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Stem Cell Research Oversight: Personal Reflections and Public Reasoning

Jason Scott Robert [a]
[a] Arizona State University

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research is becoming more acceptable, hESC research is far from ubiquitously supported. For example, opponents of hESC research have repeatedly challenged the constitutionality of Obama's legislation. The 2012 Republican Platform also underscores the fact that hESC research is still quite controversial, as it includes the following statement: "We oppose federal funding of embryonic stem cell research" (2012, 14). To be clear, the platform does not call for a ban on funding all stem cell research; in fact, it supports adult stem cell research. However, it is a significant step backward from the policy of the Obama administration and could threaten hESC research. The Republican Platform demonstrates that hESC research may not be on solid political ground even if public polls show increasing support for the research.

Another closely related worry is that the removal of ESCROs could open the door to even more legislative restrictions on hESC research. Greely may be correct that IRBs and IACUCs could take over the day-to-day operations of ESCROs, but they may not provide the same political cover. Currently, legislators who support hESC research (and who represent states that require ESCROs) are able to appeal to the fact that the main function of ESCROs is to ensure the research being performed is ethical. While IRBs and IACUCs may be able to do the same work as ESCROs (though we are not convinced of this), appealing to IRBs and IACUCs does not seem to carry the same weight. This is because overseeing hESC research is not their primary function. We also worry that opponents could use the dissolution of ESCROs as ammunition against hESC research. If ESCROs were eliminated, opponents could appeal to the lack of a specific oversight committee as a reason to halt or further restrict hESC research.

Were we to maintain ESCROs but move them into stasis "to be revived only when new developments, coming either from technological developments in the outside world or from ethical problems IRBs, IACUCS, or researchers encounter in stem cell research" (44), we worry that ESCROs would no longer serve their intended functions. While an ESCRO is in stasis, the members would return to their positions within an IRB or IACUC. They would be dealing with a broader spectrum of issues and therefore might not recognize new ethical concerns involving hESC research. Greely seems to agree with this point. He writes, "It is also possible that some problems would not be noticed except by those with day-to-day responsibility research ethics at specific institution, who, in effect, trip over the problems as part of their duties" (44). A related worry is that placing ECSCROs in stasis would leave committee members unprepared when novel issues arise. Members would have to scramble to compile all of the relevant information, protocols, and so on, which could adversely affect time-sensitive research. It is also worth noting that political views and legislation do not go into stasis. As legislation continues to change, it is prudent to have committee members carefully tracking hESC legislation and continuing to evaluate the role of ESCROs. Finally, if we place ESCROs into stasis, then they may not remain viable. Greely recognizes this point. He writes, "One wonders how long an ESCRO in stasis could be kept alive, or effective, without some regular work" (52). Thus, putting ESCROs in stasis may lead to their dissolution. But, as we have seen, dissolving ESCROs would be quite problematic.

Though we agree with Greely's claims concerning the past significance of ESCROs, we find his proposal for their future problematic. His proposal is shortsighted; it neglects the extent to which political views continue to affect hESC research. Without a committee whose sole purpose is to investigate and regulate hESC research guidelines, the future of hESC research could be in jeopardy. ■

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Stem Cell Research Oversight: Personal Reflections and Public Reasoning

Jason Scott Robert, Arizona State University

In his target article, Henry T. Greely (2013) offers a suite of personal impressions and opinions about the work of embryonic stem cell research oversight committees (ESCROs) over the past eight years and into the future. His direct

Address correspondence to Jason Scott Robert, PhD, School of Life Sciences, Arizona State University, Box 874501, Tempe, AZ 85287-4501, USA. E-mail: Jason.robert@asu.edu

experience with ESCROs is limited to Stanford University, but his role as chair of the Human Stem Cell Research Advisory Committee in California has presumably afforded him a glimpse into the inner workings of such committees throughout that state (which is home to almost one-third of all ESCROs in the United States). By contrast, I have no direct experience with ESCROs, so will be approaching these issues from a different angle altogether.

The project is straightforward: Greely wants to know about the costs and benefits of ESCROs in relation to stem cell research in the United States. To this end, he reviews the curious paths by which voluntary guidelines and recommendations issued by the National Academy of Sciences (particularly, a joint committee of the Institute of Medicine and the National Research Council) managed to manifest in ESCROs as the de facto form of human embryonic stem cell research governance in the United States; he muses about the virtues and vices of this mode of oversight as constituted both historically (since 2005) and currently; and he then looks to a future in which the core current tasks of ESCROs are assumed by other bodies, and ESCROs fade into senescence and eventually obsolescence.

Greely's piece is insightful, though sparsely referenced and admittedly limited to a relatively superficial, subjective reflection on stem cell research oversight. One limitation of the analysis is that he takes the National Academy of Sciences (NAS) guidelines and amendments as givens, questioning neither the internal nor external logics of the recommendations nor the suggested limitations on human embryonic stem cell research. When the guidelines were first released, I was not particularly sanguine about the NAS's prohibitions on hESC research; indeed, the prohibitions—on research with human embryos older than 14 days, and on creating and breeding particular kinds of part-human chimeras—struck me then as they do now as odd, farfetched, and not particularly prohibitive. As I wrote (with Françoise Baylis) at the time: If the guidelines prove worthwhile, it will be "not because of their substantive prohibitions, but because of procedural constraints introduced by their proposals for the governance of research on human embryonic stem cells. If not, then the guidelines are mostly political maneuvering" (Robert and Baylis 2005, 16).

The NAS guidelines have certainly had staying power, and, as we suggested, it is because of their procedural dimensions, and specifically the mandated creation of ESCROs at institutions conducting hESC research. ESCROs constitute the dominant form of hESC research governance in the United States. But this is also an achievement of the political maneuvering we signaled, inasmuch as the ESCRO model of governance has effectively "privatize[d] democratic politics" by moving public reasoning *in camera*. "ESCROs in effect assume responsibility for resolving broader political disagreement by appearing to perform the deliberative work requisite to achieve ethically secure ground" (Hurlbut and Robert 2012b, 724; Jasanoff 2011). Other researchers, some with roots at Stanford, laud the "widely accepted ethical standards and effectively implemented institutional rules" entailed by the current system of governance, so much so that they claim that these standards and rules "make the expansion of federal support for hPSC research unproblematic" (Owen-Smith, Scott, and McCormick 2012, 717). In response, Hurlbut and Robert argue that "these institutional developments in no way reflect—and should not be mistaken for—a resolution of broader controversy" (Hurlbut and Robert 2012b, 724). Indeed, if there is anything certain about the uncertain science of human pluripotent stem cell research, it's that it remains controversial, in the United States and beyond.

I suspect that Greely would downplay or deflate the controversy, pointing (as he does in the target article) to "widespread public support" of hESC research resulting in the likely perception that more such research is actually a benefit due to the existence of ESCROs, thanks to the political cover they provide. My colleague Ben Hurlbut and I disagree with this sentiment, and in fact with any approach to the governance of science that merely pretends that all political controversy is settled and rulemaking is the next and only order of business. "American regulatory approaches—official and unofficial—in hESC research reflect an effort to stabilize governance structures without doing the hard work of seeking underlying clarity about what good governance entails" (Hurlbut and Robert 2012b, 725).

This brings me to a second limitation of Greely's analysis, which is the failure to take note of (let alone engage) serious criticisms of local research review, combined with a lack of imagination about the governance structures that might better serve both science and society, in regard to but also beyond hESC research. Elsewhere, I have criticized the NAS committee's decision to prefer local review via ESCROs over a regional or national system of protocol review as enacted in other jurisdictions (Baylis and Robert 2006). While I appreciate that there are many pragmatic and logistical considerations pointing toward a preference for local review, the NAS failed to address a host of procedural and substantial concerns about local review that nod toward the superiority of a national system of review. Instead, the NAS claimed to be sticking with the usual practice in American research governance and insisted on local review. Inasmuch as Greely does not seriously question this move, and indeed bases his analysis of the future of ESCROs on the putatively solid foundation of local review by institutional review boards (IRBs) and institutional animal care and use committees (IACUCs), it is critical that we pause to review just what is being swept under the rug in the process.

An extensive literature records a litany of concerns about the adequacy of local review of research, especially concerning institutional review boards in regard to human subjects research (see, e.g., Emanuel et al. 2004; Federman, Hanna, and Rodriguez 2002; Wood, Grady, and Emanuel 2004; cf. Baylis and Robert 2006). These concerns center on institutional conflicts of interest (in that IRB members tend to be colleagues of researchers submitting protocols, and each institution housing an IRB has a vested interest in conducting the research); lack of ethics education for IRB

members; and lack of administrative, financial, and organizational resources. Moreover, the dispersal of research review to local institutions guards against collecting data, setting standards, evaluating IRB performance, and, if appropriate, reducing variation between sites.

Greely ignores this and related literature in his argument to expand the jurisdiction of IRBs to accommodate the current work of ESCROs on the provenance and derivation of cell lines and the clinical translation of stem cell research, and to turn over the whole issue of chimeras to IACUCs. Greely claims that, pending some legislative retractions, this would be an appropriate future for the review of hESC protocols. Oh, he would still see potential need for a national or international body to take on some governance role—not review of proposals, but rather "issue-spotting" and "worrying about new ethical developments"—as, in fact, the NAS initially proposed. But the reviews could just be left to IRBs and IACUCs.

This is an unsatisfying conclusion. While it may very well be the case that a more robust local review system than we currently have could be expanded to accommodate the review of hESC research protocols, the current system simply will not do. So, two other options present themselves: Reinvent local review of research (and not just hESC research) so as to minimize the observed liabilities, or assign the review of research protocols to another, nonlocal, body. Elsewhere, I have articulated a defense of the latter, focused primarily on transparency, independent expert review, and reduced conflicts of interest (Baylis and Robert 2006). Here, I will remain neutral between the desirability of a revamped, robust local review system and a national system of review, and conclude instead with a plea to expand our imagination about the forms of governance that should obtain, moving forward.

Greely did not mean to be either empirical or comprehensive in his assessment of the costs and benefits of ESCROs; nor was he. Instead, he voiced some thoughtful considerations about our current structure for governing stem cell research, and then offered some less thoughtful ones about how to more forward from here. I appreciate Greely's foray into this important conversation, not least because it allows us to see just how grand are the challenges of governing science in America today.

> Good science is an achievement of a good society, and not the reverse. The ways we reason together as a society, and the policy resolutions we settle on, should reflect this. Facile references to politics "standing in the way of good science"—too common in the hESC controversy—denigrate the foundations of science and democracy alike. Science depends on a space in which it can observe its internal norms and exercise its specialized skills, but in a way that coheres with, rather than contradicts, the norms and aspirations of the democratic societies in which science is embedded. (Hurlbut and Robert 2012a, 712)

It is to these grand challenges that we must now turn, as we foster some new "experiments in democracy" (Hurlbut 2010) to grapple with the unresolved tensions underlying and inflaming human pluripotent stem cell research. ■

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