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ESCRO Committees – Not Dead Yet

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In his Target Article, Hank Greely (2012) evaluates the US experiment in self-regulation for human embryonic stem cell (hESC) research known as Embryonic Stem Cell Research Oversight (ESCRO) committees. He usefully reviews the history of “one of the great applied bioethics experiments of our time,” how the oversight mechanism recommended by the National Academy of Sciences (Committee on Guidelines for Human Embryonic Stem Cell Research 2005) emerged through “voluntary, non-governmental action” and how, since then, ESCROs have functioned and changed. Greely's interest in ESCRO committees extends beyond hESC research proper to the broader subject of how a given area of scientific research develops and implements its own process of ethical review.

Greely deems ESCRO committees largely successful, providing localized review of scientific protocols for derivation or use of embryonic or other forms of pluripotent stem cells. Among other benefits, Greely notes the apparent absence of abuses in stem cell research. He also highlights the prominent role of ESCROs in providing “political cover” for what the Bush administration and some Americans regarded as ethically questionable research. He acknowledges that we may not know how many legislators found such a review mechanism reassuring – or altered their opposition to funding such research – but Greely is certainly correct that in California and elsewhere the existence of this review mechanism was seen as politically important. Despite this positive assessment, Greely submits that it is time to reassess the future of ESCROs. He proposes disbanding localized ESCROs in favor of redirecting responsibility for review of stem cell research to traditional, existing review mechanisms, Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). The argument is that these committees could handle most, if not all, stem cell research review, calling for additional expertise on an “as needed” basis.

While we agree with the claim that ESCRO committees have been a notable experiment in bioethics (or perhaps more aptly, research ethics) and successful scientific self-regulation, we are wary of an all or nothing answer to the question of whether ESCRO Committees are needed. Instead, we propose a more nuanced approach.

We begin by urging caution in choosing our next steps: If it ain't broke, why fix it? As Greely reports, many institutions have gone to considerable effort to establish local review mechanisms. In our experience, despite their short history ESCRO committees are functioning well, researchers and staff have accustomed themselves to the process, and ethical oversight seems at the very least adequate, if not good. While few would argue that stem cell research needs the political cover it did even five years ago, abortion and the status of the embryo remain hot button issues in a shifting judicial landscape. Moreover, scientific developments, such as the possibility of artificial gametes (Kashir et al. 2012) and swapping of oocyte mitochondria to reduce the risk of mitochondrial diseases (Cyranoski 2012)

continue to rearrange the ethical landscape. These considerations suggest that there should be a presumption in favor of maintaining current review mechanisms.

More important is a second, methodological objection. As Greely makes clear, we have had no formal evaluation of the ESCRO system (Greely 2012). His proposals are, as he notes, a “first effort,” based on an assessment derived largely from his experience at Stanford and anecdote. We agree with his conclusion that rigorous assessment “will be difficult and complicated”. But as Greely readily acknowledges, such an assessment is needed.

To start, it would be useful to know exactly how many ESCRO and SCRO committees exist nationwide. Our sense is that Greely's estimates are low given the many universities, research institutions, and companies that conduct and publish embryonic stem cell research. More important than the absolute number of committees is to ask: How many maintain a wholly separate ESCRO review process? And what is the comparative effectiveness of this approach?

Before concluding what is or is not needed for hESC research review, we need a more thorough understanding of how ESCRO review is now implemented. That review has not yet been done, but something can be inferred from what we do know. Based on an informal assessment by Geoff Lomax of the California Institute for Regenerative Medicine (personal communication, October 26, 2012), nearly all California ESCRO committees are now either effectively combined with the IRB (e.g., MD serves on two committees structured in this way) or closely coordinated with it (e.g., MK sits on a committee that serves an advisory role to the IRB responsible for review of stem cell research projects). In short, the system is already moving or has moved toward some of what is proposed by Greely. More generally, based on our (MD, MK) experience with nearly 20 institutions conducting hESC research, a provisional conclusion is possible: Approaches vary widely, and this is a good thing. For example, large institutions, with substantial programs of human subjects research and many researchers conducting hESC research, might opt for an ESCRO review group that serves an advisory role to an IRB committee. Conversely, smaller institutions, perhaps with little or no human subjects research, and relatively few hESC research studies, might do better with a single committee, or making use of an external review committee.

Although hESC review can effectively be handled through different mechanisms, a second question is whether something special is still needed for hESC review. As Greely notes, many of the challenges that first faced ESCRO committees have moved from matters of discussion and experiment to matters of rote policy and administration. By that argument, perhaps much if not all of hESC research can be handled administratively. We would disagree. The fact that past problems have been solved does not mean that we have already anticipated, or are prepared to address future challenges in this rapidly evolving field. Our choices about how to move forward should thus not be based on the assumption that we've settled or can avoid future ethical and/or policy issues. While a case can be made that a need to address such issues remains, we believe it can be met in two ways.

The first is already part of most review committee processes. When a committee lacks necessary experience or expertise to handle a newly identified problem, then a subcommittee can be assigned to articulate and propose solutions, or committee membership can be temporarily supplemented as needed. These approaches are widely used by IRBs and IACUCs, and in our experience have become part of what ESCRO Committees do as well. Given this option, it is not necessary to have a separate ESCRO Committee (e.g., an IRB could recruit the necessary expertise as needed), but the value of an ESCRO Committee is not precluded.

A second approach is one that is not widely applied and, to our knowledge, is unique to the San Diego region. After the passage of Proposition 71 in 2004, and the resolution of the subsequent legal challenges (summarized by the California Institute for Regenerative Medicine: CIRM 2007), multiple San Diego institutions agreed to form the San Diego Research Ethics Consortium (SDREC) (Business Briefs 2007). One of the defining elements of the SDREC was a continuing research ethics education requirement for all stem cell researchers. This requirement has largely been embraced by the stem cell research community in recognition that the ethical challenges of research do not begin and end with reviews by IRBs, IACUCs, and ESCRO committees. Instead, the goal has been to create a research community in which the culture is defined by frequent and ongoing conversations about the ethical challenges of research.

Irrespective of the question of the moral status of embryos, human cellular pluripotency and reprogramming do, at least for now, present us with a set of challenges that remain as yet unsettled ethically, legally, and socially. If, as appears to be the case, reprogramming methods have already put us in a position to make viable human gametes, we will soon face different, but even more intense, controversy as such methods move into reproductive medicine (Power and Rasco 2011). The scientific and ethical issues raised by reprogramming cells may evolve in other, unimagined ways. In short, however we move forward in the review of this science, we should encourage continued reflection on where the science is taking us and consider wider adoption of required, or at least voluntary, programs of on-going ethics education.

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