

## **Practical Strategies to Improve Informed Consent**

**By David S. Festinger and Karen L. Dugosh**

Informed consent is a key component of ethical research. The informed consent process helps to ensure that individuals understand study procedures, their rights and protections as research participants, the risks and benefits of participation, and that their decision to participate is voluntary. Regrettably, research has demonstrated that research participants generally have poor rates of comprehension and recall of consent information (Flory & Emanuel, 2004). Some individuals fail to remember important details about the study and their protections as soon as a week after they have agreed to participate in a study. Some may not even recall that they entered a research study.

Research suggests that poor comprehension and recall of consent information is heightened among vulnerable populations, such as those seeking treatment for substance abuse (e.g., McCrady & Bux, 1999). These individuals may have temporary or sustained impaired cognitive functioning as a result of the toxic effects of drugs and the maladaptive lifestyles that often accompany drug use (e.g., poor nutrition, physical trauma). Our own research conducted with individuals who have substance use issues (Festinger, Dugosh, Croft, et al., 2010; Festinger, Marlowe, Croft, et al., 2009) found that they failed to recall 60% of the consent information just two weeks after their initial consent — often before study procedures have even started, calling into question whether such participants can make informed decisions about their initial and continued involvement in research.

Although informed consent has historically been conceived of as a one-time event similar to signing a contract or a lease agreement, our research, as well as federal guidelines (e.g., National Bioethics Advisory Committee, 2001), underscores the need to treat consent as an ongoing process in which researchers must ensure that participants continue to be informed throughout the course of the study. If one of the aims of informed consent is to make individuals aware of potential risks that may occur as a result of study participation and what actions they can or should take, researchers have an obligation to ensure that participants retain this information throughout the study. For example, if a research participant who is now experiencing severe hypertension does not recall that this was one of the potential risks of an experimental drug taken several months ago, he or she may not know to inform his or her healthcare provider about the experimental drug or to inform the researcher about this adverse event.

A great deal of research has been conducted to identify ways to improve consent understanding and recall (Festinger & Dugosh, 2012; Flory & Emanuel, 2004). The majority of this research has focused on either the structure and content of the consent document or the process of presenting the information. Approaches that address the structure and content of the consent form include simplifying the language, shortening the form, using larger fonts, and including visual aids. Strategies that address the consent process include incorporating consent quizzes, providing corrected feedback to incorrect responses, and using neutral participant advocates to obtain consent. Both types of approaches are remedial in nature and are primarily focused on simplifying the cognitive task.

Given the demonstrably poor recall of consent information among research participants who have substance use disorders, we (Festinger et al., 2010) conducted a study to examine the effects of providing monthly consent quizzes with corrected feedback. In the study, clients completed an open-ended consent quiz two weeks following consent to the host study and again at months 1, 2 and 3 post-consent. Findings indicated that participants who received

corrected feedback were able to recall significantly more consent information over time than those who did not. This result held for overall quiz scores and for scores in specific content areas (i.e., study procedures, human subjects protections, and risks and benefits). Unfortunately, these gains were modest and recall rates reached only 55% after several corrected feedback sessions. Moreover, cognitive variables, including IQ, educational attainment, and neuropsychological measures of memory and attention in statistical combination, accounted for less than 50% of the variance in initial recall (Festinger et al., 2007).

These findings suggest that cognitive strategies alone are not sufficient to improve understanding and recall of consent information, particularly among individuals with substance use disorders. It is possible that many research participants simply are not interested in learning consent information or do not view it as worth their time or effort to attend to the information presented during the consent process. To examine this issue, we conducted a second study (Festinger et al., 2009), in which we manipulated motivation to recall consent information by using cash incentives. Specifically, we told half of the participants that they would receive five dollars for every question that they answered correctly on a 15-item, open-ended consent quiz administered one week post-consent. We told the other half that they would be quizzed a week later but did not offer them a cash incentive. Findings indicated that incentivized individuals recalled significantly more consent information in terms of overall quiz scores and scores in the specific content areas. Once again, however, these gains were sub-optimal, with participants recalling only 65% of the information, on average.

Findings from these two studies indicated that neither a purely remedial nor a purely motivational approach was sufficient for individuals to demonstrate a clinically meaningful level of recall of consent information. The logical conclusion was that an approach that combined both remedial and motivational strategies might be more effective. This approach would, presumably, simplify the cognitive task and increase participants' motivation to attend to the information. For this reason, we conducted a third study (Festinger, Dugosh, Marlowe, et al., in press), in which we examined the effects of an incentivized corrected feedback procedure that incorporated both the corrected feedback procedure from the first study with the incentive strategy used in the second. Findings indicated that individuals in the incentivized corrected feedback condition had significantly higher consent quiz scores (for both the total score and for the specific content areas) compared to those in a standard consent condition. Importantly, the procedure produced recall rates exceeding 80% at the final administration (compared to less than 60% in the standard group). These findings demonstrate the clinical and statistical advantages of an incentivized, corrected-feedback consent procedure for ensuring that consent is informed.

The results from this line of research have both practical and conceptual implications for improving informed consent to research, particularly among vulnerable populations, such as individuals who have substance use disorders. From a practical standpoint, researchers could begin to implement incentivized, corrected feedback in their consent procedures. From a conceptual standpoint, the findings suggest that other strategies that incorporate both remedial (cognitive) and motivational components should be developed and evaluated. While institutional review boards might resist the use of cash as an incentive, particularly with participants who have substance use disorders, it served as an effective test of motivation in our study. There are likely many other ways to increase motivation.

Based on our review of the literature, federal guidelines, and information gained from our line of research, we recommend the following practices to ensure that consent to research is informed:

- Consent should be an ongoing process rather than a one-time event.

- Understanding and recall of consent information should be assessed throughout a study.
- Consent quizzes should independently assess understanding and recall of critical elements of the consent information, including the study procedures, human subjects protections, and risks and benefits.
- Consent quizzes should use open-ended questions rather than simple true/false or multiple-choice questions. Open-ended questions rely on recall of information rather than recognition, which is more typical of everyday experience.
- Consent procedures should incorporate both remedial and motivational strategies to optimize understanding and recall.

Participants in clinical research often fail to understand or remember much of the information provided during the consent process, including information relevant to their autonomy, such as the voluntary nature of participation and their right to withdraw from the study at any time without negative repercussions. Research conducted over the past decade provides useful strategies for improving the informed consent process and further protecting human subjects. Researchers should adopt these practices and institutional review boards should require them.

## References

- Festinger, D. S., & Dugosh, K. L. (2012). Strategies for improving the informed consent process in substance abuse research. In A. Chapman (Ed), *The Ethical Challenges of Conducting and Translating Genetic Research on Addiction*. Cambridge: Cambridge University Press.
- Festinger, D. S., Dugosh, K. L., Croft J. R., Arabia, P. L., & Marlowe, D. B. (2010). Corrected feedback: A procedure to enhance recall of informed consent to research among substance abusing offenders. *Ethics & Behavior*, 20(5), 387-399.
- Festinger, D. S., Dugosh, K. L., Marlowe, D. B., & Clements, N. (in press). Achieving New Levels of Recall in Consent to Research by Combining Remedial and Motivational Techniques. *Journal of Medical Ethics*.
- Festinger, D. S., Marlowe, D. B., Croft, J. R, Dugosh, K. L., Arabia, P. L., & Benasutti, K. M. (2009). Monetary incentives improve recall of research consent information: It pays to remember. *Experimental Clinical Psychopharmacology*, 17(2), 99-104.
- Festinger, D. S., Ratanadilok, K., Marlowe, D. B., Dugosh, K. L., Patapis, N. S., & DeMatteo, D. S. (2007). Neuropsychological functioning and recall of research consent information among drug court clients. *Ethics & Behavior*, 17(2), 163-186.
- Flory, J., & Emanuel, E. (2004). Interventions to improve research participants' understanding in informed consent for research. *Journal of the American Medical Association*, 292(13), 1593-1601.
- McCrary, B. S., & Bux, D. A., Jr. (1999). Ethical issues in informed consent with substance abusers. *Journal of Consulting & Clinical Psychology*, 67, 186-93.
- National Bioethics Advisory Commission. *Ethical and policy issues in research involving human participants*, Volume I. Bethesda, MD, 2001.

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