

A Multisensory Approach to Enhance Informed Consent and Improve Study Compliance

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Introduction

Informed consent forms (ICF) contain critical information about trial design, risks and benefits, and expectations for study subjects. By nature, these documents are often long, complex, and technical. This can lead to misunderstanding and poor subject experience, or worse: unsafe participation in trials. [1-3]

Using a multisensory approach to appeal to a variety of learning styles, we attempt to improve comprehension of informed consent documents and increase compliance to study procedures.

Auditory



- Pre-recorded videos and messages allow re-listening
- Verbal explanation of ICF encourages timely questions
- Regular verbal confirmation of ongoing consent

Examples

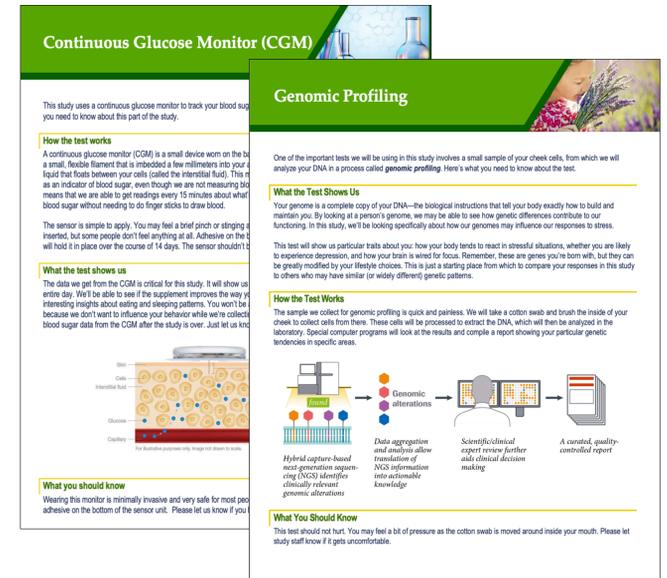
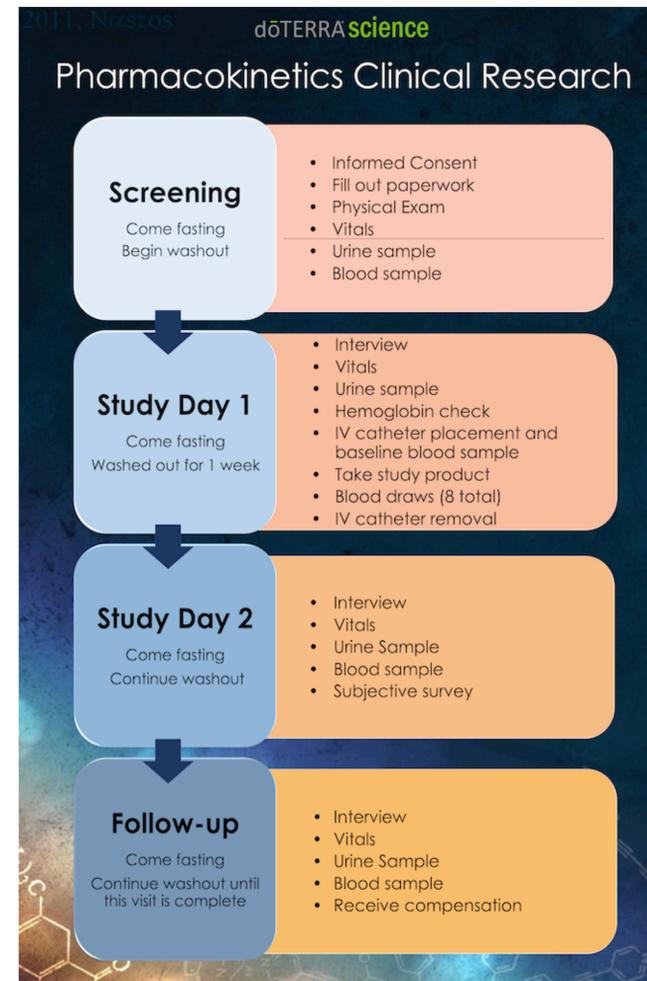


Figure 2: Colorful, simple handouts accompanying ICF give additional information about study procedures and expectations in lay language.



Figure 4: Allowing handling of study equipment during consent increased understanding and confidence.

Figure 5: Smelling essential oils helped calm participants during blood draws and study procedures.

Visual



- Pictorial depictions of study processes
- Newsletter-style explanatory documents accompany ICF
- Additional photos, cartoons, illustrations, and white space
- Shorter sentences and paragraphs

Kinesthetic



- Movement between stations during the informed consent process (e.g., different physical areas for verbal explanation, pictorial flow, hands-on interaction, etc.)
- Demonstration and handling of procedural tools to increase familiarity (e.g., touching a dummy IV catheter to understand usage)

Logical



- Poster-sized flowchart of study activities to understand patterns and expectations
- FAQ-style ICF to group ideas by category
- Active voice and fewer passive sentences in ICF and accompanying documents

Olfactory



- Optional use of essential oils during study procedures (e.g., blood draws and IV insertion) to decrease anxiety and vasovagal reaction

Results

Metric	Pre-implementation	Post-implementation
ICF Reading Level (Flesch-Kincaid Grade)	12.1	7
Anxiety and vasovagal reactions during blood draws	15%	2%
Withdrawal due to lack of understanding ICF	25% of all withdrawals	5% of all withdrawals
Engagement during consent process	Low	High

Table 1: Data showing results of multisensory approach, with metrics showing pre-implementation (2019 and prior) and post-implementation (2020 and on) of interventions.

Subjective Participant Experience Feedback

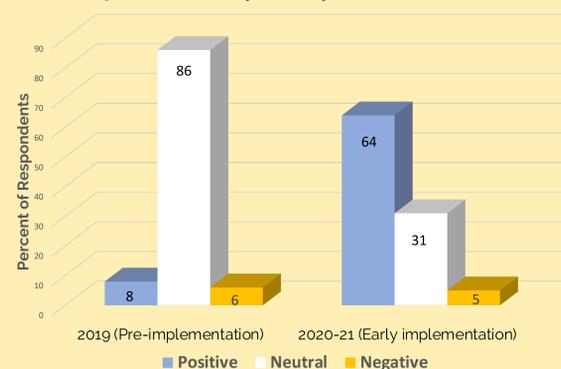


Figure 1: Subjective feedback reported by participants of clinical studies before and during implementation of a multisensory approach.

Conclusion

A multisensory approach during the consent process resulted in greater understanding, better compliance to study activities, and an overall more positive experience for trial participants. These changes are simple to implement and offer sustainable improvement over standard informed consent.

References

[1] M. Jefford and R. Moore, "Improvement of informed consent and the quality of consent documents," *Lancet Oncol.*, vol. 9, no. 5, pp. 485-493, May 2008
 [2] M. E. Falagas, I. P. Korbila, K. P. Giannopoulou, B. K. Kondilis, and G. Peppas, "Informed consent: how much and what do patients understand?," *Am. J. Surg.*, vol. 198, no. 3, pp. 420-435, Sep. 2009
 [3] N. T. Tam *et al.*, "Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis," *Bull. World Health Organ.*, vol. 93, pp. 186-198H, Mar. 2015