

## COMMENTARY

# What Should We Be Asking of Informed Consent?

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The Common Rule and much of the bioethics literature embody an idealized notion of informed consent, in which the research participant fully understands the nature of the project, its foreseeable risks and benefits, and that the primary goal of research is to advance knowledge rather than to help the individual. Numerous studies, however, demonstrate that many people neither seek<sup>1</sup> nor achieve this level of comprehension,<sup>2</sup> as is true for most decisions people make. These observations raise questions about what we be asking of informed consent.

Bromley et al.<sup>3</sup> add to this debate by addressing the role of consent in a very particular type of study, in which all the goals are not prespecified or even known; where people frequently, even continually, provide information to the investigators, sometimes actively, through questionnaires and clinical exams, sometimes passively, through release of medical information or mobile apps; and where participants, in return, will be given some results, although what or how are not yet defined. It is good news that their respondents envision an ongoing, engaged consent process, which is what this sort of longitudinal, interactive research ethically calls for. In addition, participants need to be told at the outset what the protocol envisions at that time, including any privacy and security concerns, that its scope will change, and that they will be given choices in the future about what information they want to provide and what results they want to receive. The project should update participants about agree-

gate discoveries and the occurrence of adverse events and remind them periodically about “automatically” collected information so they can revisit their choices. Such proposals about notification are not new<sup>4</sup> but should be easier to achieve given the increasing prevalence of electronic communication.

In many ways, the cases discussed by Bromley et al., are the easy ones — they involve interactions that permit decision making over time. Yet numerous questions remain. As a practical matter, what should these ongoing conversations at decision points after entry into the study look like? Do they need to meet the formal requirements of 45 CFR §46.116? The authors report that the respondents preferred a more informal process. Consent processes are daunting and scary, which is no surprise given that their purpose, as applied, is to protect investigators and institutions perhaps even more than participants.<sup>5</sup> Indeed, in the US, participants are effectively asked to assume the risk of taking part in research since they are not indemnified against research-related injuries.<sup>6</sup>

Greater clarity is also required about how much control participants have over data about them. It is one thing to ask enrollees to choose what personal information they put in and what results they get out at various times, but current policy typically precludes giving them much, if any, control over downstream uses and users. Investigators are often required as a condition of funding to ensure that participants cede these choices.<sup>7</sup> Yet evidence shows that many people have concerns about how data are used and by whom.<sup>8</sup> While regulations require that people have rights to withdraw from research, participants in the US are typically able only to limit use of data that have not already been distributed to and used by investigators and to prevent collection of new data.<sup>9</sup>

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These questions are considerably more difficult in the much more common types of research that do not involve ongoing engagement as part of the study design. If the investigators in federally funded studies at the time of enrollment plan to collect new research-specific data or contemplate returning individual research results, consent is required although the requirements of the Common Rule are so onerous that participants are almost guaranteed not to understand informed consent documents. No consent is required thereafter, especially if participants have given broad consent, which is now endorsed. In some studies, participants are required to receive results whether they want them or not. If the researchers plan to use clinically collected biospecimens and data and to remove identifiers before doing research, consent and even

leads to imposing boilerplate language, while worthy of attention, diverts attention from the critical need to develop more robust processes of oversight, engagement, and accountability that are essential for building and retaining support for trust in research.<sup>12</sup> Informed consent cannot make poorly designed or insufficiently overseen research ethically acceptable. Many of the most notorious examples of adverse research outcomes are attributable not to lack of fully informed consent but to inadequate oversight, conflict of interest, and lack of accountability.<sup>13</sup> Institutional Review Boards have never been able fully to remedy these issues, in part because they typically reside within the health care institutions where the research is conducted<sup>14</sup> and in part because they are forbidden to consider the social consequences of research.<sup>15</sup> The

**In fact, focusing on consent, a topic on which IRBs devote an inordinate amount of time and frequently leads to imposing boilerplate language, while worthy of attention, diverts attention from the critical need to develop more robust processes of oversight, engagement, and accountability that are essential for building and retaining support for trust in research.**

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notification are not required at all so long as they do not return results. These provisions vary in part due to a regulatory assessment that different types of research entail different levels of burden and risk as well as pressures to facilitate research. The law thus enables many uses of individual data without consent,<sup>10</sup> which can be ethically appropriate in many cases.<sup>11</sup>

The need to contemplate whether “informed enough” consent suffices in research in which investigators and participants interact on an ongoing basis reveals fundamental confusion about what role informed consent is supposed to serve. It is the relationship and the opportunities for conversation and choice that will make the proposal by Bromley et al. work, not informed consent documents or exactly what participants understand. Questions about the role of consent are even clearer when considered in light of the complex provisions of the Common Rule with its widely varying requirements and exemptions.

In fact, focusing on consent, a topic on which IRBs devote an inordinate amount of time and frequently

recent changes to the Common Rule diminish the authority of Institutional Review Boards even further. Thus, other mechanisms may need to be developed that involve greater transparency and accountability. Researchers themselves may need to shoulder more responsibility for respecting the interests of research participants. Informed consent cannot bear all the weight.

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