OPINION

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The Correct Conduct of Informed Consent Discussion

How to Protect and Inform Potential Study Subjects

The single most important duty performed by research personnel is the explanation and conduct of the informed consent process to potential study subjects. Informed consent provides the means by which the experimental nature of the drug study and all accompanying procedures are explained to the subjects, thus enabling them to make an informed decision about whether or not to participate in the clinical trial.

Subjects reserve the right to understand the implications of their participation in the trial—the risks versus the benefits—and to have the assurance that their rights, safety, and well-being are preserved and protected. Though there are many contributing players in the dynamic of informed consent—from site personnel conducting the informed consent form discussion to clinical research associates (CRAs) reviewing the forms for appropriate signature and documentation of the process—the ultimate responsibility of informed consent conduct rests with the principal investigator (PI).

Over the years, I have observed and reviewed the informed consent process at sites ranging from renowned academic institutions to the smallest clinics. Unfortunately, as conducted by many sites, the process is fraught with deficiencies and lacks all the required elements to ensure subjects are informed and protected. Thus, the deficient practice is perpetuated by incorrectly trained or inexperienced site staff, or by research investigators too busy to recognize that the subjects they are consenting for their studies are inadequately informed.

It is vitally important that an accurate and impartial explanation of informed consent be completed by experienced research staff, yet this duty is consistently relegated to such inappropriate personnel as data managers lacking research experience or receptionists possessing no medical training. The informed consent is required to be written to target a fifth-grade education level, appealing to the intellect of the average “everyman.” However, the consent form is typically full of complex jargon and text about the research intent and required study procedures. It is crucial, therefore, that an appropriately trained individual provide a correct and adequate explanation to the subject. This provider must be medically equipped to answer the initial questions presented by the subject, with the PI supplementing any information not otherwise
provided or fully reviewed. This hugely important task has far-reaching implications and must be adequately performed by people who fully understand what they are presenting.

**When the Staff Are Inexperienced**

In some unfortunate cases, research-naive staff (even those with nursing or medical designations and/or education) may be found consenting and enrolling subjects during the first few weeks or months of their employment. It is no insult to the enthusiasm and raw intelligence of these new staff to suggest that the PI has put too much trust in the extent of their education to compensate for lack of clinical research experience and has not considered the potentially serious impact on research subjects. Such staff explain the informed consent to the prospective study subject with no point of reference or experience to draw from, let alone what terms such as ICH, GCP, CFR, patient bill of rights, or human subject protections mean. What is their motivation for taking on duties for which they should logically realize they are unprepared?

Due to their inexperience, these individuals may lack an internal filter to alert them to this potentially dangerous conduct. Perhaps they are in awe of the PI who has provided them with a career opportunity in clinical research. Or it may be sheer ignorance or denial of their own limitations. Or it may be a case of wanting to please their mentor or employer by not questioning their direction or misplaced trust.

Just one example of potential fallout from this act is the consenting of a subject with a contraindicated medical history or allergy to an experimental treatment that will not benefit, and may actually harm, him or her. This information is supposed to be gleaned from the initial consent discussion; but it is impossible to register when the person conducting the informed consent discussion does not comprehend the information he or she is presenting. Individuals with the correct experience and judgment complete an “informed” consent discussion and open dialogue with the potential study subject to discuss all possible adverse events, eligibility criteria, contraindicated medical histories, and results of participation, thus further preventing the inappropriate enrollment of an ineligible study subject.

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What is the driving force or psychology behind the conduct of research procedures and duties by less than qualified individuals? Is there malfeasance or intent to deceive on behalf of the PI? Probably not. Rather, consider the economic incentives at stake. To recruit and retain experienced individuals requires time and financial resources; sadly, many physicians have neither the time to spare nor the desire to pay appropriately to employ experienced, qualified research personnel. Thus the adage comes to mind, “you get what you pay for.”

How can this be prevented? How can clinical investigators assure that the subjects are receiving all the information, and not just a summary review of the study “highlights” by inappropriate personnel?

I suggest the following strategies:

- Select individuals with proper credentials, education, and experience.
- Thoroughly train research-naive staff who have required medical training about the process. Have them observe others conducting informed consent. Ensure that they have read and understand the protocol and informed consent form thoroughly before conducting it.
- Have consistent standard operating procedures for informed consent form conduct.
- Have the PI sit in on the first informed consent discussion that is held for site staff for each new study.

The key to assuring that research subjects truly understand the trial and the implications of participation is an effective and comprehensive informed consent discussion. The short-term fiscal investment required for recruiting and retaining experienced research personnel is a small price to pay considering the far-reaching effects of informed consent and the absolute priority of the rights and safety of human subjects that the process, when implemented properly, reflects. *ACRP*

Elizabeth Weeks, LVN, CCRA, currently works as a CRA line manager for a full service CRO. Prior to that, she spent seven years as a CRA in the CRO industry, with responsibilities that included training and signing off field monitoring personnel, monitoring large oncology trials, and working as a lead CRA for a nationwide chemotherapy-related anemia trial. She has overseen training and assisted in the development of an entry-level CRA training program on the West Coast. She can be reached at EBWCRA@yahoo.com.