Chapter 7
Beyond Informed Consent:
A Model of Collective Guardianship for Ethical Genetic Research

Leonardo de Castro
National University of Singapore, Singapore

Chin Leong Teoh
National University of Singapore, Singapore

ABSTRACT

This chapter affirms the continuing relevance of requiring informed consent for health research in a context consisting of evolving genetic research methodologies and non-paradigmatic ways by which human beings become subjects of genetic research. The chapter also recognizes the special status of genetic materials and genetic data as subjects of research, as well as the different ways in which genetic materials and genetic data may be "owned." Different senses of ownership necessitate variable ways of implementing informed consent and these have to be clarified and carefully matched. Taking into account the specific interests expressed by human participants in human tissue research,the authors can see that these can be best promoted by a kind of oversight function delegated to ethics committees. The idea of a "one-time" or absolute consent given at the time of recruitment sounds appealing in that it minimizes inconveniences to many stakeholders, including researchers and human subjects. However, there remain valid reasons to be wary lest the system allow some types of research (or use of human research materials) that subjects would disapprove of unless sufficient pertinent information could be provided at the moment of recruitment. Thus the authors present an option for something close to "one-time" or absolute consent with safety nets in the form of oversight functions "delegated" to oversight ethics committees. The exercise of oversight function should involve flexibility to negotiate specific instructions given by the subject(s), such as those that may have something to do with uses that could have a particular religious or cultural significance.

DOI: 10.4018/978-1-61692-883-4.ch007

INFORMED CONSENT PARADIGM FOR RESEARCH ETHICS

Notwithstanding the problems and issues that have been encountered in the implementation of informed consent, the concept continues to have an indispensable relevance to research involving human subjects. The idea of informed consent for research has served a very useful purpose. Human subjects of research have come from very vulnerable populations and it has proven to be necessary to require their informed consent for participation as one of the safeguards against their being exploited. There is a highly uneven relationship between investigators and research subjects, notwithstanding efforts at research ethics education and training. For many participants, the starting point is utter ignorance and the situation is made worse by other factors such as physician dependence or economic bondage.

In international research, the consequences of the subjects' geographical distance from originators of research are being magnified. Those responsible for preparing protocols in international research are likely to be worlds apart from those who become research subjects and the latter are unable to communicate directly with the sponsoring team if they have any questions, misgivings, or apprehensions. Communication always requires intermediaries and local investigators have been known to resist making any modifications to protocols that require having to go back to the originating countries in a process that requires a large amount of time.

On the other hand, the strict implementation of informed consent for all research involving human subjects has resulted in the inability of many prospectively useful research projects to proceed or to be carried out expeditiously even when the risks to participants were not great. It is necessary to explore alternative paradigms of informed consent that can continue to protect human subjects at the same time that they enable important research projects to proceed and respect the efforts (even responsibility) of researchers to extend the frontiers of human knowledge. This is especially true in matters of genetic research where research methodologies defy paradigmatic implementation of informed consent procedures. The challenge is to find ways of safeguarding human subjects' interests while recognizing the freedom of scientists to undertake essential genetic research.

CHALLENGES TO THE INFORMED CONSENT PARADIGM

One of the reasons why informed consent for genetic research is especially problematic is that there are a number of ways by which humans could become research subjects. Not all of these ways are recognized as involving research, especially when we consider the initial starting point when an individual's genetic materials or information become candidates for use in a particular study. When we consider the opportunities for sharing of research resources among various laboratories, we realize how difficult it is even merely to determine the specific point when consent for the use of genetic materials for a specific study could and should have been secured.

In general, to become a research subject is to have oneself–or one's bodily parts or information–become the subject of investigation or examination that could yield generalizable information, where "generalizable" means that which could be inferred to be true also of others in a similar situation, or that which could be inferred to apply on a broader scale, e.g., to an individual at other times in his or her life. Thus, there are a number of possible entry points for someone (or something) becoming a research subject, including the following:

1. Having tissues/samples taken for diagnostic examination
2. Having one's records filed in a health care institution