GENETICS, PHILOSOPHY

INFORMED CONSENT 2.0

15.09.2008 1 COMMENT

PLoS medicine publishes today a piece that we wrote already last summer. As we have removed the narrative abstract (PLoS uses keypoints instead of an abstract) here is it – pleading for an update of traditional informed consent.

Informed consent (IC) is a basic requirement for biomedical research. It includes the understanding of risks and benefits of study procedures and the voluntary agreement to participate under these conditions. Genetic cohort studies storing biological materials hold great promise for medical research but also present new problems that are profoundly different from the classical
clinical trial for which the IC formula was initially developed. The classical risk/benefit analysis of physical harm doesn't take into account new threats to
the individual like uninsurability, unemployability, genetic discrimination or even disruption of family relationships.
We show here that traditional IC is no longer appropriate when dealing with studies using biological materials. Traditional IC requires that full disclosure of
all relevant information is provided to allow subjects to decide on their participation for a finite time and within a well-defined research protocol. Goals of genomic screening studies, however, may not be well defined a priori and the subject's involvement may last indefinitely.
As a solution we are advocating for these kind of studies a close researcher-participant partnership. Described by Veatch and others at the late 1980s, such a researcher-participant partnership may now be revived for genetic studies. IC should no more be seen as a once-and-for-all decision but as an ongoing process.
Several authors already suggest an exploratory or participatory process prior
to the implementation of a research project that should provide a better understanding of relevant issues. Research following the initial storage of samples needs to be likewise announced and explained by new communication channels such as email broadcasts, websites, blogs and chats. IC in the genomics era should no more be viewed as just signing a legal document at the
beginning of a study, but as a process of communication that involves researchers and participants as partners in an open dialogue, giving new force and meaning to the ethics of current research.

We have spent considerable space in this paper to explain that genetic data are not being anonymous (as genotyping of retrospectively collected samples is largely justified as samples are being "anonymous" where genotyping may not harm anybody).
In our opinion this is inadequate as genetic data are self-identifying. At least last week we get support also from a group in LA that can identify an individual in pooled! DNA that con-

tributed less than 0.1% of the total genomic DNA.
Events come thick and fast as reported by Science a week ago “Genetic privacy. Whole-genome data not anonymous, challenging assumptions”:

> The Wellcome trust has pulled data on about a dozen common diseases, and NIH has pulled data from nine genetic studies off two sites, dbGaP … and CGEMS.

They can remove the data from a public server but they can’t unmake genotyping, yea, yea.

Addendum

An interview that I have given to Genomeweb.

NACHTRAG

sandrar

10.09.2009 AT 16:46

Hi! I was surfing and found your blog post… nice! I love your blog. :) Cheers! Sandra. R.

COMMENTS ARE CLOSED.