



### **Informed Consent: Hollywood Style**

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Topic: Informed Consent

### **Problem/Issue Statement**

The cornerstone of human subject protection relies greatly on an effective informed consent process. How can we best relay the importance of effective informed consent to all key players, i.e., research volunteers, research team members, and IRB members? Comprehensive training on the essential components of informed consent should address what information must be discussed; suggest methods for assessing the subject's understanding of the information provided, and emphasize the voluntary nature of participation. We propose that educational initiatives are more effective when they are developed from data gathered from actual research participants. Is it possible to utilize quality assurance data to help to illustrate how the core protection of informed consent helps to ensure the safety and welfare of research participants?

### **Description of Program**

The Quality Improvement Program at Cedars-Sinai Medical Center's (CSMC) deploys several surveys in an attempt to collect data on the effectiveness of various programmatic initiatives. One of the tools developed by the program is the Research Participant Survey. Research Teams work in partnership with the ORC&QI to promote the survey to individuals who have completed participation in a research study. To date, 1338 survey packets have been provided to research coordinators for distribution to research participants. 594 surveys have been completed. The survey questions address basic demographics, the consent process, the experience of participating in the research study, and assess the individual's overall satisfaction with participation in research at CSMC. Participants can either complete the survey in hardcopy or using an on-line survey tool. Survey administration is completely anonymous, but participants can provide contact information to receive a \$5 thank-you store card.

Data from the survey is compiled and reviewed on a regular basis. Data from the 2008-2009 calendar year was analyzed with a focus on the participants' impressions of the informed consent process. The data suggested that while overall satisfaction was high, there was room for improvement related to communication of the purpose of the study; the distinction of research procedures from standard care practices; information related to study logistics (e.g., when, where, how much); and issues related to billing and compensation.

The IRB Education Team used the data to develop several video vignettes where actual research team members and IRB members/investigators assumed starring roles as investigators and potential research subjects. Scenarios focused on the areas identified for possible improvement by the survey data. Vignettes were designed with the intent of providing examples of best practices in informed consent by allowing the viewer to "see a process in action." Video participants reported increased understanding and empathy for the research participants whose concerns they represented, as well as for the research team members who are responsible for educating research volunteers. The video has been modified as an online module that is available for the continuing education of all research personnel. Impact of this training initiative will continue to be evaluated as part of ongoing administration of the Research Participant Survey.



Future Program Usage: The Informed Consent Video project is an example of how quality assurance data can be used to address issues that may arise in the day to day conduct of human research at your institution. Involving IRB members, members of the research community, and IRB staff in the development of the educational video was an effective means of communicating the important role of the informed consent process. We were fortunate to have a staff member who moonlights as actress/film maker by night, a common phenomenon in Los Angeles. In addition to the development of an innovative educational tool, this project demonstrated the benefit of allowing staff to explore how their outside interests and passions can be applied to the protection of human subjects.

Suggestions for implementation at other sites: Best practices in human research protection programs have a strong focus on continuous quality improvement. As many institutions collect data on the outcomes of programmatic initiatives, it is important to understand how that data can be used to refine protections and offer site-specific training initiatives. Several low-cost options exist for the development and deployment of online survey tools. Finally, while it is helpful to have an eager thespian as part of your team, it is not a prerequisite for project implementation. Our video was taped using a standard digital video recorder and online "movie maker" software. Institutions needing technical support for similar projects are encouraged to research services available through your medical media department to help determine what tools are available.