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Comments on "Give and Take? Human Bodies in Medicine and Research." Consultation Paper, Nuffield Council on Bioethics, April 2010.

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1. Introduction

Precedents set in the UK often lead the development of health policy internationally. The final report of the Working Party on Human Bodies in Medicine and Research of the Nuffield Council on Bioethics has this potential. I thus much appreciate the openness of the consultation process to international opinion.

The Working Party is charged with an ELSI mandate in its first term of reference: "[t]o identify and consider the ethical, legal and social implications of transactions involving human bodies and bodily material in medical treatment and research" (p. 8). Yet the first sentence of the "Introduction" to the Consultation Paper is more restrictive, narrowing the mandate to "ethical issues" (p. 10). The result is that the Consultation Paper is almost entirely ethical in its reasoning, with the social and legal implications of donation and volunteering marginal to its concerns. My chief concern in these comments is with the social implications of the transactions being examined by the Working Party. In the Consultation Paper the discussion of the social appears chiefly in the Glossary.

The Consultation Paper uses a particular type of ethical reasoning, normative bioethics or meta-ethics, which seeks to discover principles, values, regulations and rules for good governance of ethically problematic terrains. My comments explore the effects of this normative bioethical framing within the this Paper, in particular the displacement of the S from ELSI. I focus on the following effects of normative bioethics on the Consultation Paper: a) the substitution of an abstract bioethical subject for the social actor; b) the occlusion of the economic context in which first-in-human trials take place; c) the weakening of the distinction between research subject and patient. I argue that proposals for bioethical governance need to be made with a robust knowledge of the social and economic contexts in which their recommendations and proposals may take shape. In order to propose what should be done it is wise to carefully examine what is, expectation of governance since the sixteenth century. If this engagement between is and ought does not occur, the risk is the production of an abstracted, governing discourse that proceeds without awareness of its social and economic effects (Smith 1990: 93-100 and 164-165). My argument does not attempt to displace E with S, but to argue that the job of governing this complex terrain cannot be done without both the Ethical and the Social.

The concerns expressed herein are analytically prior to the questions raised in the Consultation Paper, although I will address a number of its questions in the context of my general observations.

2. The Bioethical Subject and the Social Actor

a) Displacement of the social actor by the bioethical subject

As a document informed primarily by normative bioethics, the Consultation Paper implicitly frames what is at stake in its deliberations as harm to human subjects. I will term this focus of concern the 'bioethical subject'. The bioethical subject is an abstraction used by bioethicists for the purposes of governing treatment and research in biomedicine and biotechnology. It is a position formed internal to bioethics as an expert discourse. In the Consultation Paper the bioethical subject is assumed to be the individual, but I should observe that not all bioethical discourse focuses on the protection of the individual. Organizations representing Indigenous peoples in the Americas have advocated two levels of consent – individual and tribal/band council - for all genomic research on indigenous peoples.[1] Recent work in public health bioethics has been concerned with infectious disease outbreaks and other public health emergencies that occur on a population basis (Annas 2010; Battin, Francis, Jacobson, Smith 2008; Holland 2007).

The Consultation Paper posits bioethical subjects as being for all practical purposes identical; they are not marked by social division in terms of gender, ethnicity, kinship, socioeconomic status, and other social statuses. To the extent, for instance, that ethnicity, family and socioeconomic status are mentioned in the Consultation Paper, they are relevant only as potential barriers to informed consent. The bioethical subject is not intrinsically characterized by social memberships and thus in consequence these do not need to be conceptualized. In the normative bioethics used in this Paper It is the bioethical subject and only the bioethical subject that may potentially be harmed in treatment and research. Informed consent is regarded as adequate for protecting the bioethical subject and is the benchmark of ethical governance; the governmental challenge is to specify the conditions for informed consent.

Anthropologists, sociologists and other social scientists have for several decades evidenced sensitivity reactions when exposed to the bioethical subject; at times these reactions are severe. Social scientists by and large work with a quite different conception of the human subject: the social actor. Since the beginnings of theorizing social action in the work of Weber a century ago, the social actor has been conceptualized as characterized by meaningful practices and intentions. The actor is embodied, with space and time coordinates organized in relation to the actor's body. Actions may be of many types, but in everyday practice (as distinguished from dreams by way of example), the social actor construes the world as a place to act on through conscious practices and plans. For meaningful action to occur, the social actor must be incorporated in human language, which in turn requires the existence of other speakers and actors to whom the social actor orients. The concept of the social actor gives rise to problematics that investigate differing forms of action, how social relations form, how social interaction is organized, how struggles for recognition occur, and how the actor is marked by social memberships from gender to citizenship.

Social science works implicitly or explicitly from a notion of the social actor oriented to and embedded in broader societal contexts characterized by differentiation of social statuses, stratification and power. This analytic stance diverges from the applied philosophy perspective of bioethics that is concerned with the horizontal proliferation of a single unit: the bioethical

[1] See the model legislation for Tribal Councils, the Indigenous Research Protection Act, that has been drafted by the Indigenous Peoples Council on Biocolonialism at http://www.ipcb.org/publications/policy/files/irpa.html , (accessed 12 July 2010).

subject. In the Consultation Paper the social actor is erased by the bioethical subject who is assumed to operate as a constant without social qualities. An example of this occurs in "The Purposes of Providing Bodily Material/Volunteering in a Trial" (p. 14), which is clearly not meant to consider the intentions of the social actor as to why or under what social and economic conditions s/he might be willing to provide bodily material. Instead the potential uses/purposes of bodily material for treatment/research are foregrounded.

Because the Consultation Paper is framed exclusively in terms of the bioethical subject, it occludes forms of social relation and stratification that are germane to traditions of inquiry based on the social actor. From the perspective of those concerned with the bioethical subject, decision-making by the social actor and its determinants are invisible. As my colleague Dr. Rachel Ariss argues in her comments to the Working Party, this renders the Consultation Document unable to examine the gendering of reproductive tissues[2] and the consequences of its deliberations for women. So too, analysis that proceeds in terms of the bioethical subject can neither see nor evaluate potential harm to cultural practices, social relations and institutional forms. These occlusions cannot be set aside as purely exterior to the concerns of the Working Group as they fall within its terms of reference.

b) Harm to cultural practices, social relations and institutions

The Consultation Paper is exclusively concerned with harm to the bioethical subject *qua* individual. This is perhaps because the document is in some senses a survey instrument. However, who/what may be harmed is not simply the bioethical individual but cultural practices, social relations, and human institutions, what might be called collective effects in contrast to individual effects. For instance, one might understand assisted human reproduction as the treatment of individual patients, but also as experimentation on human kinship. Consider, for instance, the now familiar scenario: a daughter donates eggs to her mother, the eggs are fertilized through IVF, and her mother subsequently gives birth to a child from her daughter's eggs. There is an experiment with descent (relatedness across generations – Is the child the mother's daughter or granddaughter?). There is also an experiment with kin identification and kin terminology (Who is the mother? What is a mother? Is the child a sister/brother to the egg donor? What is a sister/brother? Or perhaps a niece/nephew? What is a niece/nephew?). If we are all kinspersons, then experimentation on human kinship is no trivial matter, but again the focus on the bioethical subject renders these types of experimental effects invisible.[3]

The Consultation Paper asks, "To whom, if anyone, should a dead body and its parts belong?" (Question 25). The Paper's exclusively bioethical framing of organ donation does not recognize that transplant surgery necessitates revisions in cultural practices with respect to the dying and the bodies of the dead. A change in cultural practice is a collective effect which in this case is

[2] On the status of the products of conception, including fetal ovarian tissue, see Ariss 2003.

[3] Marilyn Strathern, Chair of the Working Party, has done the leading scholarship internationally on AHR and kinship.

associated with a second collective effect: the revision of the relation between person and body at the end of life and in death, what might be called a depersonalization of dead bodies.

Anthropologists have made very clear that social actors give the process of dying and the bodies of the dead widely differing cultural meanings. In the English and French Canadian contexts, we are expected to visit family and friends who are dying and see to it that their remains are dealt with in accordance with their wishes and the cultural traditions of which they are part. It is implicitly assumed that dying is hard to do for those who do not die instantly. The presence of intimates is regarded as helpful to those who are dying; supporting those who are dying is an act of compassion that is often emotionally difficult. These normative practices with respect to the bodies of the dead are reiterated in the Criminal Code of Canada (federal legislation applying throughout the Canadian jurisdiction), which makes it a crime to offer an indignity to a dead body and requires those with the obligation to do so, to bury the dead.[4] To agree to send an apparently breathing (brain-dead) relative for dismemberment in transplant surgery conflicts sharply with these longstanding cultural practices. The Consultation Paper, like transplant surgery in general, fails to recognize the existence of such cultural practices, to feel their moral weight, and to engage in dialogue with them.

The bodies of the dead are not objects equivalent to rocks or books, neither to those who pronounce death (Lock 2002; Lock and Nguyen 2010: 239-241) nor to their kin (Lock and Nguyen 2010: 235). Social personhood does not leave the body at death. The bodies of the dead still retain multiple memberships in terms of gender, family, occupation, ethnicity and many other forms of relatedness. The bodies of the dead, inclusive of the brain-dead, are ambiguous in terms of personhood. I am in agreement with my colleague Dr. Rachel Ariss in her comments to the Working Party that the connection between personhood and the body must be insisted upon in our time. Personhood in bodily materials may be extinguished (as it has been for blood donation), but the process should be recognized as such and made the subject of public dialogue. The Consultation Paper asks indirectly at several points if there are conditions where presumed consent to organ donation might be authorized, perhaps in the situation of "facilitating organ donation from people who die from a cardiac arrest outside hospital" (p. 20). The discussion of the "opt-out approach to organ donation" notes that the 2008 Organ Donation Taskforce decided against recommending this approach "at the present time" (p. 35). The opt-out approach would answer the question of to whom the bodies of the dead belong by granting their belonging in the first instance to biomedicine/bioscience. I note that in the Canadian context presumed consent would be politically unacceptable. It could be anticipated that Aboriginal peoples would regard medical seizure of bodies as a colonialist practice. Afro-Canadians have a strong historical memory of involuntary experimentation on Black people. In Canadian jurisdiction, families bear the social obligation to dispose of human remains; familial control is compatible with a wide variety of ethnic practices. The Working Party will be aware that there has been a long history since the early modern period of popular struggles to recover dead bodies from medical control (Richardson 1988).

[4] See s. 182, Criminal Code of Canada. The obligation to bury the dead has developed over time to mean the obligation to bury the dead in a decent and dignified manner.

Given these general considerations about harm extending beyond the bioethical subject to cultural practices, social relations and institutions, informed consent is of limited value for governing the donation of human bodily materials and the recruitment of research participants in first-in-human trials. As a stand-alone practice pertaining to the individual, informed consent does not address the range of social and cultural effects found on this terrain.

c) Decision-making by the social actor

The concept of the bioethical subject does not adequately address the reasons why people decide to participate in first-in-human trials, that is, decision-making by the social actor. A number of bioethicists and social scientists have made this observation previously (e.g. Corrigan 2003; King, Henderson and Stein 1999; Zussman 1997). In the USA, with the exception of cancer and HIV trials, the majority of participants in Phase 1 trials are men (women of reproductive age tend to be screened out) who are without medical insurance and either unemployed or underemployed (Fisher 2009: 127). The decision to participate in Phase 1 trials (both bioequivalency and first-in-human trials) in the USA is thus based on access to medical care (offered as an incentive to participation) and income. In Canada, the presence of a publicly funded health care system means that Phase 1 research participants are primarily motivated by income needs. (Graduate students in Canada participate in bioequivalency trials, though not to my knowledge in first-in-human trials, to pay for their education; there are no published studies about this.) Globally participation in Phase 1 trials (other than for cancer and HIV) is associated with poverty (Petryna 2009). Phase 1 research participants are also less likely than people of higher SES to benefit from the pharmaceuticals developed due to their costs (Petryna 2009).

In first-in-human trials, social actors seek livelihood and, in some national contexts, access to medical care. Neither "livelihood" nor "access to medical care" are listed in "The Purposes of Providing Bodily Material/Volunteering in a Trial" (p. 14). Whose perspectives are included and whose excluded when livelihood is not seen as a purpose for participation? From what social position is livelihood a motivation that can be ignored?

Informed consent as a governmental technique assumes that the bioethical subject engages with the consent process. Social actors in first-in-human trials, however, do not appear to do so very often. Jill Fisher's interesting sociological study of clinical trials found that research participants in trials showed a "general lack of interest in consent forms" (Fisher 2009: 171) as they had previously already decided to participate for reasons of access to health care, income and hope for a cure. Fisher (2009: 178) observes that conflict exists "between the regulatory assumption of "autonomous agents" who can make decisions about clinical trials based on information contained in consent forms and the structural conditions that influence people's decision making about their health care options."

More generally I note that the ethical values used for bioethical governance/regulation ("Ethical Values at Stake", p. 16) should not be construed as necessarily motivating the social actor (individual or collective). Transposing the universalistic values of bioethics to the level of the social actor (see discussion of "Altruism," p. 16) misrecognizes the range of motivations and interests actors have. It also conflates the useful Kantian and Hegelian distinction *Moralität* (moral practices undertaken reflexively according to principles that may be generalized without contradiction) and *Sittlichkeit* (the morality of everyday custom).

The well-known descriptive data outlined above is not mentioned in the Consultation Paper, nor is current UK data supplied. Because the bioethical subject has no social characteristics, the complexities of decision-making for the social actor are erased and reduced to the bioethical principle of informed consent. Thus, the Paper neglects to consider what might occur in future if

monetary incentives are lifted, and doesn't adequately deal with decision-making by actors within specific social, economic, and cultural contexts.

3. Commercial Interests: The Clinical Trials Industry

The strong normative bioethical framing of the Consultation Paper also occludes analysis of the economic context in which first-in-human trials take place, although the Glossary does discuss markets in human bodily materials. For the most part first-in-human trials are part of drug development in a global pharmaceutical industry. The Consultation Paper demonstrates little awareness of the commercial interests that motivate clinical trials, other than a contradictory treatment of supply and demand and an essentially ethical conception of commodification. The result is that first-in-human and other clinical trials are understood to be well-run and serve the public good.

a) Supply and demand

Question 14 asks, "Is it right always to meet demand? Are some 'needs' or 'demands' more pressing than others?" The more general question, as posed at the start of the Consultation Paper is "Is there a point at which it must be accepted that supply cannot meet demand?" The wording of this question presumes that supply can meet demand until a particular threshold is reached. The context is therefore one where supply meets demand until a point of exception. I think we need to consider the consequences of reversing this assumption. Let us assume a context where it is recognized that supply will never meet demand, though there may be the exceptional case where they are commensurate. We need to consider the effect this shift would have on the intensity and strategies around efforts to procure human bodies or body parts.

The Consultation Paper leaves unquestioned existing industry demand for the recruitment of research participants. However, many studies have shown that there are systemic problems with the clinical trials industry. Analysts have noted with concern that the number of pharmaceutical innovations (new chemical entities) has decreased significantly since 1961 (Gagnon 2009, Fig. 3.10: 117). More precisely, the global introductions of New Chemical Entities decreased in absolute numbers by more than 50% between 1961-1965 and 2001-2005 (ibid.).[5] This data is deeply troubling in a number of different directions, certainly indicating among other things that most clinical trials result in products of little clinical worth.

I recommend that the Working Party, rather than implicitly endorsing the demand for research subjects in first-in-human trials, question it. Solutions for the sorry state of the global pharmaceutical industry are beyond the terms of reference for the Working Party, but the demand structure of the clinical trials industry might be problematized.

b) The Concept of Commodification

In the Consultation Paper, the discussion of commodification co-occurs with dignity. Commodification is understood in relation to ethics, and presented as corrupting human beings

[5] Independent evaluations of new pharmaceuticals licensed in France argue that few new pharmaceuticals represent significant improvements over what are already available. The French medical journal *Prescrire* has since 1981 performed annual reviews of each new drug that has become available for prescription in France, comparing each drug to the existing pharmacopeia. In 2009 *Prescrire* evaluated the 120 new drugs made available in 2008. Of these, 6 demonstrated some therapeutic advance, 82 brought no advance and 23 were classified as possibly dangerous (*Prescrire* 2009; Gagnon 2009: 118-120).

by relativizing their worth. However, commodification and the buying and selling of bodies/body parts also need to be understood as social and economic relations.

Commodities are conventionally understood as use-values produced for exchange, that is, as products of human labour that are socially recognized to fulfill a human need and made for the purpose of being exchanged. In simple commodity production such as artisanal work, commodities are made by independent producers to be exchanged for other commodities. Simple commodity production continues to exist in our present, but it forms only a small part of a broader economic system in the UK and other G20 countries, which are characterized by generalized commodity production. Generalized commodity production occurs where commodities are used to create other commodities and exchange is monetized. In this extended production of commodities, labour has also become a commodity that can be bought and sold; this is not often regarded as an offence against dignity. Generalized commodity production is an expansionary economic system, creating new markets and transforming non-commodity-economic production into commodity-economic production. The movement of labour and things from non-commodity economic production into commodity-economic relations has radically different implications if the movement is into generalized commodity production rather than simple commodity production (which the anthropologists warn is not at all simple). Speaking about the "commodification of the body" leaves unclear what kind of commodification is meant. Payment for direct donation would be closer to simple commodity exchange – it happens once, and no further production is generated. Payment for donations of cells or tissue from which immortalized cell lines are developed is an example of generalized commodity exchange. HeLa cells, for example, are renewable outside the human body; these cell lines have thus been fully commoditized and entered into a global system of generalized commodity production. Thus, "need" for a "use-value" drives direct and perhaps, indirect one-time donation of a body part. But what is it that drives the circulation of fully commoditized cell-lines? Asking these questions may help the Working Party clarify where the affront to dignity lies.

The Consultation Paper makes a helpful distinction between renewable and non-renewable bodily materials. However, neither renewable nor non-renewal bodily materials are at present commodities that may be produced by means of other commodities; they are not fully commodity-economic in the way that immortalized cell lines are Renewable bodily materials such as blood have been monetized in some jurisdictions and non-monetized in others to varying effects, with debates that are well-known. In the worst cases, donors become sites of simple commodity production for the selling of products to health corporations that re-engineer their tissues for selling on global markets.

In contrast, extending, or in some regions of the world continuing to tolerate, the application of the price mechanism to non-renewable bodily materials and the formation of markets in non-renewable bodily materials clearly jeopardizes the health of the poor in the North and South. Nancy Scheper-Hughes, whose work is cited in the Glossary of the Consultation Paper, has been exemplary in documenting the systemic negative social effects of the organ trade on marginalized peoples (for an overview see Scheper-Hughes 2003). Permitting the monetizing and marketing of dead bodies might provide motivation for homicide or suicide, the latter in the context of providing for family members. Lock and Nguyen (2010: 212) report that in the USA today corpses are worth US $100,000 - $230,000.

From a Canadian perspective the buying and selling of non-renewable bodily materials would amount to an abrogation of federal responsibility in health protection. It might also be a violation of civil liberties under Section 7 of the Canadian Charter of Rights and Freedom, which grants a

"right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice." The argument presented in the Glossary that a monetary incentive "simply extends the range of choices open to the person" (Consultation Paper 2010: 39), if and when applied to the buying and selling of non-renewable bodily materials, raises issues of fundamental justice. In the Canadian jurisdiction it would and should be met with the full force of public and constitutional law. I urge the Working Party to consider calling for inter-state agreements on the buying and selling of non-renewable bodily materials.
Question 15: "Should different forms of incentive, compensation or recognition be used to encourage people to provide different forms of bodily material or to participate in a first-in-human trial?" Answers to this question reveal assumptions around whether supply should meet demand. It is in fact another way of posing the question. Distinctions should be drawn between the provision of incentives and the removal of barriers. Making people aware of options to donate and making it easy (removing the costs of donating) differ greatly from incentives that accrue material benefits to the person donating.
Question 28: "Should companies who benefit commercially from others' willingness to donate human bodily material or volunteer in a trial share the proceeds of those gains in any way? If so, how?" First, the HUGO approach to benefit sharing moves in the right direction, providing no individual compensation but setting aside funds for education, training, and health care. These funds should be administered in an arms-length way, that is, not by the companies themselves. Second, a percentage of profits should be transferred to publicly funded health care for reimbursement of the hospital costs and other care required by those with immediate or long term adverse reactions to living donations and clinical trial research. Third, companies should fund advocacy organizations for those who are or have participated in trials and donated their bodily materials. Again, funding should be arms-length. The US website CenterWatch (http://www.centerwatch.com/) is a helpful, industry-funded source of information, but much more could be done in the way of advocacy.

4. Patient vs. Research Subject

The distinction between the patient and the research subject is elided at a number of points in the Consultation Paper. This elision is one of the dangers of putting treatment and research in the same analytic plane: "In this consultation we are interesting in exploring whether meaningful parallels can be drawn between those who provide bodily material for medical treatment and research, and those who provide their bodies on a temporary basis for experimentation with no expectation of personal health benefit" (p. 13).

Throughout the Consultation Paper the discussion of bodily material is considered in relation to donation, that is, to giving. It is not considered in relation to receiving. By being taken out of the context of clinical treatment (e.g. transplant surgery, plasma transfusions, skin grafts), providing bodily material is brought closer to volunteering for a clinical trial. In this way the very different purposes of trials and treatment disappear from view.

One of the fundamental contributions of bioethics, the patient-research subject distinction, is currently under stress (Mykhalovskiy and Weir 2004) in a number of different ways. People volunteer for Phase 1 trials in order to obtain access to health care; they gain access to the status of patient by becoming research subjects. In Phase 2 and 3 trials diseased subjects may also enroll to get access to promising investigational products being tested in the trials. The line between patient and research subject is blurred under these conditions. The growth in the number

of physicians trained in evidence-based medicine brings doctors into practice who are skilled in evaluating trials and moving research-based knowledge into patient care. Clinical care and research medicine grow closer in many directions.

The bulleted points listed under the heading "Purposes of providing bodily material/volunteering in a trial", cross-cut donations of bodily materials for clinical care and the use of the body in first-in-human trials. Now first-in-human trials test for toxicity; from the perspective of their research participants their purpose is not immediately life-saving, life-prolonging, life-enhancing nor life-creating.

The Consultation Paper (p. 20) lists a number of approaches to increasing the supply of bodily material, one of them being, "Improved systems to make it easier for researchers to access blood or tissue samples 'left-over' after diagnostic procedures or treatment." The Paper does not explicitly ask if this practice would be acceptable. This would, however, be problematic as there is a need to separate materials related to treatment and research, for otherwise research may drive treatment needs. A clear demarcation between treatment and research would need to be clarified.

Question 23: "Are there circumstances in which it is ethically acceptable to use human bodily material for additional purposes for which explicit consent was not given?" This question may be interpreted to include transfers of material from clinical to research uses. Allowing a research ethics board to give approval for the use of material for which consent has not been given effectively nullifies the point of consent. If a researcher cannot determine who the tissue came from then the procedure of tissue tracing and identification needs to be addressed rather than negating the lack of clarity around consent.

The distinction between patient and research subject falls on the line between treatment and research. Patients want to be restored to a state of health so that they can get on with their lives. The clinician has a duty to treat the patient in care with the best available methods so that s/he may become well. Research has another goal: to evaluate an intervention. The intervention chosen and the dosage given are determined by the study protocol, not the patient's clinical needs. In placebo-controlled trials, research subjects may be given a dose with no known benefit. When a trial ends, its research subjects will be let go, whilst a patient will remain in treatment until his/her health has been restored or optimized under the current standard of care. Referring patients to trials when there is a treatment likely to benefit them is considered a violation of the ethics of research. There is much at stake in the distinction between treatment and research.

Aggregating treatment with research would appear to be done with the intent of streamlining regulation. Differing types of donation and all bodily materials are added to the streamlining endeavour. This proposes a novel space of abstract, fungible relations between social actors and their body parts. The relation between this proposed space of fungible bodies and the bodies of social actors characterized by personhood and social memberships requires the strictest demarcation. The inattentiveness of the Consultation Paper to the ethical stakes in the demarcation between patient and research subject is very worrisome.

Conclusion

In these comments I have tried to persuade the Working Party that its turn to normative bioethics has marginalized any consideration of the S in its ELSI mandate. I have also attempted to make a case for the significance of incorporating social thinking in its future report. The effects of an almost exclusively meta-ethical framing on the Consultation Paper led to many consequential erasures. These include the displacement of the social actor by the biological subject, the

disappearance of decision-making by the social actor, the failure to acknowledge the economics of the clinical trial industry, and the placing of an invisibility cloak around harm to cultural practices, social relations and institutions. This is a lot to ignore. I have tried to sketch how these disappearances were accomplished and some of their problematic consequences.
If the Working Party is to devise good governance proposals it must find ways of creating collaboration across the differing disciplines within its ELSI mandate. What has occurred in the Consultation Paper is an intellectual coup by normative bioethics. I would encourage a new balance be struck.

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