



Title:	Qualitative Research		
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## 1 Qualitative research

Qualitative studies, which may involve such methods as participant observation, case studies, unstructured interviews, focus groups and various other descriptive techniques, raise special issues for the IRB. Qualitative research investigators usually have a well-articulated plan for their research, often have one or more reasonably specific hypotheses to be tested, and can describe in general terms the techniques they intend to employ. However, they may undertake research projects with the full expectation that techniques will be developed in the course of research, used on the basis of opportunity, and modified as events and experiences suggest are necessary for the success of the project. As a result, qualitative research investigators may present a research protocol that does not fit the usual model contemplated by federal human subject regulations for research, if those regulations are narrowly interpreted.

Reviewing qualitative research projects requires flexibility on the part of the IRB and is facilitated by a willingness to waive some of the elements of informed consent and approve methods of consent that are culturally appropriate. If the study protocol approved by the IRB is intended to encompass development of one or more research instruments, it may also be necessary to give relatively wide professional latitude to scientists in the application of approved methods so that an investigator does not need to come back to the IRB repeatedly for approval of changes that would be considered normal and routine under the circumstances. However, the IRB should make clear to the investigator that any significant changes, including all changes that could increase risk for the human subjects (for example, the addition of a new topic in a survey), must be approved in advance by the IRB.

Finally, the IRB may need to consider an informed consent process that is multi-layered and takes place over time as the research develops and the investigator is better able to articulate both areas of further interest and the methods being employed for studying them. Whatever flexibility the IRB decides is appropriate in the specific research context, that determination must include adequate protection for the welfare and rights of the human subjects in that specific context.