



advocates for
informed choice

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Jerry Menikoff, Director
Office for Human Research Protections
1101 Wootton Parkway
Suite 200
Rockville, MD 20852

Dear Mr. Menikoff:

I am the Executive Director of Advocates for Informed Choice (AIC), a non-profit organization that advocates for the legal and human rights of children born with disorders of sex development (DSD) and their families. I write to express AIC's grave concern over possible non-IRB-approved clinical research on children that has been reportedly conducted under the auspices of New York-Presbyterian Hospital and Weill Cornell Medical Center of Cornell University (WCMC), under the direction of Dr. Dix P. Poppas. I am referring to the questionable follow-up tests used by Dr. Poppas for assessing clitoral sensitivity in the young girls who received "nerve sparing ventral clitoroplasty" operations under his care. On behalf of the children and families who form AIC's constituency, young girls who are now being urged to undergo these non-standard follow up examinations, and the American public generally, AIC requests a prompt investigation into this matter to ensure that these children are not being subject to ethically problematic or explicitly prohibited practices.

The follow-up tests employed by Dr. Poppas are unorthodox and may expose the patients to significant risk of psychological harm.

In a published paper, Dr. Poppas reports employing an unorthodox technique of applying medical vibratory devices to the genitals of girls and young women ages 5 to 24 years old to collect data on post-operative clitoral sensitivity.¹ Poppas' 2007 paper in the *Journal of Urology* details the procedure of stimulating the girls' clitorises with "medical vibratory devices" while the girls are conscious. More specifically, the girls are subjected to annual visits in which Poppas touches their surgically modified clitorises with a cotton-tip applicator and/or with a "vibratory device," and asks them to rate the sensation they feel on a scale of 1 to 5. Using the vibrator, he touches on their inner thighs, labia minora, and the introitus of their vaginas. My colleagues and I are unaware of any other clinician using this technique. Further, Poppas also reports performing "capillary perfusion testing," a technique in which the physician presses a finger nail on the girl's clitoris to observe blood flow as a sign of healthy tissue. Dr. Ken Zucker, Psychologist-in-Chief and Head of the Gender Identity Service in the Child, Youth, and

¹ Yang J, and Poppas D. Nerve Sparing Ventral Clitoroplasty: Analysis of Clitoral Sensitivity and Viability. *Journal of Urology*, Vol. 178, 1598-1601, October 2007.

Family Program at Toronto's Centre for Addiction and Mental Health and Professor with the Departments of Psychiatry and Psychology at the University of Toronto, has publicly responded to this report by stating, "Applying a vibrator to a six-year-old girl's surgically feminized clitoris is developmentally inappropriate."² Given the well-documented psychological harm that can come to girls with DSD as a result of excessive visual genital exams,³ it seems likely that Poppas's far more invasive tests pose substantial risk of psychological harm to young girls.

Dr. Poppas's follow-up tests may constitute research involving human subjects as defined in 45 CFR 46.102, without the protections for human subjects outlined in Subpart A of 45 CFR 46, or the additional protections for children outlined in Subpart D of that section.

While Poppas' clitoroplasty operations themselves may not constitute research, the "clitoral sensitivity" and "vibratory sensitivity" tests he performs on conscious girls as young as age six are conducted with the purpose of generating data for his published research papers and demonstrating the success of his techniques for parents of prospective future patients. This would appear to constitute "research" with human subjects under the definition in 45 CFR 46.102(d), because there is an intention to develop or contribute to generalizable knowledge. While Poppas reports IRB approval for retrospective chart review, he does not report IRB approval for the postoperative "sensory testing."⁴ IRB approval is mandated when doctors are conducting medical tests for research purposes, regardless of whether there is also a treatment purpose, in order to protect the rights of their human subjects.⁵ As evidenced by his own words, Poppas is continuing ongoing annual "long-term follow up...to document long-term sexual function using this nerve sparing ventral approach for clitoroplasty," making clear that the tests are an ongoing effort to chart data and produce generalizable knowledge. Thus, IRB oversight and special protections for vulnerable human subjects are required by law.

Even if Dr. Poppas' post-operative exams received IRB approval, the IRB's reasoning merits review.

If an IRB did, in fact, approve the clitoral sensory testing techniques used on girls as described in Poppas' study, the IRB's reasoning merits review. How could it justify such a procedure in the face of such great potential psychological harm to the patient? Poppas' follow up exams do not seem to offer benefit to the patient. If the girls' clitoral

² Dreger A, and Feder EK. "Bad Vibrations." Bioethics Forum, June 16, 2010. Available at <http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4730&blogid=140>.

³ Lee, P.A., Houk, C., Ahmed, S.F., et al. Consensus Statement on Management of Intersex Disorders. *Archives of Disease in Childhood*. 2006;91;554-63.

⁴ Yang J, and Poppas D. Nerve Sparing Ventral Clitoroplasty: Analysis of Clitoral Sensitivity and Viability. *Journal of Urology*, Vol. 178, 1598-1601, October 2007.

⁵ See Office of Human Research Protections, "OHRP Research Involving Children Frequently Asked Questions." Available at <http://www.hhs.gov/ohrp/researchfaq.html#q17>.

function was damaged by the surgical procedures, which are themselves highly controversial, there is no way to restore that function. (Indeed, it is not clear that the patients stood to benefit from either treatment or follow-up, since a larger-than-average clitoris presents no documented risk of harm.) Were the girls' rights to assent, or to withhold assent, fully ensured? Were the parents informed of the risk of psychological harm? It is hard to imagine children or their parents agreeing to such a study if they were fully informed of the risks, the lack of prospective benefit, and the option to decline.

Even if no legal violation has technically occurred, the practice of both “clitoral sensory testing” and cosmetic genital surgery without IRB approval raises significant ethical concerns and threatens to further erode public trust in research.

WCMC's characterizations of Poppas's surgical procedure as a safe and effective, standard-of-care treatment may have misled some parents to believe the follow up examinations to be standard in the field, when they are not. Parents who have been encouraged to subject their young daughters to these tests may not have been provided fully informed consent as would happen formally under an IRB-approved protocol. The WCMC website claims that “Our approach to the clitoroplasty leaves the patient with intact clitoral sensation, painless sexual arousal, a viable and sensate glans clitoris and appropriate erectile function during sexual arousal.”⁶ Readers are not informed that there is no evidence that having a big clitoris puts a girl at psychological risk. WCMC's website makes no mention of the risks of nerve damage, incontinence, urinary tract infections, inability to experience orgasm, or many other problems associated with genital surgery and the follow up exams receive no mention. The fact that WCMC makes such unsubstantiated public claims without qualification leaves us concerned about what parents are told privately about both the risks of surgical treatment and of their child's participation in research.

The surge of public outrage that has arisen since reports of Poppas's techniques became widely known demonstrates the potential for erosion of public trust in research.⁷ AIC believes that transparency and oversight are critical when an institution undertakes ethically controversial treatment, particularly when such treatment is related to research involving vulnerable human subjects. The public has a right to know what institutional controls and informed consent processes are protecting human subjects. The public also needs to know that we can count on federal agencies to vigorously enforce the laws protecting vulnerable subjects. To do otherwise risks ethical catastrophe and the further erosion of public trust in medical research.

⁶ Weill Cornell Medical College, Department of Urology. “The Surgical Management of Congenital Adrenal Hyperplasia.” Available at <http://www.cornellurology.com/pediatrics/genitoplasty.shtml>.

⁷ See e.g., Public Comments, Dreger A, and Feder EK. “Bad Vibrations.” Bioethics Forum, June 16, 2010. Available at <http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4730&blogid=140>; Savage D. “Female Genital Mutilation at Cornell University.” Slog, June 16, 2010. Available at <http://slog.thestranger.com/slog/archives/2010/06/16/female-genital-mutilation-at-cornell-university>; Mair L. “The Most Disturbing Thing You'll Read All Day.” <http://www.lizmair.com/blog.php?Index=615>.

Conclusion

AIC calls for rigorous investigation by the OHRP into possible regulatory violations in this matter. We also believe that children who have been involved in research without the protection of IRBs should now be advised of the information that may not have been made available to them at the time of testing, and that their parents should be given the most recent information from studies indicating the potential long-term risks of both cosmetic genital surgery and excessive genital examination in children with DSD.

By way of background, you may be aware that we earlier sent you our concerns about another matter involving a related population at WCMC and NYPH, namely the prenatal administration of dexamethasone on women suspected of carrying a child with congenital adrenal hyperplasia (CAH). We became aware of Dr. Poppas's practices through our research into prenatal dexamethasone, and felt we must alert you to this issue as well, as we have failed to obtain any response ourselves from WCMC about the prenatal dexamethasone experiments.

Sincerely

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