More Nuanced Informed Consent Is Not Necessarily Better Informed Consent

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as well as those who provide the samples, again, because we are all one another’s neighbors.

Another important consequence of adopting the “love thy neighbor” perspective is reducing the regulatory emphasis on informed consent and increasing the focus on a risk benefit assessment. No one would want their acts of generosity and fellow love to become the source of regret. For that reason, this consideration would make it critical for research ethics to focus on minimizing risks of harm. Therefore, instead of following the Grady group’s suggestion of trying to identify studies that some donors might find objectionable or that might conflict with their sensitivity or values, I am recommending that the oversight and approval process should focus on ensuring that the science of a proposed study has merit, ensuring that the information requested is actually needed, and identifying any likely sources of harm and trying to minimize them.

Informed consent must remain as an important element in the ethical conduct of research. Yet it is important to note the important real differences between, on the one hand, clinical research where interventions are imposed or withheld and thereby may introduce risks of harm, and, on the other hand, research with biological samples where the risks are de minimis. Informed consent is critically important in clinical research because the significance of the risks has to be assessed in light of the individual’s priorities and goals. In research with biological samples, sharing information with participants and eliciting their agreement to their samples’ future use are important for demonstrating transparency and securing trust and, as Grady and colleagues note, particularly because people typically want to be asked. There will, however, be times when consent is not feasible and times when other considerations are overriding, and then, because of its social benefit, research may proceed without consent.

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In the era of Big Data, even a little information can go a long way in partially or wholly identifying anonymous individuals and/or disclosing their private and personal information. In a well-documented case, an anonymized Netflix database was de-anonymized by correlating data with publicly available information (Narayanan 2008). Additionally, seemingly benign Facebook “likes” and other user generated content have been shown to allow for the identification of ostensibly private and undisclosed characteristics of many users on the social media website (Kosinski 2013). In another example, social networks in Facebook were shown to be strongly predictive of sexual orientation (Jernigan 2009). A further group was able to predict an individual’s marital status, religion, and other characteristics from a list of apps uploaded on their smartphone (Seneviratne 2014). And the retailer Target has been able to infer whether shoppers are pregnant based on ostensibly uninformative shopping habits (Duhigg 2012).

In general, social media and the concomitant evolving sharing norms and privacy mores have resulted in an unimagined growth of online, publicly available, cross-referable material that can be used to characterize and/or

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identify heretofore anonymous individuals in large data sets.

In light of this, the potential development of an informed consent process that includes a detailed checklist, an option raised, albeit not adopted, by the working group described by Grady and colleagues (2015), is particularly problematic—not just because of the onerous potential costs of administering such a system, but because such a system would require patients to delineate what types of research they allow to be done on their biosamples, and what types of research are *verboten*. Given the preceding examples, it would seem possible for investigators to cross reference these checklists with other information in the data set, and with publicly available information, to determine, to some degree of statistical accuracy, identifying information about individuals in the data set, for example, religious affiliation, social status, level of education, geographical location, gender, sexual orientation, and/or political leanings. Succinctly, the checklist method’s de facto necessity of tying potentially privacy-revealing information to anonymized data seems to raise real privacy concerns.

Although the working group in Grady and colleagues concludes by favoring a broad consent (i.e., nonchecklist) model, we would like to suggest an alternative to the informed consent system that better takes into account the motivations for the aspirational checklist model, and is arguably also better able to deal with the evolving complexities of research, changing social values and other unpredictables and/or unknowables, while still protecting the privacy and anonymity of the patient.

As summarized by Grady and colleagues, the informed consent process that accomplishes the necessary goals of respect for persons, beneficence, and justice ought to result in an informed consent procedure that provides: respect for donors; donor control over their samples; the ability to make a decision as to the risks and burdens of the research; protecting and possibly promoting their fundamental values; transparency; and the resulting public trust regarding decisions about donating and researching biospecimens.

In general, informed consent in clinical research requires that the patient providing the biosample read and consent to scientific concepts that are at minimum difficult to communicate to the lay public through lengthy and confusing formulaic language—often falling short of the theoretical ideals of informed consent (Grady 2015), the researchers’ best efforts to the contrary notwithstanding. Moreover, it seems unlikely that the informed consent procedure could adequately predict and therefore inform the patient supplying the biological sample of unforeseen future research efforts. As such, respect, beneficence and justice are arguably denied to the patient in the practical application of the standard informed consent model.

Moreover, irrespective of whether or not secondary uses of anonymized biospecimens is human subject research per se, or necessitates further informed consent (Secretary’s Advisory Committee on Human Research Protections [SACHRP] 2011; Council for International Organizations of Medical Sciences 2002), patients arguably ought to be respected and given some control over the nature of downstream and off-site research on their biological submissions, particularly in the area of genomics where anonymity of samples can never be absolutely guaranteed (Clayton 1995).

Rather than trying to fix a very broken informed consent model, perhaps a new paradigm is needed in lieu of the informed consent system established by the Common Rule (45 CFR § 46.116 2009). Particularly in the area of clinical research, and especially in trending areas of research where technological changes happen quickly and often, a power of attorney model that essentially allows the patient to outsource his or her ability to consent to more capable professionals might be more respectful, efficient, and more empowering to the patient.

Simplistically, the power of attorney is an agreement between two parties—neither need actually be an attorney—wherein one gives the other party, the attorney/fiduciary, the rights to act in the first party’s (i.e., the principal) place. In the example of clinical research, the fiduciary could be one of the professional research ethics consult services (RECS) (Cho 2008), designated as the principle’s proxy for all things relating to informed consent. This use of RECS arguably approximates the use of proxy decision makers and/or advance directives by incapacitated adults in medical treatment and research settings.

RECS comprising outside professional ethicists, practitioners, and lay members can provide, on behalf of the patients within a cohort, the guarantee that they will independently and fairly assess all research projects employing the biospecimens, stewarding these samples throughout their shelf life, and ameliorating the general unease in the public regarding donors’ inability to adequately control what happens to biological samples downstream (McEwan 2013). In some instances, individuals could be given the option to select from a small set of RECS, for example, socially left, central, and right leaning RECS, with patients matching up their ideologies as closely as possible to a particular RECS. Essentially, these RECS would provide the granular control/oversight that would otherwise be provided by the checklist model, employing ethical analyses that account for changing societal conditions and technology, in analyzing each new project associated with the biosample.

By granting patients the right to create a power of attorney for their biosamples, we are providing them with the ideals of capacity, choice, and sovereignty, which undergird the idea of autonomy (Walker 2013). Professional and knowledgeable RECS could secure the well-being of the biosamples, thus providing beneficence and justice. Moreover, acting on an international scale, RECS could provide some much needed cross-institutional standardization for risk assessment, data sharing, and protocol review of studies employing secondary uses of biological samples (Goldenberg 2015).

Finally, the use of a power of attorney to outsource consent to RECS might also help solve another pressing
and nontrivial concern: assuaging the apprehensions of the extended families of sample donors, especially in the area of genomic research, wherein the standard informed consent model focusing on the individual fails to account for the family’s interests arising from their shared DNA. Ironically, while it’s the donor’s autonomy and sovereignty that heretofore restricted the decision making regarding the sample to only necessarily account for one of the many family members affected by the research on the sample (i.e., the donor), in our model, this same autonomy and sovereignty could now also empower a potentially morally obligated RECS, operating in the capacity of a proxy informed consenter, to also, in its due diligence, at least consider the potential repercussions of all research on the biosample for the donor’s extended family as well.

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Broad Consent Is Consent for Governance

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BROAD CONSENT: FROM CONTENT TO CONTEXT

In recent years, novel types of consent have been proposed for research with biological samples, one of these being broad consent. The exact scope, justification, and definition of broad consent have been topics of ongoing debate. In their article, Grady and colleagues (2015) propose to define broad consent as “consent for an unspecified range of future research subject to a few content and/or process restrictions” (Grady et al. 2015, 35). In doing so, they make a noteworthy departure from the conventional definition of broad consent, being “permission for a broad range of research purposes that were not specified at the time of..."