Comments on "Draft National Institutes of Health Guidelines for Human Stem Cell Research Notice"*

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1. THE MISSING KEY CONDITION JUSTIFYING USE OF AN EMBRYO AS AN HESC SOURCE

Demand by funded investigators for human embryonic stem cells ('hESC') will induce embryo-destructive derivations of hESC. Heeding this, the drafters of the Guidelines recognize that using an hESC line will be morally permissible only if the previously occurring derivation of hESC was permissible. For permissibility of hESC derivation from an embryo, the Guidelines demand the satisfaction of conditions pertaining to the embryo's donation. These conditions are set forth as II.B.1–7 of the Guidelines and hereafter called the 'Guideline Donative Conditions' ('GDC').

As the following will explain, NIH is correct to suppose that the permissibility of a derivation turns on the circumstances of embryo donation. But the GDC present a problem of underinclusiveness and overinclusiveness. On the one hand, conspicuous by its absence from the GDC is the condition most crucial to the moral permissibility of using donated embryos solely as means (the general practice of which hESC derivation is a special case). The omitted condition is that the embryo donors have prohibited intrauterine transfer. On the other hand, some of the GDC are not requisites of permissibility.

The straightforward solution to this problem is to insert the crucial condition and to omit the nonrequisites. The dual effects of this solution will be, first, to establish tenable criteria determining which new cell lines will be eligible for use in funded research, and second, to provide in a principled way for eligibility of extant lines.

I recently published a study, *The Morality of Embryo Use* (Cambridge University Press, 2008), hereafter denoted as 'M,' that presents a putative consensus

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justification for embryo use in medicine, and for embryonic stem cell research in particular. Much of the reasoning presented below encapsulates reasoning developed there. Bracketed references to M below denote the full development of the respective topics.

The first section of these comments, directed toward the first of the foregoing effects, will present reasons for the following. (1) The significance of the GDC, and any alternative conditions of embryo donation, is not scientific but moral. The test of adequacy is whether satisfaction of proposed conditions yields a tenable moral justification for embryo sacrifice. (2) To be tenable, a candidate justification must be a justification on which a federal agency operating within our constitutional system may predicate policy, and must be a justification that falls within an overlapping consensus on conceptions of justice, as best we may espy such, within our pluralistic society. (3) The respective insularities and defects of the commonly invoked defenses for using donated embryos disqualify any of those standard defenses from serving as a consensus justification. Although informed consent of progenitors is necessary insofar as they are research subjects, informed consent by them does not suffice to justify use of embryos distinct from them. The set of plausible justificatory conditions has been winnowed to that condition that happens to be missing from the GDC. (4) The justification clinched by a progenitor prohibition on intrauterine transfer may be advanced within public reason without appeal to any premise peculiar to any particular moral or religious view, and hence such justification occupies a place in an overlapping consensus. (5) Absent such prohibition, embryo use is not justified. (6) It is therefore appropriate to adopt a rule, in a text to be proposed, setting forth requisites for use of embryos as hESC sources. (7) Nonrequisite conditions warrant a place in the Guidelines, but should be recast as indicia of satisfaction of the requisites.

1.1 *DONATIVE CONDITIONS ARE MORAL CONDITIONS*

Given the separation of church and state, not to mention the range of moral and religious views held within our pluralistic society, the drafters of the Guidelines

do not regard themselves as arbiters between rival moral views. But the drafters inexorably are crafting rules for moral effect. No scientific considerations motivate the condition that a fertility patient has received an explanation of options. Or that no one has offered her inducements, or that she has consented to something. It is concern for morality, knowing that embryos are an object of moral concern, that motivates such rules. Because hESC research lies at the intersection of science, morality, and policy, the drafters are faced with the need to define research that, by some account that the government may tenably suppose, is morally justified (or in their phrase, is "ethically responsible" [74 Fed. Reg. 18578]). Given this motivation of the GDC, we must ask the question, are the GDC the factual conditions of a tenable justification?

1.2 *THE CONSTRAINT OF PUBLIC REASON*

The only way to answer that question is to ascertain the methods and sources to which the government may have recourse in deciding what constitutes a justification of embryo use. Moral permissibility is not a matter of fact, but often a bone of contention between competing moral views. But this is a case in which we as citizens, and the government on our behalf, may productively seek an understanding of what is permissible by confining ourselves to reasoning that does not invoke any premise peculiar to any particular moral or religious view. We may impose on ourselves the constraint of "public reason" developed by the philosopher John Rawls ("The Idea of Public Reason Revisited," 64 *University of Chicago Law Review* 765–807 [1997]). When operating within public reason, we accord respect to verdicts rendered by comprehensive moral and religious views, but on questions of justice discussed in the public arena, we demand of all discussants not only that they conform to principles of reasoning and rules of evidence, but that they support their verdicts with reasons that lie within an overlapping consensus of conceptions of justice. Discussants may press a conclusion by appeal to a doctrine of their particular moral or religious view only if they can independently support the conclusion by reasoning that falls within an overlapping consensus. For example,

the Aristotelian-Thomistic view that a conceptus is not ensouled until day 40 in the male and day 90 in the female [M, 155–158], or the Judaic doctrine that a conceptus is "mere water" prior to day 40, cannot be offered as justifications for hESC research, since those tenets lack such independent support.

When a resolution of an issue is reached through public reason, the resolution will enjoy better prospects for stability and harmony than those of resolutions reached by mere majoritarian rule, or by selecting one secular view over others. Sometimes adherence to public reason issues in a resolution even of vexing matters, and sometimes not. I have constructed, by adhering to public reason, a putative consensus justification for the use of donated embryos in service of humanitarian ends. Of this practice, hESC research is a special case. This justification is summarized in section 1.4. Its value will become more clear after we attempt to muster the other defenses of hESC research, for we shall learn that after subjection to the tests of logic and public reason, none of the nonsecular defenses are left standing.

1.3 *FAILURE OF CONVENTIONAL DEFENSES OF EMBRYO USE*

1.3(a) *STANDARD NONSECULAR ARGUMENTS*

Leaving aside secular arguments, which unless independently supported are unavailable to the government by virtue of the separation of church and state, not to mention the constraint of public reason, the most familiar argument for embryo use is that surplus embryos will die anyway. This argument is defective. Imminent death by one means does not alone justify a killing by another means [M, 51–52]. A utilitarian defense of embryo use founders for inability to adduce unit comparable interval scale utility measures, and of course such a defense holds no water for nonutilitarians [M, 12–19]. The nonindividuation argument predicated on the possibility of monozygotic twinning has been refuted by the counterexample of mitosis and exposed as unsound in other respects, while all attempts at rehabilitation have failed [M, 59–98, 148]. The view that a microscopic embryo "does not seem like a person to me" is parried by discussants who declare that every

embryo "does seem like a person to me." The contention that an embryo is a "clump of cells" is refuted by observing that the contention fails to take account of potential. The surprising discovery is that, even when sympathetically viewed, each of the nonsecular arguments for embryo use founders in some way [M, 4, 56, 146, 148, 189–190, 214–217].

1.3(b) *INFORMED CONSENT OF PROGENITORS, THOUGH NECESSARY INSOFAR AS THEY ARE RESEARCH SUBJECTS, IS NOT SUFFICIENT TO JUSTIFY USE OF EMBRYOS*

The orthodox justification for use of a human subject in research is informed consent. Many drafters of hESC policy and legislation, with ample support from commentators, have supposed that justification of embryo use follows from informed consent of embryo progenitors. So the drafters have trained their sights on prescribing that donees of embryos obtain progenitor informed consent. They draft procedures therefor, or they prescribe compliance with the Common Rule (45 CFR Part 46). In the GDC, apart from the conditions that the embryos were created "for reproductive purposes" and "were no longer needed," the principal weight-bearing member is informed consent, as evidenced by a "written consent form for donation" (II.B.7, par. 1). The other conditions of the GDC may be understood to subserve this member insofar as they provide for its parts (e.g., voluntariness and understanding of pertinent information).

But the aforementioned supposition that embryo use is justified by progenitor informed consent is mistaken [M, 231–232]. Informed consent is justificatory if (i) the research subject and the person consenting are identical, or (ii) for subjects incapable of consenting or of discerning their best interests, if another person consents while acting on behalf of and in furtherance of the best interests of the subject. In the case of embryos donated for use in experiments that will destroy them, neither (i) nor (ii) obtains. An embryo is not a body part of either progenitor, but a distinct cleaving human organism. The embryo is incapable of consenting, and there is no sense in which killing the embryo may be said to serve its interests. While informed consent avails for experiments involving subjects whose welfare is

protected (as in 45 CFR 46.116) in the hope that they will survive, it does not avail for subjects that assuredly will be killed.

Informed consent is necessary as to progenitors insofar as they are research subjects. (The mother's informed consent is necessary insofar as the embryo originates from her oocyte; the male coprogenitor's consent is necessary for like reason as to his sperm. Some may argue that paternal consent is not requisite, but promulgation of the present policy does not seem an appropriate occasion for the federal government to stake a claim to that controverted position.) But as just shown, progenitor informed consent is not sufficient for use of embryos as means.

There is a progenitor act that does ground a justification of embryo use. To that we now turn.

1.4 *ARGUMENT FROM NONENABLEMENT AND ITS LINCHPIN*

The aforementioned consensus justification for hESC research rests on the following "argument from nonenablement" [M, 21–58]. A woman from whose oocyte an extracorporeal embryo is formed is, with the coprogenitor, the only person in the world privileged to decide whether the embryo will be transferred into a uterus. Although progenitors do not own embryos, we deny that anyone but progenitors is privileged to meddle in decisionmaking about them. The progenitor privilege is exclusive in default of anyone else possessing the privilege. A woman does not lie under a duty to undergo a transfer into her of an embryo existing outside her. Nor does she lie under a duty to surrender for adoption an embryo that she declines to bear. Imposing that duty would present such adverse incentives and consequences for fertility patients, including compelled remote parenthood, that we should be hard pressed to find any moral view asserting the duty. A decision to decline intrauterine transfer into self or other is a morally permissible exercise of discretion. Suppose then a progenitor exercise of discretion to decline intrauterine transfer of an embryo, followed by donation of the embryo under instructions that state that the embryo be used in medical research or therapy, and that forbid transfer of the embryo or of any totipotent cell taken from the embryo into a woman or into an

artificial uterus. This is a restricted gift, a donation conditioned on a prohibition. In consequence of the progenitor prohibition on intrauterine transfer conditioning the gift, the embryo will never gain the enabling environment of a uterus, and will be confined to the tissue culture dish. While a genetic account of developmental potential eludes us, we may observe the boundedness of situation-dependent potential as represented by a probability density function of a continuous random variable defined on a sample space of developmental outcomes. In the dish, the embryo's developmental potential is so bounded that the embryo will not complete gastrulation. We, any of us, cannot gain anything for this embryo—nor for any other being—by classifying the embryo as a person for purposes of the duty not to harm. We cannot provide the embryo gestation, which has permissibly been barred, nor spare the embryo discomfort or frustration, since the embryo cannot attain the capacity to experience either. By forgoing use of the embryo in research, we may only assure that the embryo perishes in vain. During the embryo's remaining life, it is not nomologically possible for it to acquire any morally significant property that it does not already possess, and hence if we do not presently classify the embryo as a person, no possible person may plausibly be said to correspond to the embryo. Meanwhile scientists reasonably believe that use of embryos in research could contribute to the relief of human suffering. Embryos barred from the womb present a means by which we might relieve suffering in actual lives at no cost in potential lives. In this situation, the duty of mutual aid—the duty to aid those in need when we may do so without imposing an unreasonable burden—bids us undertake such research. Whereupon it becomes not only permissible and virtuous to use donated embryos in such research, but a fulfillment of a collective duty.

The foregoing argument from nonenablement is a consensus argument insofar as it does not invoke any premise peculiar to one or another moral or religious view. The bounded developmental potential of an embryo in the dish is a biological circumstance. The duty of mutual aid, the discretion of persons to elect whether they shall undergo medical procedures—these are common to all leading

moral and religious views. Hence it may be shown that the argument from nonenablement compels assent even within those moral and religious views commonly interpreted to condemn all embryo use [M, 140-180]. The argument from nonenablement occupies a place in an overlapping consensus of conceptions of justice. Public policy may gather the widest and most stable support by locating hESC research transparently within conduct shown morally permissible—this as best public reason allows us to see the conditions that confer permissibility. On the basis of the argument from nonenablement, we arrive at the following *Public Policy on Embryo Use*: "Scientists may conduct, and the government shall support, biomedical research using human embryos that, before or after formation, have been donated to medicine under donor instructions forbidding intrauterine transfer" [M, 234]. (As the phrase "before or after formation" indicates, the argument from nonenablement justifies creation of embryos in research as well as use of surplus embryos. But only the latter practice is pertinent to the Guidelines.)

According to the argument from nonenablement, permissible exercise of discretion to bar an embryo from the womb so bounds the developmental potential of the embryo as to ground a justification for its use by a donee. The justification of hESC use thus devolves from autonomous decisions of people from whose cells extracorporeal embryos originate. These are active and unilateral decisions, not mere consents to what someone else proposes. There are two important sorts of decisions. First, progenitors give embryos to medical research and therapy. They do not merely acquiesce, they choose to give. Apart from the earlier mentioned inefficacy of progenitor informed consent, the expression "written consent form for donation" [II.B.7, par. 1] contravenes common usage. When someone transfers an object to another without demanding anything in return, we do not say that they "consented to the transfer" of the object, we say that they "gave" the object to the other [M, 232]. Second, in the circumstances in which the consensus justification arises, progenitors do not merely consent to a condition that intrauterine transfer shall not occur. Rather they direct that intrauterine transfer shall not occur [M, 28].

By contrast, a requirement for "a statement that embryos donated will not be transferred to a woman's uterus" appeared in NIH's previous "Guidelines for Research Using Human Pluripotent Stem Cells" (65 Fed. Reg. 51976, 51980 [August 25, 2000], II.A.2.e[vii]). But this requirement was only that such a statement be "included" in "the informed consent process"—a condition so weak as to be satisfiable by a sentence in a document written by an investigator whom a donor never meets. Clarity about who originates the prohibition on intrauterine transfer is indispensable, because there exists only one person in the world (with coprogenitor) privileged to impose that prohibition.

1.5 *ABSENT A PROHIBITION ON INTRAUTERINE TRANSFER, NO CONSENSUS JUSTIFICATION OF EMBRYO USE*

In default of a progenitor prohibition on intrauterine transfer of an embryo, all of the following obtain: intrauterine transfer remains permissible, the embryo's developmental potential is not bounded at gastrulation, it is nomologically possible that the embryo attains sentience and develops to term, and therefore the consensus justification of embryo use does not apply to that embryo. Whereupon it may plausibly be argued that classifying the embryo as a person could gain birth for its developmental successor, that a possible person corresponds to the embryo, and that it is wrong to interfere with the embryo's development [M, 26, 232, 245].

1.6 *RECOMMENDED ELIGIBILITY RULE*

1.6(a) *TEXT*

On the basis of the foregoing reasoning, it is recommended that the following replace the first paragraph of II.B.:

> "Human embryonic stem cells may be used in research using NIH funds if (1) the cells were derived from an embryo created in the course of clinical treatment for infertility, (2) the progenitors of the embryo donated the embryo on the conditions, set forth in written instructions accepted by the recipient, that (a) the recipient shall use the embryo solely in medical research or therapy, and (b) never may the embryo or any totipotent cell taken from the embryo be

> transferred into a woman or into an artificial uterus, (3) the progenitors did not receive any financial or other consideration in exchange for donation of the embryo, and (4) the progenitors were informed, prior to the donation, that (if such be the case) the embryos will be sacrificed to derive embryonic stem cells, and that a line of such cells many be maintained indefinitely. The foregoing is hereafter referred to as the 'eligibility rule' ('ER')."

1.6(b) *EXPLANATION*

ER is intended to be inclusive of all conditions that should be mandatory. The following explains some of its provisions. In ER's clause (1), the empirical fact that ministrations to a woman fall within the category of infertility treatment is both more verifiable and attainable than the condition that an embryo was "created for reproductive purposes" (II.B., par. 1). The mental states of patients lie beyond direct observation, and such indications as we have suggest that patients do not intend procreation as to every embryo created [M, 50–51]. (Since clause (1) does no work in the argument from nonenablement, hence is not necessary to the consensus moral justification, it could be omitted, but it is included here because it expresses an NIH decision on scope.) In (2) of ER (on which see [M, 27ff.]), "medical research or therapy" is appropriately narrower than the Guideline's phrase "research purposes." Clause (3) differs from the condition in the GDC that "no inducements were offered for the donation," which could prove too broad. If patients read convincing yet circumspect presentations, in disclosure documents composed by hESC investigators and delivered to them by their physicians, concerning the promise of hESC research, such presentations might appropriately induce embryo donations.

The reasoning for omitting the condition that an embryo was "no longer needed for this purpose" is as follows. When fertility patients decide whether to store embryos, they do not speak of their needs, but instead of their wishes, their wants. 'Need' suggests some kind of clinical calculation of embryo inventory against planned transfer procedures, and this betokens physician involvement. Such was yet more strongly suggested in the predecessor of this phrase, "were in excess of clinical

need," used in NIH's 2000 guidelines (65 Fed. Reg. 51979–51980) and recent proposed legislation (H. R. 7141, The Stem Cell Research Enhancement Act of 2008). Reference to 'need' risks getting the order of authority muddled. It should be kept clear that the physician proposes, the patient disposes. In order to make applicable the argument from nonenablement, a decision against intrauterine transfer must be made solely by progenitors. When a decision against intrauterine transfer is taken, it is manifest that the progenitors no longer need or want the embryo for reproductive purposes. The ban on intrauterine transfer is a stronger action than recognition of lack of need or want. Thus if ER is adopted, a condition about lack of need or want would be redundant.

In defense of redundancy, it might be surmised that, in hopes of discouraging creation of embryos for research purposes, requiring the condition that an embryo "is no longer desired for this purpose" would somehow block the possibility that a patient might begin fertility treatment intending to donate some resultant embryos to research. But imposing that condition or any other like it would not deter such behavior, since whenever patients chose to donate embryos, they could easily affirm such a condition. It appears that many patients expect, when they begin fertility treatment, that they will end with surplus embryos, and that they will donate at least some of them to research.

Clause (4) corresponds to the conditions at II.B.7.c, d., and e.

1.7 *RECOMMENDED ENUMERATION OF INDICIA OF ELIGIBILITY*

It is recommended that II.B. continue with

> "The following are relevant indicia, to which investigators should be alert, of fulfillment of the requirements of ER, particularly in respect of the understanding by a prospective embryo donor of circumstances pertinent to donation, and of the voluntariness of the donation",

and that the rest of the GDC, suitably modified, be enumerated thereafter except as noted below. The following comments on those conditions.

'Donation' implies voluntariness. Hence condition 7a. is redundant and may be omitted. Conditions 3., 4., 5., and 6. are useful as indicia of voluntariness, but are not mandatory of themselves for moral justification by the argument from nonenablement.

Conditions 1., 7b., 7h., and 7i. provide very useful information whose disclosure should be encouraged. It may be pointed out that donors should be fully informed about the context as they decide to give embryos to a suitable donee for use in hESC research, and that the information that they possess will bear upon interpretation of the donative instruments concerning what donees may do with the donated embryos. Mention of 1., 7b., 7h., and 7i. could well be preceded by, "Prior to donation, the donor received a written disclosure, prepared by the principal investigator who received the donation, of the following pertinent information." [M, 232–233] But ignorance of 1., 7b., 7h., and 7i. would not be so material as to preclude voluntary donation, and so they may remain indicia.

Conditions 7f. and 7g. are vestigial from rules designed to prevent the prospect of direct benefit from research from becoming an incentive to elect an abortion. These conditions are dispensable here insofar as the risk of an objectionable incentive is different: an embryo produced by IVF would not be a genetic match to either progenitor or their children.

On the plausible assumption that fertility patients undergo fertility care voluntarily, their informed consent concerning embryo creation, while obviously mandatory, is not and need not be mentioned in the Guidelines. The conditions enumerated within 7., which follow the informed consent provisions of the Common Rule (45 CFR. 46.116), are here endorsed solely as indicia of fulfillment of the requirements of ER. The Common Rule itself is inapplicable here, as it is designed to satisfy an abiding concern—that the welfare of the subject must be protected—that *ex hypothesi* is ignored here. Thus contrary to the mistaken supposition noted in sec. 1.3(b) above, the Common Rule is unavailing as to use of surplus embryos in hESC research. The Common Rule is inapplicable to progenitors as to creation of embryos

from their cells (when they are patients and not research subjects), it applies to progenitors insofar as they later are research subjects, but it is inapplicable to embryos as research subjects because the research involving the embryos will sacrifice them.

2. SOLUTION TO PROBLEM OF EXTANT CELL LINES

2.1 *REQUIREMENTS CONCERNING PROVENANCE APPROPRIATE*

That NIH imposes requirements on the provenance of cell lines is entirely appropriate inasmuch as the morality of using embryo derivatives depends upon the morality of the derivations. The fact that the requirements pertain to the past does not impugn their appropriateness. Insisting on a specific sort of provenance will not constitute an *ex post facto* law of the sort prohibited by Art. I, sec. 9 of the Constitution. NIH is not penalizing past conduct. The agency is not enforcing anything. Nor do NIH's requirements abrogate any contract rights, past or present, since there is no entitlement to a grant (the last a familiar point reiterated in Executive Order 13505, "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells," 74 Fed. Reg. 10667–10668 [March 11, 2009], §4[c]). Assigning significance to cell provenance is not retrospective rulemaking of the sort often called into question. NIH may condition research grant eligibility on the provenance of research subjects just as NIH may condition training grant eligibility on the provenance (e.g., graduation from a doctoral program) of a candidate.

2.2 *EVIDENCING BY DOCUMENTS*

NIH has come in for criticism for requiring documentary evidence when, it is said, what matters is whether an appropriate condition has been met, not whether a document evidences it. This criticism asserts a cogent point, but by virtue of the following, the point misses the mark here. In the instant situation, NIH may impose requirements only on its funded investigators, the recipients of embryonic derivatives, not on unfunded persons performing the derivations. NIH appropriately demands that its downstream funded investigators intrude into the matter of derivation so as assure that the embryonic derivatives were permissibly derived. (This mandated intrusion undermines the notion that the downstream studies are

not conflatable with the derivations and hence not part of "research in which a human embryo or embryos are destroyed." Hence arises another compelling reason for legislation overriding the Dickey Amendment so as to provide either that (i) NIH may fund studies of hESC and impose conditions on donation of their embryonic sources, notwithstanding the provision barring funding of "research in which a human embryo or embryos are destroyed," or (ii) NIH may fund derivations.) NIH has appropriately recognized that its applicants will not have been present at derivations, and that those who perform derivations may have an incentive to gloss over past circumstances and to sign certifications perfunctorily. Hence it is not overweening to demand documents that originated at the time of embryo donation and that bear donor signatures.

But despite this rationale for the drafters' approach, the predicament adduced by investigators using extant lines is that conditions may have been satisfied without satisfaction having been documented.

2.3 *RECOMMENDATION*

To this predicament, the solution recommended here is, in general, to rely on the ability to infer compliance with ER from any competent evidence. More particularly, NIH could resolve the use of extant cell lines according to when the pertinent grant was or will be issued.

(a) For studies already funded (which by dint of prior policy would pertain to presidential lines), NIH could require that there have occurred an explicit or inferable compliance with ER clauses (1), (2), and (4). As to the linchpin condition (2), NIH could allow the inference that a donation to research that was known to destroy its embryo subjects—a fact about the research known when (4) obtains—implied a decision against intrauterine transfer, even if the donative instrument did not include an explicit prohibition as such. NIH could also introduce a presumption that clause (3) of ER was satisfied in the absence of evidence of an inducement there proscribed. If investigators are now studying lines that do not pass muster with the benefit of inferences thus allowable, time and funds could be granted to restructure

their research so as to substitute other lines.

(b) For future studies using extant lines, NIH could accept inferences as above concerning ER clauses (1), (2), and (4), and indulge the presumption concerning (3). But it bears emphasis that an inference should not be deemed sufficient when an opportunity arises to be explicit [M, 232]. Hence as to any line created after the effective date of the Guidelines, the agency should insist on fulfillment of (2) in the written manner prescribed, i.e., by written progenitor instructions stating that an embryo shall be used solely in medical research or therapy, and that intrauterine transfer is forbidden.

2.4 *GRANDFATHERING NOT PRACTICED*

The foregoing principled ground for funding would not waive any moral requisites, decline to apply requirements to past circumstances, or bow to the expediency of using extant lines. Since a ban on intrauterine transfer is the linchpin of moral justification, a principled ground does not obtain for waiving insistence upon it—no matter what good faith contrary understanding of justification may have been held by donees in the past. Instead the foregoing strategy consists in first winnowing ER to the moral requisites, then recognizing that there may exist competent nonwritten evidence of fulfilling those requisites.

3. CHIMERAS

3.1 *PROHIBITION UNWARRANTED*

Because the argument from nonenablement justifies experimentation with any embryo barred from the womb, III.A. could be deleted. But it is evident that NIH regards this exclusion as important in public perception.

3.2 *INELIGIBILITY OF DOWNSTREAM STUDIES, IF INTENDED*

The question arises whether studies of derivatives of blastocysts described in III.A. would be fundable. Presumably NIH intends not. But to read III.A. as barring such, NIH would have to adopt an aggregative interpretation of the phrase “research in which” used here, an interpretation of that phrase that NIH must oppose in order to maintain, in respect of the Dickey Amendment, that it may fund use of hESC even if not derivations. Hence it would do well not to use the phrase “research in which”

here, and to add a clause excluding such downstream studies from funding.

4. MINOR CORRECTION

The first sentence of II.C. provides that eligible lines "were derived consistent with section II.A and B . . . ." Section II.A imposes no conditions on derivation, and the appropriate modifier of the verb phrase in the quoted expression is an adverb. Hence the quoted expression could be corrected to read "were derived consistently with section II.B . . . ."