Françoise Baylis, Professor and Canada Research Chair www.noveltechethics.ca
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Inclusion of pregnant women:

It is widely recognized that pregnancy is a near-automatic exclusion criterion for research participation, "regardless of the costs of exclusion or the magnitude or likelihood of the risks of participation."[1]

The near complete exclusion of pregnant women from research on drugs and biologics means that there is little clinical trial data on the basis of which health care providers can make treatment recommendations for pregnant women.[2] This includes women with underlying health conditions who become pregnant, and healthy pregnant women who become sick.

There are several reasons to pursue research involving pregnant women. These include[1,3]:

- Developing effective treatments for pregnant women
- Promoting fetal safety (avoiding clinical use of drugs and biologics that are harmful to the fetus)
- Reducing harm from the reticence to prescribe potentially beneficial drugs and biologics (suboptimal care)
- Allowing access to benefits of research participation

Justice requires that if pregnant women are going to use drugs and biologics to manage their health, then we need to study these drugs and biologics in that population. More generally, we need to learn to make reasoned decisions about risk in pregnancy (which may include taking responsible and calculated risks), both with respect to pregnant women and developing fetuses. We also need to recognize that there are responsible ways in which to manage risk.

Mandatory contraception:

It is common practice in Canada and elsewhere for researchers to mandate the use of contraception by women of childbearing potential while enrolled in clinical trials. This practice

[1] Anne Drapkin Lyerly, Margaret Olivia Little, and Ruth R. Faden, "The Second Wave: Toward Responsible Inclusion of Pregnant Women in Research," *Int J Fem Approaches Bioeth* 1, no. 2 (2008): 5-22, at 6.
[2] Anne Drapkin Lyerly, Lisa H. Mitchell, Elizabeth Mitchell Armstrong, Lisa H. Harris, Rebecca Kukla, Miriam Kupperman, and Margaret Olivia Little, "Risk and the Pregnant Body" *Hastings Center Report* 39 no. 6 (2009): 34-42
[3] Anne Drapkin Lyerly, Margaret Olivia Little, and Ruth R. Faden, "Pregnancy and Clinical Research," *Hastings Center Report* 38, no. 6 (2008) inside back cover

is deeply problematic for several reasons. Consider, for example, women who are not sexually active (e.g., nuns), are not sexually active in a heterosexual relationship (e.g., lesbians), or are sexually active in a heterosexual relationship with a male partner who has had a successful vasectomy. Why should they be required to use contraceptives? Or, consider women who have had a hysterectomy or a successful tubal ligation, women with certain types of infertility, or women with male partners who have certain types of infertility. Requiring these women to use birth control as a condition of research participation is offensive and should not be permitted under any circumstances.

Current practice with respect to mandatory contraception is also often discriminatory in its exclusive application to women. There is no ethical justification for the blanket requirement of contraceptive use only by women of childbearing potential. If the worry is the risk of fetal harm, then it is important to recognize potential male contributions to this harm.

REFERENCES

Baylis, F., & Halperin, S. 2012. Research involving pregnant women: Trials and tribulations. *Clinical Investigation* 2(2), 139-146. DOI: 10.4155/CLI.11.183.

Baylis, F. & Kaposy, C. 2011. Ideal ethical standards for contraceptive use in research. [Letter to the Editor] *IRB: Ethics & Human Research,* 33(2), 19-20.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. 2010. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.* Available at: www.pre.ethics.gc.ca.

Health Canada Guidance Document "Considerations for inclusion of women in clinical trials and analysis of data by sex." DRAFT January 9, 2012.

Kaposy, C. & Baylis, F. 2011. The Common Rule, pregnant women, and research: No need to "rescue" that which should be revised. *American Journal of Bioethics* 11(5): 60-62.

Kaposy, C. & Baylis, F. 2010. Ethical evidence-based guidelines for contraceptive use in research. *IRB: Ethics & Human Research* 32(5), 1-9.

Baylis, F. & Kaposy, C. 2010. Wanted: Inclusive guidelines for research involving pregnant women. *Journal of Obstetrics and Gynaecology Canada*. 32(5), 473-476.

Baylis, F. 2010. Pregnant women deserve better. *Nature* 465, 689-690.

Baylis, F. 2010, January 15. An unnecessary risk. *The Mark News*. http://themarknews.com/articles/830-an-unnecessary-risk