Evaluation of an Interdisciplinary Decision Guide for Infant Feeding Assessment

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Consent to Participate in a Research Study

IRB Study # 20-2786
Title of Study: Evaluation of an Interdisciplinary Decision Guide for Infant Feeding Assessment
Principal Investigator: Kelsey Thompson

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CONCISE SUMMARY
This study aims to test a tool to assist early intervention speech-language pathologists and occupational therapists in completing feeding evaluations for infants. You are being asked to participate in this study because of your relevant experience working in early intervention with young children with feeding disorders.

Your participation in this study will involve a survey where you will be presented with two case studies. After reading each case, you will be asked to answer some questions about it. Your participation in this study will take about 15-minutes. There are not direct benefits of participating, however we hope this tool will help speech-language pathologists and occupational therapists working in early intervention. Potential risks include risk of breach of confidentiality of information provided in this study.

What are some general things you should know about research studies? You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

What is the purpose of this study? The purpose of this research study is to gain more information about how speech language pathologists (SLPs) and occupational therapists (OTs) working in early intervention make decisions when assessing infants with feeding delays/disorders.

In phase one of this study, we developed a tool using a series of questionnaires with providers at UNC Health. In phase two (your participation) we are completing a small study of the tool to determine if it helps SLPs and OTs and if it is easy to use.

You are being asked to be in the study because of your work in early intervention with infants and/or feeding disorders.

How many people will take part in this study? If you decide to be in this study, you will be one of approximately 56 SLPs and OTs in this research study.

What will happen if you take part in the study? Your part in this study will last approximately

15-minutes. If you choose to participate in this study, you will complete an online questionnaire. This questionnaire will ask you to read two feeding case studies and answer some questions about your impressions of the child's eating skills and your opinion on the tool. It will also ask a few questions to gain some information about your prior experience.

What are the possible benefits from being in this study? Research is designed to benefit society by gaining new knowledge. You may not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study? We anticipate few risks in this study. While safeguards are in place to protect your data, breach of confidentiality is a potential risk of participating. You could experience fatigue, frustration, or stress while viewing feeding videos.

How will your privacy be protected? All of the data you provide will be stored anonymously. This means that there will be no way for anybody to ever link your data or the results of the study to your identity.

ClincalTrials.gov Registration
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information,

then the researchers may not use the Certificate to withhold that information. "

What if you want to stop before your part in the study is complete? You can withdraw from this study at any time, without penalty by exiting the survey.

Will you receive anything for being in this study? Will it cost anything? You will receive a $25 gift card for participating in this study. There are no costs associated with being in the study.

Who is sponsoring this study?
This research is funded by the National Institutes of Health. This means that the National Institutes of Health is paying for research supplies for this study. The researchers do not, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study? You have the right to ask, and have answered, any questions you may have about this research. Contact the principal investigator listed above with any questions, complaints, or concerns you may have.

What if you have questions about your rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns, or if you would like to obtain information or offer input, please contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participants will be shown a link that says "I consent."