**The dataset represents data from the study by Abd-Elsayed et al. “A randomized controlled study to assess patients’ understanding of and consenting for clinical trials using two different consent form presentations”. *Minerva Anestesiol* 2012; 78: 564-73.**

**Dataset: Informed Consent**

Approximately 2.3 million patients participate in more than 80000 government and

Industry sponsored trials each year in the United States, and many more participate in unfunded research. The ethical basis for clinical research was expressed in the Belmont Report and includes “autonomy”, “beneficence”, and “justice”. The key aspect of autonomy is voluntary consent based on full understanding of potential risks and benefits.

Potential research subjects generally obtain most information about studies from the investigator who obtains consent, and from the written consent document. Consent documents often contain ten or more pages of single-spaced text which is daunting for most patients. Presumably, the content of the consent document affects patients’ willingness and ability to understand the proposed study. For example, shorter consent forms are generally better understood than longer ones. The physical appearance of the consent document may similarly influence patients’ willingness to carefully read the consent document and thus learn about the proposed study. It is thus possible that patients will be more receptive to read an elegantly presented consent document. We therefore tested the hypothesis that the presentation of consent documents in an enhanced format improves patient attention, understanding and therefore willingness to consent for clinical research. We also examined the relationship between patients’ demographic criteria and consenting.

This study was conducted in the context of obtaining written informed consent for three large clinical trials at the Cleveland Clinic. Patients eligible for these underlying studies simultaneously participated in our evaluation of an enhanced consent document which was conducted with Institutional Review Board approval and waiver of consent due to the nature of the study and the tested hypothesis.

Eligible patients were randomly assigned to enhanced or routine presentation of the consent documents. Computer-generated assignments, stratified by underlying study, were utilized. The text and font of the conventional and enhanced consent documents were identical. However, the enhanced document was printed on 20-pound, cream-colored bond paper and presented in a blue folio. Blue was chosen because it is perceived as calming and pleasant to human subjects. In contrast, patients assigned to routine presentation were given a stapled set of photocopied pages which is our usual practice.

The primary outcome was the effect of the enhanced format on the proportion of patients consenting. Secondary outcomes included understanding of the study intervention and major associated risk, the relationship between patients’ demographic and clinical characteristics, their personal belief about risk of participation in research, presence of friends or family members during the interview, time to make the decision, and whether patients felt pressured to participate.

At the time, 523 patients had been approached. Records for two of these patients were lost (Group variable missing). Six patients in each group were unwilling to discuss research with the consenting coordinator (RefusedPresentation variable = yes) and the consent document format was not verifiable for ten of the patients (OnTheEnvelope variable does not match Group variable); we thus removed them from the analysis. In all, we analyzed data from 251 patients approached with the standard format documents and 248 approached with the enhanced format documents.