Abstracts of Note: The Bioethics Literature

This section is meant to be a mutual effort. If you find an article you think should be abstracted in this section, do not be bashful—submit it for consideration to feature editor Kenneth V. Iserson care of *CQ*. If you do not like the editorial comments, this will give you an opportunity to respond in the letters section. Your input is desired and anticipated.

Chen DT, Meschia JF, Brott TG, Brown RD, Worrall BB. Stroke genetic research in adults with impaired decision-making capacity: A survey of IRB and investigator practices. *Stroke* 2008;39(10):2732–5.

Impaired decisionmaking capacity is common in individuals with stroke and other severe brain disorders, such as Alzheimer's disease. The severity of the neurologic problem is believed to be, at least partially, under genomic control. Including such individuals in genetic risk studies is important if they are to be scientifically valid. Federal regulations do not address enrolling adults with impaired capacity in genetic research. This study surveyed sites in 2003 and 2007 that are participating in an ongoing North American study investigating genetic risks for stroke. One hundred percent (49/49 centers) in 2003 responded to the survey; in 2007, 91% (40/53 centers) responded. The study looks at sibling pairs. If an individual is affected by stroke, letters are sent to siblings inviting participation, and a blood sample is obtained. In 2003 institutional review boards (IRBs) at 40% of sites did not permit use of surrogate authorization; 35% did not in 2007. Eighty-two percent of centers did not enroll individuals lacking capacity in 2003 and 85% did not enroll them in 2007. The study indicates that even where surrogate enrollment is allowed, it is not used frequently. It is unclear whether researchers avoid approaching individuals who cannot give consent, surrogates refuse study participation, or there is some other reason. Research advance directives and awaiting return of decisionmaking ability are other possibilities. However, research advance directives are not practical for situations in which there is a sudden incident, such as a stroke or a traumatic brain injury. Awaiting return of decisionmaking ability is often not practical because of a high fatality rate. Federal regulations do address surrogate enrollment in research with minimal risk to children, but the regulations are silent with respect to adults. *The absence of clear guidelines and regulations for enrolling adults with impaired decisionmaking capacity in genetic studies has significant implications for the scientific validity of genomic research.*

Dhir R, Patel AA, Winters S, Bisceglia M, Swanson D, Aamodt R, Becich MJ. A multidisciplinary approach to honest broker services for tissue banks and clinical data: A pragmatic and practical model. *Cancer* 2008;113(7):1705–15.

These authors describe the development of a novel IRB-approved process that allows efficient acquisition of specimens and clinical data for researchers. An Honest Broker facility was implemented at the University of Pittsburgh in 2003 and is being increasingly utilized by researchers, with a 25% increase in the numbers of requests each year since its implementation. Patient confidentiality and privacy issues, both ethical and legal, create a bottleneck as researchers try to access data and tissue specimens from the Tissue Bank and Cancer Registry. One approach to solving this dilemma is to remove all personal identifiers from the tissue specimens or the data before they are given to researchers. Although that may be sufficient for some studies, being able to follow the progress of particular patients over time is required in other studies. The Honest Broker system was created to provide another approach beyond simply making data or tissue specimens anonymous. The Honest Broker facility trains individuals in ethics and confidentiality issues to work as honest brokers. They are not connected to either the clinical work that is being done or the research that is being undertaken. The other element developed for the facility was a computerized database system that allows requests for tracking and retrieval of the

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desired information. *The Honest Broker facility removes personal identifying information from tissue specimens or clinical data but attaches an Honest Broker identifying tag to the information so that further requests for information about specific patients over time can be provided by the honest broker utilizing their identification tag.* The researchers are thus completely unaware of specific people that the tissues or clinical data are attached to but they can still receive additional information about them through the Honest Broker. This approach has worked successfully at the University of Pittsburgh, has met all prevailing federal and state laws, and has passed review by the IRB.

Ehrich K, Williams C, Farsides B. The embryo as moral work object: PGD/IVF staff views and experiences. *Sociology of Health and Illness* 2008;30(5):772–87.

A ''hot-button'' issue—politically, legally, and ethically—revolves around the use of embryos for research. In 1990, after contentious debate, the United Kingdom established that pre-14-day embryos lack distinct individual moral status. In 2001, the Human Fertilization and Embryology Regulations Act permitted the destruction and disposal of pre-14-day embryos. Recent review accepted the law as settled, discouraging further public debate.

This study examined the perception of U.K. staff working with embryos in the field of preimplantation genetic diagnosis (PGD) and in vitro fertilization (IVF). The authors found ambivalence and uncertainty among professionals working in this field despite it being lawful. They then discuss how these complex attitudes and feelings among a range of professionals can be resolved in support of meeting their common objectives.

The authors conceptualize pre-14-day embryos as ''moral work objects'' around which workers in this field create meaning and purpose in activities that remain morally contested among the broader public. The treatment goal of PGD is to produce healthy babies. This requires discarding embryos that are not suitable for transfer to the woman's womb for implantation. Couples at risk for having a child with a serious genetic condition can be offered PGD. IVF is used to create embryos in a laboratory, which can be tested for genetic disorders and then transferred to the woman where successful implantation may take place. PDG embryos affected by genetic disease may be donated for research or discarded.

The authors conducted 26 staff interviews and five ethics discussion groups at one PGD/IVF site between May and December of 2005. The interviews were structured as ''guided conversations'' lasting between 1 and 2 hours. The interviews were followed later by the ethics discussion groups. Topics for the ethics discussion groups came from an analysis of the 26 staff interviews and from asking participants during the individual interviews what issues they felt were important. *This process showed that staff had a variety of attitudes toward the pre-14-day embryos, which ranged from viewing them as ''babies'' to a ''bunch of cells.'' Staff who viewed the pre-14-day embryos as ''babies'' described mixed feelings about the fate of embryos; those who saw them as a ''bunch of cells'' did not grant any human status to them and were consequently untroubled by discarding the embryos.* There was a wide range of views found among the staff regarding their work with the pre-14-day embryos. Staff persisted in their work because the aims of their work led to the greater good of ''healthy babies'' despite ambivalence regarding disposal of pre-14-day embryos that could not be used.

Hunt LM, Megyesi MS. Genes, race and research ethics: Who's minding the store? *Journal of Medical Ethics* 2008;34:495–500.

The United States requires that minorities be included in federally funded biomedical studies to assure that all individuals benefit from medical research irrespective of their racial identity. To monitor this, the National Institutes of Health follow a convenient course of using the racial or ethnic categories used by the U.S. Census Bureau. Despite their broad use, these categories were never intended to serve as scientific variables. Rather, they were meant to serve only as bureaucratic and political measures. Medical and genetic professionals have argued that these race and ethnicity classifications are primarily cultural rather than biological and do not correspond to genetic variation. In fact, only a very small percentage of genetic variation can be accounted for by racial classifications. Further, pursuing genetic causes of racial and ethnic health disparities directs resources away from further studying the social and

environmental causes that are already known to account for much of the variability in chronic disease distribution.

These authors, using a standardized set of open-ended questions, interviewed the principal investigators for 30 human genetics studies. They found that Census Bureau racial and ethnic labels were key variables in this research, although all the researchers believed that these variables are inadequate and that race is not a scientifically valid variable. Despite this, those interviewed defended their use of these labels as an intermediate utilitarian step toward understanding actual underlying biological differences. They argued that, if a particular gene was found for hypertension in one racial group, then later researchers could look at all the different population groups to determine who has the gene and who may require a particular medication or intervention. Thus, they claim, when an actual biological cause is found, race and ethnicity disappear as a confounding factor.

The researchers acknowledge that race or ethnicity is a proxy variable for a wide array of crucial environmental factors, such as access to healthcare, socioeconomic status, diet, and education. These elements may affect how genes influence racial or ethnic disease distribution. Yet some of those interviewed noted that those misunderstanding their research might interpret it as saying that some racial or ethnic groups are genetically inferior. Such misunderstandings could lead to discrimination, difficulty obtaining employment, or even open the door to eugenic practices.

Many of the interviewed researchers defended the status quo, feeling that changes are unnecessary and that researchers' good intentions and nondiscrimination policies are adequate to protect studied populations. Their belief is that any problems with misinterpretation can be addressed through community education, although they are unclear as to what education would be effective. Two minority researchers who were interviewed acknowledged not only that there are problems with using the racial/ethnic variables, but also that scientists must have a better understanding of the potential social implications of their studies. *This study's authors argue that it is imperative that more effective strategies be developed to address the use and scientific validity of racial and ethnic variables in human genetics research.*

These Abstracts of Note were compiled by Barry Morenz.