16452	05/12/2009 at 01:18:17 PM	Self			COMMENT: DRAFT NIH GUIDELINES FOR HUMAN STEM CELL RESEARCH Information as well as provisions concerning induced pluripotent stem (iPS) cells and their direct cloning potential must be added to paragraphs on Informed Consent and on Ineligible Research In the draft NIH Guidelines for Human Stem Cell Research, the paragraphs dealing with Informed Consent (i.e. section IIB7) must be amended to include induced pluripotent stem (iPS) cells, in addition to embryonic stem (ES) cells. This is necessary because the induction of pluripotency in cells creates severe ethical problems connected with the gain of developmental potential. Specifically, it has been shown experimentally that viable individuals can be cloned not only from ES but also from iPS cells using the direct cloning procedure of tetraploid complementation (TC) (1). This is a peculiar property of pluripotent cells (ES and iPS cells), not shared by any somatic cells like fibroblasts. Long term in-vitro propagation, storage and a possible worldwide spread of cells with this potential, carrying the donor's individual genome, open aspects that may be of considerable concern for the donors, e.g. including questions of personality rights, legal aspects (inheritance) etc. The fact that (reproductive) cloning is presently banned at least in Western World countries does not argue against the necessity to provide this information to cell donors, since direct cloning by TC can be performed even after long term storage of cells, and cell use will be difficult to control after banking and eventual world-wide spread including countries with differing ethical standards. Even today legal norms differ already considerably between countries; moreover, ethical standards are also known to change over time. Whereas direct reproductive cloning (by TC) from iPS and ES cells has so far only been reported to be effective in the mouse, experts have no doubt that it can also be successful in the human if ever attempted. The scientific basis and the ethical implications have been discussed in various publications (2, 3). One aspect where these implications become legally relevant is patentability (4), but other legal aspects (inheritance, problems of person identification by DNA technology for example in case of crime) may also be of concern since it will remain difficult to permanently and securely exclude any cloning risk with these peculiar cells. For NIH funding, it should be of interest to note that prospects how this dilemma can possibly be dealt with technically during iPS cell derivation are recently being discussed (including a change of research focus which in this context should be on genes involved in pattern formation during mammalian embryogenesis) (5, 6). SPECIFIC SUGGESTIONS: In paragraphs IIB7 # e and # h (Informed Consent)of the present Draft Guidelines, appropriate wording referring to the cloning aspects just mentioned should be added, in particular with respect to iPS cells. In section III (Ineligible Research) a new point C referring to the same aspects with appropriate wording should be added. REFERENCES: (1) Wernig, M.; Meisner, A.; Foreman, R.; Brambrink, T.; Ku, M.; Hochedlinger, K.; Bernstein, B.E.; Jaenisch, R.: In vitro reprogramming of fibroblasts into a pluripotent ES-like state. Nature 448: 318-324 (2007). (2) Denker, H.-W.: Early human development: New data raise important embryological and ethical questions relevant for stem cell research. Naturwissenschaften 91: 1-21 (2004). (3) Denker , H.-W.: Potentiality of embryonic stem cells: an ethical problem even with alternative stem cell sources. J. Med. Ethics 32: 665-671

					(2006). (4) Denker, H.-W.: Totipotency/pluripotency and patentability. Stem Cells 26: 1656-1657 (2008). (5) Denker, H.-W.: Human embryonic stem cells: The real challenge for research as well as for bioethics is still ahead of us. Cells Tissues Organs 187: 250-256 (2008). (6) Denker, H.-W.: Induced pluripotent stem cells: How to deal with the developmental potential. Reproductive BioMedicine Online 19 Suppl. 1: 34-37 (2009). **********, MD PhD Professor (em.) of Anatomy and Developmental Biology University ********** **********

Listing of Comments on Draft NIH Human Stem Cell Guidelines

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On April 23, 2009, the National Institutes of Health (NIH) published draft stem cell guidelines for public comment in the Federal Register. The purpose of these guidelines are to implement President Barack Obama's Executive Order 13505 "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells," which was issued on March 9, 2009.

NIH received 49,015 comments by May 26, 2009, the closing date of the comment period, and have compiled these comments on this website. Any comments received via email or mail after the May 26 deadline are not included on this website. In reviewing the comments, NIH determined that 60 comments were inappropriate (i.e., contained SPAM responses or offensive language), and these comments have been excluded from this website. In addition, to protect the identities and personal information of individuals who submitted comments, NIH has removed personally identifiable information from the comments on this website even though individuals consented that the information provided could be made available for public review and posting.