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BEST PRACTICES

Informed Consent for Research

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"The ability to obtain valid informed consent is a skill that can be learned and taught just like any other clinical skill." (Philip W. Lavori, personal communication, 3/25/02.)

Valid and meaningful informed consent is the cornerstone of the ethical conduct of clinical research -- but obtaining informed consent is not a simple or certain process. Despite established procedures for obtaining the informed consent of volunteer research subjects, important questions remain about how to ensure that the risks and benefits of participating in research are accurately communicated and understood. To assess the quality of informed consent, and ultimately to improve it, VA's Cooperative Studies Program (CSP) in the Research and Development Office has initiated a major new study called "Enhancing the Quality of Informed Consent" (EQUIC). EQUIC will result in a series of tools to assist researchers in adapting and implementing best practices in the informed consent process and, thereby, help ensure the ethical conduct of research.

EQUIC represents an important and novel approach to issues surrounding informed consent. It recognizes that - just as for medical treatment - procedures for obtaining informed consent should be based on evidence.

This study proceeds from the following rationale:

> "Clinicians practice accepted state-of-the-art medicine while simultaneously innovating and improving it. In the same way, we must employ accepted methods of informed consent while seeking to innovate and improve them. …. [And we must recognize that] as in medicine, innovation may also have unintended and unknown consequences and, more importantly, innovations intended to improve informed consent may not actually do so."[1]

Accordingly, EQUIC will rigorously study the effects of various procedures for obtaining informed consent. This will be done in the context of ongoing multi-site, controlled clinical trials, using a set of methodological studies piggy-backed onto ongoing CSP studies. Paralleling the treatment and control arms of each of these ongoing clinical trials, EQUIC investigators will randomize sites to test the effects of promising innovations in informed consent.

EQUIC's design is based on a conceptual paradigm that identifies five components of the informed consent process:

1. Assessing the decision-making capacity or competence of the prospective research volunteer;

2. Disclosing relevant information about the proposed research;

3. Ensuring that the prospective volunteer understands the information;

4. Ensuring that the prospective volunteer is positioned to make a voluntary choice; and

5. Authorizing a decision by the prospective volunteer, typically by signing a consent form should they choose to participate.

A key component of the study is the development of a brief assessment tool to determine how well each of these five elements, and general measures, were met at the time the subject was invited to enroll in one of the parent clinical studies. EQUIC investigators will administer the Brief Informed Consent Evaluation Protocol (BICEP) questionnaire by telephone, shortly after subjects are approached for consent to participate in the clinical study. BICEP asks subjects, for example, to comment on whether or not they felt pressured to consent, whether they were asked to sign a consent form, and what they understand are the goals of the clinical study. Analysis of the BICEP data and refinement of the questionnaire are now nearing completion.

In a series of planned sub-studies, EQUIC will test specific innovations aimed to improve one or more of the five components of informed consent or one of several global measures such as satisfaction with the process. An illustration of an innovation pertinent to #3 above, for example, would identify subjects with low literacy and tailor the consent process with special educational techniques such as repetition. Or, subsequent to a subject's enrollment, EQUIC might periodically test their retention of information that was provided about the clinical study.

To date, EQUIC includes 8 parent clinical studies, and subjects are being enrolled at 14 VA facilities. At least six more facilities are expected to join the study, pending IRB approval. The first sub-study, called EQUIC-Self-Monitoring (EQUIC-SM), is scheduled to start in late June at approximately 26 sites (with an additional 40 sites projected).2 This intervention is based on the assumption that, even when the individuals who obtain informed consent are highly skilled, the inevitable routinization of the process reduces their concentration and ability to ensure that each consent is really informed and meaningful. The intervention tested in this phase of EQUIC is a questionnaire that makes the informed consent process very explicit and asks the person obtaining consent to examine

their own performance. EQUIC-SM is seen as an activation device as well as a measurement tool. The questions include, for example:

> Do you have any doubts about whether the patient understood all of the relevant information about the study? (#7)
>
> Did the patient actually read the consent form? (#9)
>
> Were you able to answer all of the patient's questions about the study? (#12)

If the self-monitoring procedure tested in EQUIC-SM is effective in improving the quality of informed consent, it will be a valuable contribution to the growing set of best practices for research. In particular, EQUIC's process-oriented, evidence-based, patient-centered approach to improving human subjects protection will make EQUIC products useful complements to the more traditional rules-oriented, paperwork-based, committee-centered approach.

EQUIC investigators are well aware that experimenting with informed consent within the context of real clinical trials raises some ethical issues. These are said to be similar to issues inherent in all other clinical experiments involving human subjects. The investigators say it is necessary to strike the right balance between burden and risk, the requirement for equipoise and the need for valid informed consent. (For further discussion on this, see Lavori, Sugarman, Hays and Feussner.)

For more information about EQUIC, please contact: Philip Lavori, Ph.D., at the Cooperative Studies Program Coordinating Center, VA Palo Alto Health Care System.

References:

1. Lavori PW, Sugarman J, Hays MT, and Feussner JR. Improving informed consent in clinical trials: A duty to experiment, Controlled Clin Trials 20:187-193, 1999.

2. Cain C, Lavori PW, and Sugarman J. Enhancing the quality of informed consent - Self-monitoring (EQUIC-SM), A component of VA Cooperative Studies Program #476.