Understanding Informed Consent in Bioinformatics Research: Cross-Cultural Issues

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Abstract. Cultural factors, such as language, gender roles, and emphasis on individuality should be attended to in bioinformatics research studies for reasons related to ethics and generalizability. These factors must be addressed during the informed consent process when patients make decisions about study participation. Observations of Institutional Review Board meetings and interviews with principal investigators of bioinformatics studies revealed that only particular cultural factors, such as language, are considered during the informed consent process.

Purpose. The purpose of this exploratory study was to examine how investigators and Institutional Review Boards (IRBs) address cultural factors during the informed consent process in bioinformatics research. We sought to uncover cultural beliefs that encourage or discourage participation of potential research subjects and to determine if and how both the IRB and researchers address these cultural beliefs during the informed consent process.

Background. Minority and traditionally underserved populations may decline study participation if cultural factors prohibit their understanding or acceptance of the informed consent process. This is of concern as minority populations have a right to participate in research to benefit from any medical gains. Furthermore, without minority participation, study findings are not likely to be generalizable to a broader population. For these reasons, it is imperative that diversity is addressed during the informed consent process, where patients make decisions about study participation.

Methods. A systematic review of literature identified cultural factors that influence understanding and acceptance of the informed consent process. Observations of two IRB meetings and interviews with a convenience sample of principal investigators of five bioinformatics research projects were conducted to determine what cultural factors, if any, were considered when designing the informed consent process for a given study. Results of the literature review were compared to procedures used by the IRB and by researchers studying bioinformatics topics at a large Midwestern university to identify gaps between the literature and current practices.

Results. Review of IRB meetings and consent procedures showed that although some cultural factors such as language were often taken into account, many others were not explicitly addressed. Those that were cited in the literature as important, but not systematically considered included whether a patient holds an “independent” or “interdependent” image of self, trusts medical professionals, and has traditionally Western views of illness and healing. Observations and interviews revealed that reasons for failing to consider cultural factors included beliefs that the target population did not include minorities, that the purpose of the study was focused on a process rather than on persons, and that culture was not “of concern.”

Conclusions. Previous studies have shown that there is a broad range of cultural beliefs that both encourage and discourage study participation. By failing to address cultural factors, IRBs and bioinformatics researchers run the risk of alienating minority populations, thereby effectively denying them study participation and sacrificing external validity. Future work should be conducted to explore how to make both the IRB and researchers more willing and able to consider and address the cultural issues of informed consent.

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References.