February 17, 2023

Stephanie Chang, M.D., FACOG Residency Program Director Obstetrics and Gynecology University of Texas Southwestern Medical Center

Via Email: <u>stephanie.chang@utsouthwestern.edu;</u> <u>obgyn-residency@utsouthwestern.edu</u>

Dear Dr. Chang:

Thank you in advance for your time. I am writing on behalf of People for the Ethical Treatment of Animals—PETA entities have more than 9 million members and supporters globally—as well as the undersigned board-certified fellows of The American Congress of Obstetricians and Gynecologists, Drs. Stephanie Singer and Rixt Luikenaar. Based on the information presented in the enclosed supplemental brief, we urge the University of Texas Southwestern Medical Center (UT Southwestern) to adopt a public policy prohibiting the use of live animals in its obstetrics and gynecology (OB/GYN) residency training program in favor of humanrelevant, non-animal methods.

You can contact me directly via e-mail at <u>ShriyaS@peta.org</u>. Thank you for your consideration of this social-important issue, and we look forward to your response.

Sincerely yours,

Shriya Swaminathan Science Policy Advisor International Laboratory Methods Laboratory Investigations Department

Minym

Stephanie Singer, DO, FACOG Park City Gynecology Park City, UT

Rixt Luikenaar, MD, FACOG, MBA Rebirth Health Center Holladay, UT



PETA

Washington

1536 16th St. N.W. Washington, DC 20036 202-483-PETA

Los Angeles

2154 W. Sunset Blvd. Los Angeles, CA 90026 323-644-PETA

Norfolk

501 Front St. Norfolk, VA 23510 757-622-PETA

Info@peta.org PETA.org

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Supplemental Brief: Replacing Animal Use in OB/GYN Residency Training at UT Southwestern February 17, 2023

Prepared by PETA

UT Southwestern Records Confirm Animal Use in OB/GYN Residency Training On November 16, 2022, PETA submitted a public records request regarding the use of live animals and animal parts in UT Southwestern's OB/GYN residency training program.¹ On December 14, 2022, the University provided a spreadsheet documenting OB/GYN residents' participation in trainings that use live animals.²

Majority of OB/GYN Residency Programs Use Animal-Free Training Methods

Based on PETA's ongoing survey of all OB/GYN residency programs accredited by the Accreditation Council for Graduate Medical Education (ACGME), an overwhelming majority of these residency programs have reported that they *do not* use live animals in their training. Instead, these programs—such as the ones at Rush University,³ Aurora Sinai Medical Center,⁴ and others—use advanced, human-relevant simulators, which are reported in the medical literature to be equal, if not superior, to using live animals.

You may also be aware that the Department of Defense (DOD) issued a policy on May 15, 2014, that bans the use of animals for OB/GYN residency training and several other medical education areas by all branches of the military, unequivocally stating that "suitable simulation alternatives can replace the use of live animals."⁵

Federal Provisions Require the Replacement of Animal Use When Possible

There are federal ethical provisions in place regarding minimizing the use of animals in experiments and training:

• The eighth edition of the Guide for the Care and Use of Laboratory Animals states, "The *Guide* ... endorses the following principles: *consideration of*

https://www.peta.org/blog/obgyn-residents-trade-practice-live-pigs-high-tech-simulators/

¹People for the Ethical Treatment of Animals. Records Request. November 16, 2022. Accessed on January 10, 2023.

https://www.peta.org/wp-content/uploads/2023/01/2022-11-16-prr-ob-gyn-ut-southwestern.pdf² UT Southwestern. Responsive Records. December 14, 2022. Accessed on January 10, 2023. https://www.peta.org/wp-content/uploads/2023/01/2022-12-14-responsive-records.pdf

³ People for the Ethical Treatment of Animals. OB/GYN Residents Trade Practice on Live Pigs for High-Tech Simulators. June 28, 2016. Accessed March 18, 2022.

⁴ People for the Ethical Treatment of Animals. Hospital Swaps Live Pigs for Tech in OB/GYN Training After PETA Talks. Accessed March 18, 2022.

https://www.peta.org/blog/victory-aurora-sinai-medical-center-wisconsin-replaces-live-pigs-high-techsimulators/

⁵ Department of Defense. Determination for the use of Animals in Medical Education and Training. May 15, 2014. Accessed March 18, 2022.

http://www.specialoperationsmedicine.org/documents/TCCC_2016/06%20TCCC%20Reference%20Docu ments/ASDHA%20Memo%20140515%20LTT%20Policy.pdf

alternatives (in vitro systems, computer simulations, and/or mathematical models) to reduce or replace the use of animals.^{°6} [*Emphasis added*]

- The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985) states, "The animals selected for a procedure should be of an appropriate species and quality and *the minimum number required to obtain valid results.*"⁷ [*Emphasis added*]
- The U.S. Animal Welfare Act was enacted to ensure minimal protection of animals in laboratories and to prevent redundant experimental studies, which waste precious resources and harm animals. Section 2143(e)(3) of the act calls for "improved methods of animal experimentation, including methods which could reduce *or replace animal use*" and section 2143(d)(2) states the need for scientific training using "methods that minimize or *eliminate the use of animals* or limit animal pain or distress."⁸

Combining the Accreditation Council for Graduate Medical Education's (ACGME) requirement for "ethical, humanistic training" that uses "simulation,"⁹ with the federal provisions that compel the minimization of animal use—which in the case of OB/GYN residency training the number of animals used should be zero given the precedents set by the DOD, Rush University, Aurora Sinai Medical Center and others in fully replacing their use of animals for this purpose—we urge UT Southwestern to prohibit the use of animals in its OB/GYN residency training.

Anatomical Differences Between Species Restrict Transferability of Clinical Skills

There are significant differences in anatomical structures and vasculature between humans and other animals. In medicine, where lifesaving decisions must often be made within seconds, familiarity with human anatomical structures is crucial. Pigs and other animals cannot accurately mimic human anatomy, and major anatomical variances exist between humans and other animals due to the differences between quadrupeds and bipeds.

For example, humans' bipedal nature results in a thorax that is vertically oriented and appears quite different from other mammals. The pig heart, as it sits in the thorax, is rotated counterclockwise as compared to the human heart, resulting in different locations for key structures such as the left ventricle and atrium. The vasculature of the heart and

https://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/220_ObstetricsAndGynecology_2020.pd

⁶ National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. (2011). *Guide for the Care and Use of Laboratory Animals*. https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf

⁷ National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. (2011). *Appendix B to the Guide for the Care and Use of Laboratory Animals: U.S. government principles for the utilization and care of vertebrate animals used in testing, research, and training*. https://www.ncbi.nlm.nih.gov/books/NBK54048/

⁸ United States Department of Agriculture Animal and Plant Health Inspection Service. (2017). USDA Animal Care: Animal Welfare Act and Animal Welfare Regulations. United States Department of Agriculture Animal and Plant Health Inspection Service.

⁹ American Council for Graduate Medical Education (n.d.) *ACGME Program Requirements for Graduate Medical Education in Obstetrics and Gynecology.*

lungs is also significantly different between pigs and humans, with pigs having a left azygous vein that drains into the coronary sinus and only two pulmonary veins in comparison with up to five in humans.¹⁰

Differences in other organs, such as the shape and arterial supply of the spleen,¹¹ orientation of the pelvis, and the shape of the liver¹² limit the realism and utility of animals like the pig in surgical training. A 2016 study in the *Journal of the Royal Army Medical Corps* stated the following regarding the use of pigs: "Training courses based on animal models and cadavers have been used extensively to prepare surgeons for deployment in recent conflicts. However, they are expensive and provide a one-off opportunity to practice advanced techniques in models that are either anatomically incorrect (pigs) or have altered tissue characteristics with no vascular perfusion (cadavers). [Instead, a]bdominal multivisceral organ retrieval [in clinical settings] is the ultimate laparotomy and takes the surgeon to parts of the retroperitoneum and thorax otherwise not seen during standard surgical training."¹³

With respect to the genitourinary structures, pigs possess a "bicornuate" uterine structure, wherein the uterine body elongates into two uterine horns. This increases the distance from the cervix to the entrance of the Fallopian tubes when compared to the distance observed in human women. Key structures such as the cervix, vagina, and Fallopian tubes also have different lengths in pigs versus humans. Pigs have a longer urogenital sinus that connects to the external genitalia through a common opening. On the contrary, adult women only have vestiges of the urogenital sinus, which is considered to be part of the external genitalia, and the urethra and vagina have separate external openings. In addition to these prominent differences, there are also a myriad of microscopic anatomical differences between pigs and humans within each organ.¹⁴

Human-Relevant OB/GYN Simulators Offer Myriad Benefits

In the past several decades, technological advances in the medical simulation field, heightened institutional financial constraints, educators' need for better teaching and assessment tools, and growing concern about animal use in invasive and terminal laboratory experiments, have all contributed to a paradigm shift in biomedical education where simulation-based learning has become the medical best-practice standard. Unlike animal-based laboratories, innovations in biomedical simulation technology ranging from high-fidelity human patient simulation (HPS) to computer-assisted learning

¹⁰ Lelovas, P.P., Kostomitsopoulos, N.G., & Xanthos, T.T. (2014). A comparative anatomic and physiologic overview of the porcine heart. *Journal of the American Association for Laboratory Animal Science*, *53*(5), 432–438.

¹¹ Pereira-Sampaio, M.A., Marques-Sampaio, B.P. (2006). Anatomical study and proportional analysis of the pig spleen arterial segments. *Cells Tissues Organs*, *182*(1),32-34.

¹² Nykonenko A, Vávra P, Zonča P. Anatomic peculiarities of pig and human liver. (2017). *Exp Clin Transplant*, *15*(1), 21-26.

¹³ O'Reilly, D., Lordan, J., Streets, C., Midwinter, M., & Mirza, D. (2016). Maintaining surgical skills for military general surgery: The potential role for multivisceral organ retrieval in military general surgery training and practice. *J R Army Med Corps, 162*(4), 236-238. <u>https://pubmed.ncbi.nlm.nih.gov/26243807/</u>.

¹⁴ Lorenzen E, Follmann F, Jungersen G, Agerholm JS. A review of the human vs. porcine female genital tract and associated immune system in the perspective of using minipigs as a model of human genital Chlamydia infection. Vet Res. 2015;46:116. Published 2015 Sep 28. doi:10.1186/s13567-015-0241-9

(CAL) software and virtual reality programs for OB/GYN training have created important new cost-effective ways to accurately model human anatomy and physiology,¹⁵ create immersive scenarios that mimic real-world medical cases,¹⁶ provide students with vital opportunities to repeat medical procedures until proficiency,¹⁷ improve provider confidence and transference of learned skills to clinical practice, ¹⁸ and allow educators to receive objective performance feedback.¹⁹

In obstetrics training, there are low- and high-fidelity hybrids composed of human simulators and computer software that can be used to simulate an operative vaginal delivery,²⁰ breech vaginal delivery,²¹ shoulder dystocia,^{22,23} eclampsia,²⁴ postpartum hemorrhage,²⁵ amniocentesis and fetal blood sampling,^{26,27} and more. A non-animal simulation curriculum has also been developed to address deficiencies in managing obstetric emergencies.²⁸

¹⁵ Cook, J., Rao, V. V., Bell, F., Durkin, M., Cone, J., Lane-Cordova, A., & Castleberry, L. (2020). Simulation-based clinical learning for the third year medical student: Effectiveness of transabdominal and transvaginal ultrasound for elucidation of OB/GYN scenarios. Journal of Clinical Ultrasound, 48(8), 457-461.

¹⁶ Nitsche, J., Morris, D., Shumard, K., & Akoma, U. (2016). Vaginal delivery simulation in the obstetrics and gynaecology clerkship. The clinical teacher, 13(5), 343-347.

¹⁷ Larsen, C. R., Oestergaard, J., Ottesen, B. S., & Soerensen, J. L. (2012). The efficacy of virtual reality simulation training in laparoscopy: a systematic review of randomized trials. Acta obstetricia et gynecologica Scandinavica, 91(9), 1015-1028.

¹⁸ Pliego, J. F., Wehbe-Janek, H., Rajab, M. H., Browning, J. L., & Fothergill, R. E. (2008). OB/GYN boot camp using high-fidelity human simulators: enhancing residents' perceived competency, confidence in taking a leadership role, and stress hardiness. Simulation in Healthcare, 3(2), 82-89.

¹⁹ Madsen, M. E., Konge, L., Nørgaard, L. N., Tabor, A., Ringsted, C., Klemmensen, Å. K., ... & Tolsgaard, M. G. (2014). Assessment of performance measures and learning curves for use of a virtual-reality ultrasound simulator in transvaginal ultrasound examination. Ultrasound in Obstetrics & Gynecology, 44(6), 693-699.

²⁰ Dupuis O, Moreau R, Pham MT, Redarce T. Assessment of forceps blade orientations during their placement using an instrumented childbirth simulator. BJOG. 2009 Jan;116(2):327-32.

²¹ Deering S, Brown J, Hodor J, Satin AJ. Simulation training and resident performance of singleton vaginal breech delivery. Obstet Gynecol. 2006 Jan;107(1):86-9.

²² Fahey JO, Mighty HE. Shoulder dystocia: using simulation to train providers and teams. J Perinat Neonatal Nurs. 2008 Apr-Jun;22(2):114-22.

 ²³ Deering S, Poggi S, Macedonia C, Gherman R, Satin AJ. Improving resident competency in the management of shoulder dystocia with simulation training. Obstet Gynecol. 2004 Jun;103(6):1224-8.
 ²⁴ Ellis D, Crofts JF, Hunt LP, Read M, Fox R, James M. Hospital, simulation center, and teamwork training for eclampsia management: a randomized controlled trial. Obstet Gynecol. 2008 Mar;111(3):723-31.

²⁵ Deering SH, Chinn M, Hodor J, Benedetti T, Mandel LS, Goff B. Use of a postpartum hemorrhage simulator for instruction and evaluation of residents. J Grad Med Educ. 2009 Dec;1(2):260-3.

²⁶ Pittini R, Oepkes D, Macrury K, Reznick R, Beyene J, Windrim R. Teaching invasive perinatal procedures: assessment of a high fidelity simulator-based curriculum. Ultrasound Obstet Gynecol. 2002 May;19(5):478-83.

²⁷ Tongprasert F, Tongsong T, Wanapirak C, Sirichotiyakul S, Piyamongkol W, Chanprapaph P. Experience of the first 50 cases of cordocentesis after training with model. J Med Assoc Thai. 2005 Jun;88(6):728-33.

²⁸ Maslovitz S, Barkai G, Lessing JB, Ziv A, Many A. Recurrent obstetric management mistakes identified by simulation. Obstet Gynecol. 2007 Jun;109(6):1295-300.

In gynecology training, simulators ranging from partial task trainers to virtual reality systems are available.²⁹ For instance, researchers have validated a cost-effective nonanimal simulation model to teach vaginal hysterectomy,³⁰ and another study found that high-fidelity simulators were "cheaper than practicing on laboratory animals" in the long term.³¹ A low-cost, low fidelity, animal-free simulator was also shown to have significantly improved OB/GYN trainee confidence in performing abdominal hysterectomies.³² The use of pigs to teach *in utero* stenting has been described as "cumbersome," while a non-animal trainer constructed out of simple materials was concluded to be "efficient," "reutilised more than 30 times," and "replicates the sensation of piercing through the uterine cavity during a clinical scenario."³³ A laparoscopic training curriculum for gynecology residents has also been developed to teach common surgical tasks, such as bead and peg manipulation, passing of a specially-designed "key," cutting of lines and circles on a two-layer latex glove, suturing, and intra- and extracorporeal knot tying.³⁴

A retrospective study at The University of Texas Medical Branch at Galveston, Department of Obstetrics and Gynecology, reported that "simulator-based training may play an integrative role in developing the residents' surgical skills and thus improving the surgical outcomes of hysterectomy."³⁵ This conclusion arose from clinical outcomes of patients who had undergone total abdominal hysterectomy, vaginal hysterectomy, total laparoscopy-assisted hysterectomy, or robot-assisted hysterectomy that was performed by residents before and after a simulation lab training. This animal-free simulation training at the institution included the da Vinci Trainer (Mimic Technologies) for robotic surgery, the 3-Dmed Trainer platform (3-Dmed) as a laparoscopy trainer, and the Surgical Female Pelvic Trainer (SFPT) with Advanced Surgical Uterus (Limbs&Things) as an open surgery trainer.³⁵ Furthermore, an abdominal laparotomy training curriculum using exclusively non-animal methods demonstrated construct validity, and improved performance of residents in the study.³⁶

²⁹ Hart R, Karthigasu K. The benefits of virtual reality simulator training for laparoscopic surgery. Curr Opin Obstet Gynecol. 2007 Aug;19(4):297-302.

³⁰ Greer JA, Segal S, Salva CR, Arya LA. Development and validation of simulation training for vaginal hysterectomy. J Minim Invasive Gynecol. 2014 Jan-Feb;21(1):74-82.

 ³¹ van de Ven J, Houterman S, Steinweg RA, Scherpbier AJ, Wijers W, Mol BW, Oei SG; TOSTI-Trial Group. Reducing errors in health care: cost-effectiveness of multidisciplinary team training in obstetric emergencies (TOSTI study); a randomised controlled trial. BMC Pregnancy Childbirth. 2010 Oct 8;10:59.
 ³² Stickrath E, Alston M. A Novel Abdominal Hysterectomy Simulator and Its Impact on Obstetrics and Gynecology Residents' Surgical Confidence. *MedEdPORTAL*. 2017;13:10636. Published 2017 Sep 29. doi:10.15766/mep_2374-8265.10636

³³ Nitsche JF, McWeeney DT, Schwendemann WD, et al. In-utero stenting: development of a low-cost high-fidelity task trainer. Ultrasound Obstet Gynecol. 2009;34(6):720-723. doi:10.1002/uog.7311

 ³⁴ Kirby TO, Numnum TM, Kilgore LC, Straughn JM. A prospective evaluation of a simulator-based laparoscopic training program for gynecology residents. J Am Coll Surg. 2008 Feb;206(2):343-8.
 ³⁵ Asoğlu MR, Achijan T, Akbilgic O, Borahay MA, Kılıc GS. The impact of a simulation-based training

lab on outcomes of hysterectomy. J Turk Ger Gynecol Assoc. 2016;17(2):60-64. Published 2016 Jan 12. doi:10.5152/jtgga.2016.16053

³⁶ Greenawald L, Uribe J, Shariff F, et al. Construct validity of a novel, objective evaluation tool for the basics of open laparotomy training using a simulated model. *Am J Surg.* 2017;214(1):152-157. doi:10.1016/j.amjsurg.2015.12.022

Request for Action

As PETA and physicians from Harvard Medical School noted in a 2018 paper published in the journal *Simulation in Healthcare*:

Scientific, legal, ethical, and economic factors have prompted curricular reforms around the world that have led to a dramatic decrease in the use of live animals for training in biomedical fields in favor of simulation-based education. Facilities that continue to use animals for these purposes will have less ethical and legal justification given that comparable courses are taught in many locations elsewhere without animal use.

The choice of which medical training modalities to use should be based on key metrics such as what method improves provider knowledge, confidence, proficiency, and accuracy and for all of these criteria studies and government regulatory decisions confirm that providers trained via human simulation meet or exceed the standard set by those trained using live animals for coursework in ... obstetrics and gynecology³⁷

Based on the information we've presented, we urge UT Southwestern to replace its use of live animals for OB/GYN residency training with more effective, ethical and economical non-animal methods.

³⁷ Pawlowski, J. B., Feinstein, D. M., & Gala, S. G. (2018). Developments in the transition from animal use to simulation-based biomedical education. Simulation in Healthcare, 13(6), 420-426.

May 4, 2021

Stephanie Chang, M.D. Residency Program Director Department of Obstetrics and Gynecology UT Southwestern Medical Center

Dear Dr. Chang

Thank you in advance for your time. I'm writing on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters, as well as the undersigned board-certified Fellow of The American Congress of Obstetricians and Gynecologists- Dr. Stephanie Singer, to inquire about the current training methods used in UT Southwestern Medical Center's obstetrics and gynecology (OB/GYN) residency program.

Would you please let us know whether your OB/GYN residency program uses animals or if it uses exclusively non-animal training methods? If animals are currently being used for OB/GYN residency training, could you please share information regarding the training and which skills procedures are involved?

You may be aware that the Department of Defense issued a <u>policy</u>—which went into effect on January 1, 2015—banning the use of animals for OB/GYN residency training and several other medical education areas, unequivocally stating that "suitable simulation alternatives can replace the use of live animals." If UT Southwestern Medical Center's OB/GYN residency program is currently using animals for training purposes, PETA would be eager to help you transition to using more effective, ethical and economical non-animal simulation methods.

You can contact me directly via e-mail at <u>ShriyaS@peta.org</u>. Thank you for your consideration, and we look forward to your reply.

Sincerely yours,

Shriya Swaminathan Research Associate International Laboratory Methods Division Laboratory Investigations Department

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Stephanie M. Singer, DO, FACOG Park City Gynecology Park City, UT

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

PETA

Washington, D.C.

1536 16th St. N.W. Washington, DC 20036 202-483-PETA

Los Angeles

2154 W. Sunset Blvd. Los Angeles, CA 90026 323-644-PETA

Norfolk

501 Front St. Norfolk, VA 23510 757-622-PETA

Berkeley

2855 Telegraph Ave. Ste. 301 Berkeley, CA 94705 510-763-PETA

Info@peta.org PETA.org

Affiliates:

- PETA Asia
- PETA IndiaPETA France
- PETA Australia
- PETA Germany
- PETA Netherlands
- PETA Foundation (U.K.)