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Informed consent process for vulnerable populations: a multifaceted approach

When conducting the research involving human subjects, it is the responsibility of the investigator to protect right and welfare of the research subjects. In general rule of research, every subjects must agree to participate in writing before they can enroll in a research. Informed consent is essential for the biomedical research. It is a communication process between the researcher and the potential research subjects that starts before the research is initiated and continues throughout the study¹. In Thailand, informed consent process includes providing the informed consent form together with information sheet. Despite its importance, obtaining informed consent is often a complex process, which raise concerns about the extent to which participants are truly informed. Effective implementation is especially difficult among research participants who have limited health literacy. Usually, these potential participants are from traditionally high-risk groups, including underrepresented minorities and children. Therefore, a study by Heerman² implemented an innovative approach that use low health-literacy communication strategies and visual aids to augment and potentially replace the traditional approach to informed consent.

A randomized controlled trial (RCT) by Heerman² was developed to prevent childhood obesity as part of the Growing Right Onto Wellness Trial (GROW). The study enrolled 839 mother-child pair consented to participate in 3-year family-centered, community-based behavioral RCT. All 839 participants were from low-income, underserved populations at highest risk for obesity, and all children were between 3 and 5 years old. The informed consent procedures for this population of mothers and children began with the “traditional” approach, by using a formal informed consent document that was reviewed in the participant’s language of choice, and was signed before participation. However, this study supplemented by drawing on enhanced communication techniques from low health-literacy and health-communication literature. GROW employed a multifaceted approach to enhance informed consent that included (1) the use of effective health communication and low-literacy techniques, (2) the use of visual aids and graphics to promote understanding and guide the reader toward key study concepts, and (3) careful attention to child dissenting behaviors.

The study team also developed 4 visual aids. These forms adhered to principles for development of low health-literacy print materials, including the use of white space, clear visual images, avoidance of jargon, and the use of easy-to-read figure captions. The study team used these visual aids while reading through the consent form with the participants, pointing to visual representations of important aspects of the informed consent process and the proposed research while talking through the written consent document. The first visual aid was an overview of study procedures and highlighted randomization, the purpose of each arm

of the RCT, the study timeline, and potential compensation for participation. The second aid detailed what participants could expect from each of 6 data collection sessions throughout the study period by using pictures to explain specific type of data collection. A third and fourth form were developed to explain in detail the specific activities of the intervention and control group.

Additionally, children were involved in this study, the study team was trained to identify dissenting behaviors. An example of a dissenting behaviors would include crying during data measurements. In these circumstances, children were encouraged to take a break from procedure and were provided health snack. Parents were encouraged not to force their children to participate in the data collection management, or to try offer a reward for participation. If a child subsequently displayed dissenting behaviors after redirection and encouragement, the child's behavior was considered dissenting, and he or she was removed from the trial.

If the research study involves participants from a wide range of cultural and education backgrounds, the research team needs to put their effort to deliver communication to ensure understanding of all potential participants. This study give an advance informed consent to build on the strong health-communication literature to not enhance but replace the currently cumbersome and confusing informed consent process. Therefore, the investigators need truly understand that informed consent in research means more than simply obtaining the signature of the potential research subjects.

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Source:

- ¹ Dunn CM, Chadwick GL. Protecting study volunteers in research; a manual for investigatove site. CenterWatch, a division of Thomson Health care, Inc. 2004. The United States.
- ² Heerman WJ, White RO, Barkin SL. Advancing informed consent for vulnerable populations. *Pediatrics*. 2015;135(3):e562-e4.