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May 23, 2013

John Prout, CEO
Donna Nienaber, J.D., General Counsel
TriHealth-Good Samaritan Hospital
619 Oak Street
Cincinnati, OH 45206

Most Rev. Dennis M. Schnurr
Archbishop of Cincinnati
100 East Eighth Street
Cincinnati, OH 45202

Dear Mr. Prout, Ms. Nienaber, and Archbishop Schnurr:

We, the undersigned, along with our respective human rights organizations, wish to draw your attention to a problematic study currently being conducted at TriHealth Good Samaritan Hospital in Cincinnati. This study, entitled, *Gomco Versus Mogen: Which is Best? A Randomized Controlled Trial (GMRT)*[1], is currently enrolling newborn infants at TriHealth's Good Samaritan Hospital, in Cincinnati, Ohio, under the guidance of principal researcher Mounira A. Habli, MD, along with Michaela Eschenbacher, and Rachel Sinkey. The stated purpose of the study is to determine babies' pain levels and bleeding resulting from circumcision with each of two respective circumcision clamps, with a hypothesis that one clamp causes less pain and bleeding than the other.

We believe that this study inflicts unnecessary pain and suffering upon infants, violates both the spirit and the letter of widely accepted bioethical principles and international human rights law, and thus exposes the researchers and Good Samaritan Hospital to professional and public sanction as well as potential legal liability. Further, the study, which is taking place within a Catholic hospital, also violates Catholic doctrine and is inconsistent with TriHealth's own *Code of Ethical Business and Professional Behavior*.[2] We demand that the study be discontinued immediately.

I

The study, "Gomco Versus Mogen: Which is Best?", violates fundamental bioethics, as elucidated in the *Nuremberg Code* (1947), the *Declaration of Helsinki* (1964), the *European Convention on Human Rights and Biomedicine* (1997), and other international treaties, all of which forbid experimentation upon subjects who cannot consent. Infants are an especially vulnerable class. Calling these children 'participants' or 'volunteers,' as the TriHealth-Good Samaritan study does, is disturbingly cynical and dishonest. This study violates principles 1, 4, 6, and 10 of the ten principles of the *Nuremberg*

[1] Responsible Party: TriHealth, Inc., Good Samaritan Hospital, ClinicalTrials.gov, Identifier: NCT01726036; Other Study ID Numbers: H-11121. Contact: Michaela Eschenbacher, MPH; Principal Investigator: Mounira Habli, MD.

[2] TriHealth's Code of Ethical Business and Professional Behavior. Available at: http://www.trihealth.com/discover-trihealth/about-us/code-of-ethics/Code-of-Ethical-Business-Behavior-2012.aspx

Code[3] (developed after the medical abuses of WWII), in particular, the fundamental First Principle, which states:

> "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."

Principles 4, 6, and 10 state, respectively, that "the experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury," that "the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment," and that, "during the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe…that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject."

The *Declaration of Helsinki* reasserts the reasoning of *Nuremberg*. It was adopted by the World Medical Assembly in 1964, and has been amended numerous times since, most recently at Seoul in 2008.[4] The Cincinnati study clearly violates Principle Nine of the *Declaration of Helsinki*, which states:

> "Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence."

In addition, the study violates Federal Regulations that are in place to implement the *Declaration of Helsinki* in that the risk to a child enrolled in a medical study/experiment should be not greater than the risks he would encounter in everyday life.[5]

Further, the ***European Convention on Human Rights and Biomedicine* (1997),**[6] has stated without equivocation:

> "Article 5 – General rule – An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.
> Article 20 – Protection of persons not able to consent to organ removal:
> (1) No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5."

II

The researchers in this study of circumcision clamps will no doubt claim that they have "proxy" or "surrogate" consent – the consent of the parents of the newborn infant subjects. However, proxy consent is only valid for intervention or treatment needed to save the life or health of a person who cannot himself or herself consent to such intervention; proxy consent is *not* valid for non-

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[3] *Permissible Medical Experiments.* Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10: Nuremberg October 1946–April 1949. Washington: U.S. Government Printing Office (n.d.), vol. 2, pp. 181-182.

[4] World Medical Association, Declaration of Helsinki (1964). Available at http://www.wma.net/en/30publications/10policies/b3/. Accessed May 20, 2013.

[5] Department of Health and Human Services, 2. Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects, 45 C.F.R. §46.

[6] European Convention on Human Rights and Biomedicine (1997). Adopted at Oviedo, 4 April 1997. Available at http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm. Accessed May 20, 2013.

therapeutic interventions. The Bioethics Committee of the American Academy of Pediatrics has provided the following guidance to practitioners[7]:

> "...[P]roviders have legal and ethical duties to their child patients to render competent medical care based on what the patient needs, not what someone else expresses. The pediatrician's responsibilities to his or her patient exist independent of parental desires or surrogate consent."

III

No individual child-patient may be denied well-known standards of comfort and safety, even to establish useful protocols—and even when the procedure is necessary. Every patient is entitled by widely recognized ethical and legal principles to be subjected only to those procedures that are therapeutically necessary and demonstrably beneficial, including all the pain relief that medical science is able to provide, for those events which are proven necessary.[8] In the study at issue here, the circumcision of healthy, normal infants does not qualify as an exception.

IV

The study being conducted will provide no information of value, even if the information were obtained ethically. Numerous studies have examined infant pain inflicted by circumcision,[9] [10] [11] [12] [13] and have found the procedure to be painful and the effects of the pain to be long-lasting. Furthermore, babies are known to have died from blood loss following circumcision, including a recent case from Sacramento, California, and a 2009 case from South Dakota.[14] Additionally, we find this study's hypothesis – that the Mogen clamp is superior to the Gomco clamp – to be suspect, given that the best (indeed, the only) way to avoid circumcision-related pain and bleeding is to avoid this unnecessary surgery altogether. [15] [16] [17] [18] [19]

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[7] American Academy of Pediatrics Committee on Bioethics. *Informed consent, parental permission, and assent in pediatric practice*. 95 Pediatrics 314-7 (1995). Available at: http://www.cirp.org/library/ethics/AAP/ Accessed February 10, 2007.

[8] Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 7th ed. New York: Oxford University Press; 2012. 480 p.

[9] Kirya C, Werthman Jr. MW. Neonatal circumcision and penile dorsal nerve block—a painless procedure. *J Pediatr* 1978:92(6):998-1000.

[10] Benini F, Johnson C, Faucher D, *et al.* Topical anesthesia during circumcision in newborn infants. *JAMA* 1993;270(7):850-3. Available at http://jama.jamanetwork.com/article.aspx?articleid=407985. Accessed May 20, 2013.

[11] Lander J, Brady-Freyer B, Metcalfe JB, *et al.* Comparison of ring block, dorsal penile nerve block, and topical anesthesia for neonatal circumcision. *JAMA* 1997; 278:2158-62. Available at http://jama.jamanetwork.com/article.aspx?articleid=419531. Accessed May 20, 2013.

[12] Kurtis PS, DeSilva HN, Bernstein BA, Malakh L, *et al.* A comparison of the Mogen and Gomco clamps in combination with dorsal penile nerve block in minimizing the pain of neonatal circumcision. *Pediatrics.* 1999 Feb;103(2):E23 doi: 10.1542/peds.103.2.e23 Available at http://pediatrics.aappublications.org/content/103/2/e23.long. Accessed May 19, 2013.

[13] Taddio A, Pollock N, Gilbert-MacLeod C, *et al.* Combined analgesia and local anesthesia to minimize pain during circumcision. *Arch Pediatr Adolesc Med* 2000;154(6):620-3. Available at http://archpedi.jamanetwork.com/article.aspx?articleid=349706. Accessed May 20, 2013.

[14] https://www.indianz.com/News/2011/001573.asp

[15] Machmouchi M, Alkhotani A. Is neonatal circumcision judicious? *Eur J Pediatr Surg.* 2007 Aug;17(4):266-9.

[16] Kaweblum YA, Press S, Kogan M, Levine M, Kaweblum M. Circumcision Using the Mogen Clamp. *Clinical Pediatrics*. 1984;*23*(12):679-682.

[17] Kaufman GE, Cimo S, Miller LW, et al. An evaluation of the effects of sucrose on neonatal pain with 2 commonly used circumcision methods. Am J Obstet Gynecol. 2002;186:564–568.

[18] Taeusch HW, Martinez AM, Partridge JC, et al. Pain during Mogen or PlastiBell circumcision. J Perinatol. 2002;22:214–218.

It is unconscionable, dangerous, and unethical to subject more babies to an unnecessary, risky and traumatic surgery in order to study what has already been documented beyond what should be sufficient to discontinue this unnecessary surgery altogether.

V

The Gomco and Mogen clamps are questionable devices, and both present known and documented hazards about which the Food and Drug Administration has provided ample and detailed warnings.[20], [21] Using such devices in a study raises serious liability issues, in addition to ethics concerns. Both Mogen and Gomco clamps have been implicated in a number of lawsuits for serious circumcision-related injuries, including three recent suits with awarded damages of $4.6, $7.5, and $10.8 million.[22] As the public's awareness increases with regard to the unnecessary nature of circumcision and its attendant risks and harms, lawsuits for lack of true consent and for injuries to children are also increasing. Circumcision rates are on the wane; the U.S. rate will fall below 50% by spring of next year, and is already below 25% and dropping on the U.S. West Coast[23].

A physician or hospital using devices with a documented history of causing harm may incur legal liability for any future damages that occur, and will be unable to claim the risk posed was unknown.

VI

Given the Roman Catholic Church's longstanding prohibition against non-therapeutic amputations, and its position on surrogate consent, it is surprising – to say the least – that this study is being conducted within the walls of a Catholic hospital. Catechism Paragraph 2297 provides, in part:

> "Except when performed for strictly therapeutic medical reasons, directly intended *amputations*, *mutilations*, and *sterilizations* are against the moral law. . . ."

In its *Ethical and Religious Directives for Catholic Health Care Services*,[24] the Church also recognizes the problem of surrogate consent for children facing non-therapeutic procedures that involve known risk to the patient (Directive 31), and then extends such protection from adults to fetuses (Directive 51), an age range that surely embraces newborns:

> Directive 31: "No one should be the subject of medical or genetic experimentation, even if it is therapeutic, unless the person or surrogate first has given free and informed consent. In instances of non-therapeutic experimentation, the surrogate can give this

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[19] Shockley RA, Rickett K. What's the best way to control circumcision pain in newborns? *J Fam Pract* 2011;60(4):233a-233b.

[20] Feigal DW. Potential for Injury from Circumcision Clamps. U. S. Food and Drug Administration. August 29, 2000. Available at http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm062279.htm. Accessed May 20, 2013.

[21] Kurtis PS, DeSilva HN, Bernstein BA, Malakh L, Schechter NL. A comparison of the Mogen and Gomco clamps in combination with dorsal penile nerve block in minimizing the pain of neonatal circumcision. *Pediatrics*. 1999;103;e23.

[22] Hennessy-Fiske M. Injuries linked to circumcision clamps. *Los Angeles Times*. 26 September 2011. Available at: http://articles.latimes.com/2011/sep/26/health/la-he-circumcision-20110926

[23] Maeda J, Chari R, and Elixhauser A. Circumcisions in U.S. Community Hospitals, 2009. *HCUP Statistical Brief #126*. February 2012. Agency for Healthcare Research and Quality, Rockville, MD. Available at http://www.hcup-us.ahrq.gov/reports/statbriefs/sb126.pdf

[24] United States Conference of Catholic Bishops. *Ethical and Religious Directives for Catholic Health Care Services*, Fifth Edition, 2009. 43p. Available at http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf. Accessed May 20, 2013.

consent only if the experiment entails no significant risk to the person's well-being. Moreover, the greater the person's incompetency and vulnerability, the greater the reasons must be to perform any medical experimentation, especially non-therapeutic."

Directive 51: "Non-therapeutic experiments on a living embryo or fetus are not permitted, even with the consent of the parents."

Based on all of the above, we ask you to ensure that those charged with supervising this study immediately suspend it and, further, that they release recruited families from any obligation to participate.

Please convey confirmation that the study has been suspended to:

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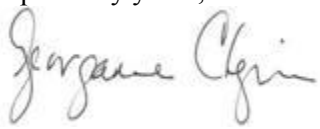
In addition, please provide Ms. Chapin with contact information for the Institutional Review Board that approved this study, and with information as to the sources of all funding, direct and indirect, for this study.

Respectfully yours,



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[1] Responsible Party: TriHealth, Inc., Good Samaritan Hospital, ClinicalTrials.gov, Identifier: NCT01726036; Other Study ID Numbers: H-11121. Contact: Michaela Eschenbacher, MPH; Principal Investigator: Mounira Habli, MD.

[2] TriHealth's Code of Ethical Business and Professional Behavior. Available at: http://www.trihealth.com/discover-trihealth/about-us/code-of-ethics/Code-of-Ethical-Business-Behavior-2012.aspx

[3] *Permissible Medical Experiments.* Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10: Nuremberg October 1946–April 1949. Washington: U.S. Government Printing Office (n.d.), vol. 2, pp. 181-182.

[4] World Medical Association, Declaration of Helsinki (1964). Available at http://www.wma.net/en/30publications/10policies/b3/. Accessed May 20, 2013.

[5] Department of Health and Human Services, 2. Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects, 45 C.F.R. §46.

[6] European Convention on Human Rights and Biomedicine (1997). Adopted at Oviedo, 4 April 1997. Available at http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm. Accessed May 20, 2013.

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[10] Benini F, Johnson C, Faucher D, *et al.* Topical anesthesia during circumcision in newborn infants. *JAMA* 1993;270(7):850-3. Available at http://jama.jamanetwork.com/article.aspx?articleid=407985. Accessed May 20, 2013.

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[13] Taddio A, Pollock N, Gilbert-MacLeod C, *et al.* Combined analgesia and local anesthesia to minimize pain during circumcision. *Arch Pediatr Adolesc Med* 2000;154(6):620-3. Available at http://archpedi.jamanetwork.com/article.aspx?articleid=349706. Accessed May 20, 2013.

[14] https://www.indianz.com/News/2011/001573.asp

[15] Machmouchi M, Alkhotani A. Is neonatal circumcision judicious? *Eur J Pediatr Surg.* 2007 Aug;17(4):266-9.

[16] Kaweblum YA, Press S, Kogan M, Levine M, Kaweblum M. Circumcision Using the Mogen Clamp. *Clinical Pediatrics*. 1984;*23*(12):679-682.

[17] Kaufman GE, Cimo S, Miller LW, et al. An evaluation of the effects of sucrose on neonatal pain with 2 commonly used circumcision methods. Am J Obstet Gynecol. 2002;186:564–568.

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[21] Kurtis PS, DeSilva HN, Bernstein BA, Malakh L, Schechter NL. A comparison of the Mogen and Gomco clamps in combination with dorsal penile nerve block in minimizing the pain of neonatal circumcision. *Pediatrics*. 1999;103;e23.

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[23] Maeda J, Chari R, and Elixhauser A. Circumcisions in U.S. Community Hospitals, 2009. *HCUP Statistical Brief #126*. February 2012. Agency for Healthcare Research and Quality, Rockville, MD. Available at http://www.hcup-us.ahrq.gov/reports/statbriefs/sb126.pdf

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