mother-child attachment.

The significance of the Well Baby Initiative as a Public Health Initiative

The Well Baby Initiative is a public health effort to raise awareness about the critical importance of early childhood language development. For the intervention, *TMW-WB* will be integrated into the recommended and routine postpartum Well Baby visits. If successful, we aim to scale the *TMW-WB* Initiative to the national level so that the Well Baby curriculum will be available for all parents to watch during routine Well Baby visits nationwide. As a public health approach to disparities in early language environments, cognitive development, and later school readiness, *TMW-Well Baby* offers the potential for the development of a new standard of care for pediatricians.

Purpose

The purpose of the proposed study is to determine the efficacy of a multi-media educational curriculum, presented as interactive video module, in strengthening the early learning environments of vulnerable children, and positively impacting their language and cognitive development. Through evidence-based strategies, the *TMW-WB* curriculum teaches parents how to harness the power of their words to build their child's brain and impact their child's learning trajectory.

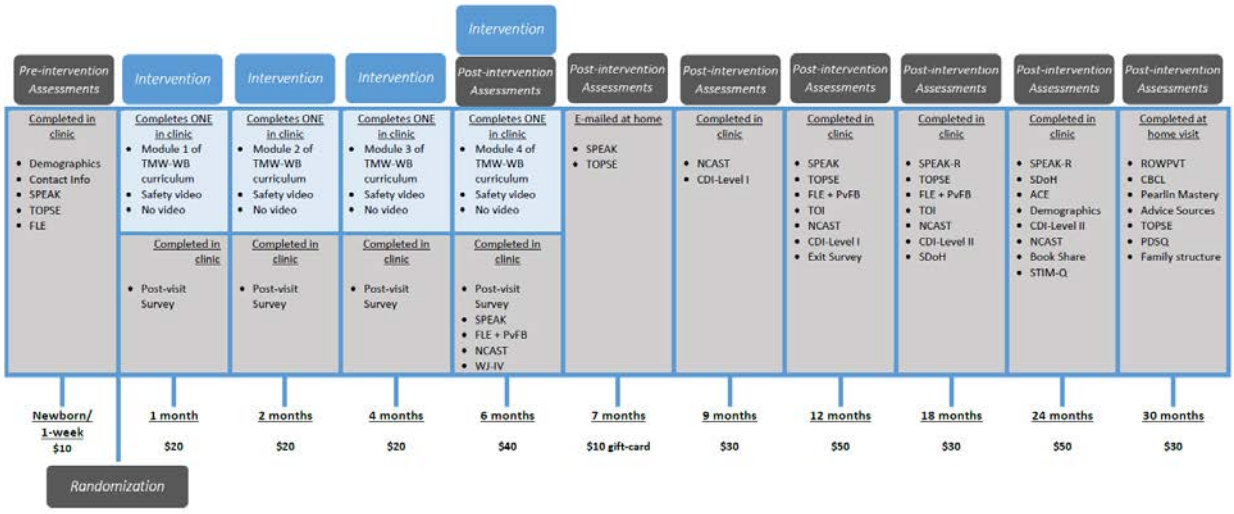
We hypothesize that the *TMW-WB* intervention will be more effective in improving parent knowledge of child language development, parent-child interactions, and child language outcomes for low-SES English and Spanish-speaking families than the *Neutral Video* or *Usual Care* comparators (more on these below). Additionally, we expect that parents who receive the *TMW-WB* educational intervention will report receiving more consistent anticipatory guidance and demonstrate an improved understanding of the critical importance of their child's early language environment for cognitive development and school readiness. The hypothesis relies on the existing research data supporting the idea that parental understanding and beliefs will alter parental behavior, and consequently, that increased parental linguistic input will impact their child's cognitive development.

We propose a three armed randomized-controlled trial to evaluate the effectiveness of the Thirty Million Words-Well Baby curriculum in reducing early language disparities among low-SES infants; specifically impacting parents by improving parent knowledge of child language development, parental language input and parent-child interaction, and children by improving language development outcomes and child-parent interaction The Thirty Million Words-Well Baby curriculum will constitute the treatment arm of the study (arm 1). The *Neutral Video* arm (arm 2), will act as the first control group. In the *Neutral Video* arm, participants view educational videos about infant safety. A second control group, the *Usual Care* arm (arm 3), will receive care as usual at their clinic. The same divisions will be made for those participants in the Spanish-speaking group.

Protocol

Study Timeline:

Participants will be recruited at Lawndale Christian Health Clinic (LCHC), Advocate Medical Group (AMG), Friend Family Health Center at the University of Chicago Medical Center (FFHC) or PCC Community Wellness Center (PCC) at their first well-baby visit. More on this in the section labeled Recruitment. If the parent and child are eligible for the study, the parents will be asked to give informed consent for the study. More detailed information is provided in the Consent section below. Please see the following figure for a graphical representation of the study timeline:



Surveys and Assessments: SPEAK: Survey of Parental Knowledge and Expectations about cognitive development, SPEAK-R: Survey of Parental Knowledge and Expectations-Research edition, TOPSE: Parenting Self-Efficacy Tool, FLE: Family Life Events Survey of family structure, the household, and the child's caretaker(s), TOI: Survey of Theories of Intelligence, Post-Visit Survey: Feedback survey about the participant's Well-Child appointment, NCAST: NCAST Teaching Scale of Parent-Child Interactions, WJ-IV: Woodcock-Johnson IV Test of Cognitive Abilities: Verbal Reasoning Assessment, MacArthur CDI-Level I: MacArthur-Bates Communicative Development Inventories: Words and Gestures (Short form) 8- to 18- months, MacArthur CDI-Level II: MacArthur-Bates Communicative Development Inventories: Words & Sentences (Short form) 16- to 30-months, SDoH: Social Determinants of Health survey, STIM-Q: Measurement of the cognitive home environment, ACE: Adverse Childhood Experiences survey, Book-Sharing: short book sharing activity between caregiver and child. Collected and shared by partner clinic: EPDS: Edinburgh Postnatal Depression Scale (or other standardized depression scale), ASQ: Ages and Stages Questionnaire, ROWPVT: Receptive One-word Picture Vocabulary Test, CBCL: Child Behavior Checklist, Pearlin Mastery Scale. Advice Sources: a survey about where parents seek advice about child development. Past parenting style experience surveys: PDSQ and family structure survey.

Following consent, patients will be asked to complete four surveys and provide contact information. The first survey is a simple demographics questionnaire indicating their race/ethnicity, age, income and education level, as well as the birth-order rank of the child who will be participating in the study. Second, patients will fill out a Family Life Questionnaire detailing the family structure of the household and the child's caregivers. Parents will be asked to fill out two final questionnaires that assess knowledge and beliefs. The Survey of Parental Expectations And Knowledge about Language Learning (SPEAK), providing a measure of their knowledge of child language development. Last, parents will complete the TOPSE, a tool for measuring Parenting Self-

Efficacy. If parents are called into the pediatrician's office before they have finished, they will be asked to complete the questionnaires after the visit is over. Questionnaire and assessment data will be collected digitally on the secure online project database REDCap. Research assistants will be assigned the task of obtaining consent, conducting the survey, and delivering the educational intervention Consent forms, questionnaires and assessments will be delivered in Spanish for Spanish speakers by a Spanish-speaking Research Assistant.

At the one-month Well Baby visit, participants in the *Usual Care* arm of the study will receive care as usual. Participants in the *Neutral Video* arm will watch the first of four short videos (approximately 5-10 minutes) about infant safety. Patients in the *TMW-Well Baby* arm will watch the *Module 1* video intervention. This module presents information on child language and cognitive development. Videos will be shown in the waiting room, or during the period after the nurse completes the child's vitals and before the pediatrician sees the patient. Should a video still be running when the pediatrician enters the room, it will be stopped and completed after the pediatrician has left. After the visit, patients in all arms will be asked to complete the Post-Visit survey about their visit, indicating the areas and level of anticipatory guidance they received during their visit, their overall satisfaction levels, and their unmet needs for guidance and requests for more information. At this visit, the health clinic may collect information using a standardized depression scale. This provides information on the covariates parental language ability and depression level. Results from the depression scale will be shared by the patient's pediatrician, both because pediatricians need to administer a depression scale anyway and in an effort to reduce burdens associated with housing the study in the clinic. If the clinic does not administer a depression scale, the Edinburgh Postnatal Depression Scale (EPDS) will be administered by the research staff.

At their two-month Well Baby visit, patients in the *TMW-Well Baby* arms will watch the *Module 2* video intervention , while patients in the *Usual Care* arm will receive care as usual, and patients in the *Neutral Video* arm will watch an infant safety video. All measures will be taken in the same way as at the one-month Well Baby visit.

At their four-month Well Baby visit, patients in the *TMW-Well Baby* arm will watch the *Module 3* video intervention , while patients in the *Usual Care* arm will receive care as usual, and patients in the *Neutral Video* arm will watch an infant safety video. All measures will be taken in exactly the same way as at the one-month Well Baby visit.

At their six-month Well Baby visit, patients in the *TMW-Well Baby* arms will watch the *Module 4* video intervention, while patients in the *Usual Care* arm will receive care as usual, and patients in the *Neutral Video* arm will watch an infant safety video. After the visit, patients in each group will be asked to complete the Post-Visit survey about their appointment. Additional measures will be taken at this visit. The SPEAK will be administered for a second time, the Verbal Comprehension section of the Woodcock-Johnson Test of Cognitive Abilities assessment will be completed, and the participants will be asked to carry out an NCAST PCI teaching task, which is a measure for assessing parent-child interaction via scalable teaching tasks that parents teach their children. Finally, the depression scale results will be shared by the patient's pediatrician, as well as the Ages and Stages Questionnaire (ASQ), if applicable. The Ages and Stages Questionnaire is a screening questionnaire that pinpoints developmental progress in children between the ages of one month to 5 years.

At age seven-months, or about one month after their six-month Well Baby visit, participants will be emailed two follow-up surveys (i.e. the SPEAK and TOPSE surveys). If they complete these

surveys within four weeks of receipt, they are eligible for a $10 gift card to be emailed. If the surveys are not completed, participants will not receive the gift-card and will complete these surveys at their next Well-Baby visit.

At their nine-month Well Baby visit, all patients will participate in a second NCAST PCI teaching scale task with their child. At this visit, the MacArthur-Bates Communicative Development Inventories: Short Form Vocabulary Checklist: Level 1(MacArthur-CDI) will be administered. Finally, the depression scale and ASQ results will be shared by the patient's pediatrician, if applicable.

At their twelve-month Well Baby visit, all patients complete the Family Life Events, SPEAK and TOPSE surveys again. Participants will also participate in a third NCAST PCI teaching scale task with their child. The MacArthur-Bates Communicative Development Inventories Short Form Vocabulary Checklist: Level 1 (MacArthur-CDI) will be administered. Finally, any depression scale and ASQ results will be shared by the patient's pediatrician, if applicable.

We are offering participants the opportunity to extend their participation in the study to their 18-month and 24 –month well child visits. If participants choose to extend their participation in the study:

At their 18-month Well Baby visit, participants will complete the MacArthur-Bates Communicative Development Inventories Short Form Vocabulary Checklist: Level 2 (MacArthur-CDI), the Family Life Events survey, a survey about social determinants of health, the Theories of Intelligence (TOI) survey, and the SPEAK-R survey. Also, participants will participate in a NCAST PCI teaching scale task with their child. Finally, any depression scale and ASQ results will be shared by the patient's pediatrician, if applicable.

At their 24-month Well Baby visit, participants will complete the MacArthur-Bates Communicative Development Inventories Short Form Vocabulary Checklist: Level 2 (MacArthur-CDI), the StimQ Cognitive Home Environment survey, a survey about Social Determinants of Health (SDoH), a survey about Adverse Childhood Experiences (ACEs), repeated select demographics questions, and the SPEAK-R. Also the participants will be asked to carry out an NCAST PCI teaching task and a short book-sharing activity with their child. Finally, any depression scale and ASQ results will be shared by the patient's pediatrician, if applicable.

We are offering participants the opportunity to extend their participation in the study to a 30-month home visit. If participants choose to extend their participation in the study:

Around age 30-months, participants will complete the Receptive One-word Picture Vocabulary Test (ROWPVT), two surveys about previous parenting style experiences (PDSQ and family structure), Child Behavior Checklist (CBCL), the TOPSE, a survey about seeking advice about child development, and the Pearlin Mastery Scale.

Recruitment

Participants will be recruited from Lawndale Christian Health Center (LCHC), Advocate Medical Group (AMG), Friend Family Health Center at the University of Chicago Medicine (FFHC) and PCC Community Wellness Center (PCC). All study locations are federally qualified health centers in Chicago serving low-SES English-speaking and Spanish-speaking families and their infants. Patients will be recruited in the clinic waiting room before being called in for the infant's first Well Baby visit at approximately 1 week after birth. If interested, patients will move to a more

private space in the waiting room area, where they will be screened for eligibility. If families are eligible and would like to participate, they will be consented.

Consent

All participants will be asked to read and sign an Informed Consent Form following the delivery of a script. For Spanish speaking participants, informed consent and all consent materials will be administered and completed in Spanish with a Spanish-speaking Research Assistant. Trained research assistants will go over the consent form one section at a time, answering any questions along the way. We will ask permission to obtain contact information including name, address, telephone and email in order to contact subject and complete follow-up survey. Research staff will keep one copy and the participant will keep one copy. This will take place during the first well baby visit at LCHC, AMG, FFHC, or PCC clinics while the potential study participant waits to see the pediatrician. So that Dr. Suskind or her research team may contact the participants in the future, we will consent for permission to keep contact information from this study (name, address, phone number, and email address) in a password-protected database.

Randomization

We will use the website Research Randomizer to generate a randomization table. We will use the service to generate a dummy set of 500 unique unsorted numbers where each unique number is paired with a participant number (1-250, sorted). In an Excel spreadsheet, the first half of the dummy number set) will be assigned evenly to the Treatment condition (arm 1) and the other half will be assigned evenly to the Control conditions (arms 2 or 3). Then, the data in the columns "participant", "condition" and "dummy" will be sorted using the Excel "Sort by" function on the column "dummy". The participant numbers are now unsorted and randomly assigned to either one of the two experimental conditions: Treatment or Control. This will allow us to ensure equal sample sizes for all treatment and control conditions. A separate randomization table will be crated in the same way for the Spanish-speaking group.

Participants

Participants will include a goal of 250 Spanish- and 250- English speaking parent-child dyads (500 parent-child dyads; a total of 1000 subjects) from LCHC, AMG, FFHC, and PCC. These participants will be randomly assigned to either the *TMW-Well Baby, Neutral Video*, *or Usual Care* conditions in English or Spanish as described above. All 500 parent-child dyads will be allocated to one of the six experimental conditions: *TMW-Well Baby* English, *Neutral Video* English, *Usual Care* English, *TMW-Well Baby* Spanish, *Neutral Video* Spanish or *Usual Care* Spanish.

Exclusion criteria

Exclusion criteria is as follows: 1) participants (i.e. parents and their children) who live over 200% of the federal poverty line, 2) parents under the age of 18, 3) children older than 1 month old (at start of study), 4) parents who do not have legal custody of their child, 5) parents whose child does not live with them, 6) parents who are unable to commit to the intervention requirements, 7) foster parents, 8) children who have experienced any of the following conditions: premature birth (36 weeks or less), cleft lip or cleft palate (and syndromes associated with clefts), Neurocutaneous syndromes (nf1 and 2, tuberous sclerosis, etc), Trisomy, cerebral palsy, history of failing a hearing test, syndromes associated with sensorineural hearing loss (alport, jervell-lange-nielsen, waardenburg, treacher-collins, etc), TORCH infection, Head bleeds or history of intraventricular hemorrhage (IVH), or has had a tracheal intubation, 9) parents who have earned or are currently working toward a graduate or professional degree (e.g. M.A., M.S., M.B.A).

Payment

Patients who participate in this study will receive a total of $200 in cash and gift-cards, plus an additional opportunity to receive $80 in cash if they choose to extend their participation in this study. Of the initial $200, $190 will be received in cash divided across seven sessions – $10 at the first Well Baby visit and enrollment, $20 at the one-, two-, four-month Well-Baby clinical visits, $40 at the 6-month visit, $30 at their 9-month visit, and $50 at their 12-month well baby visit. At 7-months participants are eligible for a $10 gift-card to their choice of Wal-Mart of Target.

Participants will have the opportunity to complete study activities at the 18-month and 24-month Well-Baby clinical visits. Participants will be paid $30 in cash for completion of these tasks at the 18-month visit, and $50 in cash for completion of these tasks at the 24-month visit.

Participants will have the opportunity to complete study activities at a 30-month home visit. Participants will be paid $30 in cash for completion of these tasks at the 30-month home visit.

Risks and Benefits of Participation

Risks are minimal, relating mostly to loss of confidentiality. Testing involves answering a questionnaire, providing demographic information, and in-clinic videotaping. The data will be stored in password-protected computers and stored in locked file cabinets. Benefits include the chance to provide feedback to clinic providers on each of the Well Baby visits attended. For those in the *TMW-Well Baby* intervention groups, there is the possible benefit of increased knowledge of the importance of early childhood language for cognitive development.

Analysis

Paired t-tests will be used to analyze total survey scores before and after intervention. ANOVAs will be used to evaluate differences in outcomes based on SES and other variables in intervention *vs.* control group.

Confidentiality and Data Sharing

The raw data will only be made available to the PI and study personnel listed on the protocol. Contact information for the participants will be stored on password-protected computers. Survey participants' names will be replaced with numerical codes such that survey scores will not be attached directly to the participants' contact information in order to protect anonymity. Via a data-sharing contracts agreement, de-identified data will be shared with LCHC, AMG, FFHC, and PCC. After the completion of their participation in the study, video data collected during the duration of the study will be shared with the participant upon their request. *After a participant requests copies of their video data, research personnel will prepare flash drives using their video files. Once the flash drives are ready, they will be in contact with the participant to coordinate a time to drop-off the flash drive to the participant.* All results from surveys and assessment measures will be shared under this agreement. The data will be carefully monitored to protect patient privacy. All paper data will be stored in a locked cabinet in a locked office with access allowed only to researchers affiliated with the project.

Files from the 24 month book-sharing activity will be shared with a contracted third party transcription service in order to prepare the video files for analysis. The videos files will be de-identified by extracting the audio before sending. Only the audio recording will be sent to the transcription service and they will be saved under a coded ID number so that the transcription service receives no identifiable participant information. The contractor will listen to and transcribe each audio file, which is a necessary first step before any analyses can be done on the videos. Files will be shared using UChicago Box and staff from

the transcription service will need a password in order to access the audio recordings. Files will be removed from UChicago Box after they are complete.

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