AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

April 18, 2023

Aaron B. Caughey, M.D., Ph.D. Chair Department of Obstetrics and Gynecology Oregon Health & Science University

Via e-mail: caughey@ohsu.edu

Dear Dr. Caughey:

Thank you in advance for your time. I'm writing on behalf of People for the Ethical Treatment of Animals—PETA entities have more than 9 million members and supporters globally—regarding the apparent disturbing mutilation of live pigs during obstetrics and gynecology (OB/GYN) residency training conducted at Oregon Health & Science University (OHSU).

Based on the information presented below, we urge OHSU to adopt a public policy prohibiting the use of all animals for its OB/GYN residency training and switch fully to more effective, ethical, and economical animal-free training methods—which many other leading programs and the U.S. Department of Defense have already done, as described in the enclosed briefing.

In a set of public records that PETA received from OHSU in response to our October 22, 2021, request,¹ we learned that at least 64 residents had participated in five live-animal labs from 2019 to 2021 in OHSU's OB/GYN residency training program,^{2,3,4} which involved invasive and

https://www.peta.org/wp-content/uploads/2022/03/2021-10-22_OB-GYN Residency Records-Request OHSU OB-GYN.pdf

²OHSU. USDA and Porcine OB/GYN Data 2021. Accessed March 18, 2023. https://www.peta.org/wp-content/uploads/2022/03/USDA-and-Porcine-ObGyn-Data-2021-redacted.pdf

³OHSU. USDA and Porcine OB/GYN Data 2020. Accessed March 18, 2023. https://www.peta.org/wp-content/uploads/2022/03/USDA-and-Porcine-ObGyn-Data-2020-redacted.pdf ⁴OHSU. USDA and Porcine OB/GYN Data 2021. Accessed March 18, 2023.



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¹People for the Ethical Treatment of Animals. Records Request. October 22, 2021. Accessed March 6, 2023.

https://www.peta.org/wp-content/uploads/2022/03/USDA-and-Porcine-ObGyn-Data-2021-redacted.pdf

PETA Switzerland

deadly procedures on pigs.^{1,2,3,4}

On April 18, 2022, we sent a letter to Dr. Amy Stenson, OHSU's OB/GYN residency program director, outlining federal provisions that mandate a reduction in the use of live animals when possible, describing the poor translatability of skills from training on animals to performing procedures on human patients and detailing advanced animal-free methods that afford superior OB/GYN training.⁵ Despite repeated follow-ups,^{67,8,12} we haven't yet received a response. On March 30, 2023, PETA, along with two boardcertified fellows of The American College of Obstetricians and Gynecologists, Dr. Stephanie Singer and Dr. Rixt Luikenaar, also wrote to the OHSU Board of Directors about the matter, requesting that the board take action by ensuring the replacement of the use of live animals in OHSU's OB/GYN residency program.⁹

On April 17, representatives from PETA attended a meet-and-greet event featuring OHSU Executive Vice President and Dean of the School of Medicine Dr. David Jacoby, where they had the opportunity to address this issue directly. Dr. Jacoby informed PETA's representatives that you had advised him that continuing to use pigs during OB/GYN residency training is still necessary—however, the evidence described in the enclosed brief confirms that using animals for this purpose is not only unnecessary but also counterproductive, and it outlines the prevalence and superiority of animal-free OB/GYN training methods.

Therefore, we respectfully urge you to reconsider your position and end OHSU's use of live animals in its OB/GYN residency training, in favor of advanced non-animal training methods.

¹OHSU. IACUC Protocol IP00817. Accessed March 18, 2023.

https://www.peta.org/wpcontent/uploads/2022/03/IACUC-protocol-IP00817.pdf-redacted.pdf

²OHSU. High Fidelity Simulation-Manikin Based ObGyn Post-Partum Skills. Accessed March 18, 2023. <u>https://www.peta.org/wp-content/uploads/2022/03/ObGyn-Curriculum-HighFidelity.pdf</u>

³OHSU. OB Skills. Accessed March 18, 2023. <u>https://www.peta.org/wp-content/uploads/2022/03/OB-Skills-2019-2021-Objectives-and-Equipment-redacted.pdf</u>

⁴OHSU. Porcine Laboratory Surgical Tasks. Accessed March 18, 2023.

https://www.peta.org/wpcontent/uploads/2022/03/Porcine-Labarotory-Surgical-Tasks-redacted.pdf ⁵ Swaminathan S. Letter to Dr. Amy Stenson. PETA. April 18, 2022. Accessed March 18, 2023.

https://www.peta.org/wp-content/uploads/2022/05/PETA-re-animal-use-in-UTHSCLife-Force-training.pdf

⁶Swaminathan S. E-mail follow-up with Dr. Amy Stenson. PETA. June 8, 2022. Accessed March 18, ⁷. <u>https://www.peta.org/wp-content/uploads/2023/03/2022-06-08-follow-up-ohsu.pdf</u>

¹. <u>https://www.peta.org/wp-content/uploads/2023/05/2022-06-08-1010w-up-onsu.pd1</u> ⁸Swaminathan S. E-mail follow-up with Dr. Amy Stenson. PETA. October 11, 2022. Accessed March 18,

^{2023. &}lt;u>https://www.peta.org/wp-content/uploads/2023/03/2022-10-11-follow-up-ohsu.pdf</u> ¹²Swaminathan S. Letter to Dr. Amy Stenson. PETA. March 2, 2023. Accessed March 18, 2023.

https://www.peta.org/wp-content/uploads/2023/03/2023-03-02-letter-to-ohsu-re-obgyn-trainingonanimals.pdf

⁹_Swaminathan S. Letter to OHSU Board of Directors. PETA. March 30, 2023. Accessed April 17, 2023. <u>https://www.peta.org/wp-content/uploads/2023/04/2023-03-30-letter-to-ohsu-bod.pdf</u>

You can contact me at <u>ShriyaS@peta.org</u>. I look forward to your response regarding this important issue. Thank you.

Sincerely yours,

Shriya Swaminathan Science Policy Advisor International Laboratory Methods Division Laboratory Investigations Department

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Enclosure

Supplemental Brief: Replacing Animal Use in OB/GYN Residency Training at OHSU

Supplemental Brief: Replacing Animal Use in OB/GYN Residency Training at Oregon Health & Science University March 30, 2023

Prepared by PETA

Most 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 them have reported that they *don't* use live animals in their training. Instead, such programs, including those at Rush University¹ and Aurora Sinai Medical Center,² use advanced, human-relevant simulators, which are reported in the medical literature to be equal or superior to using live animals.

The U.S. 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."³

Federal Provisions Require the Replacement of Animal Use When Possible

Federal ethical provisions are 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 alternatives* (in vitro systems, computer simulations, and/or mathematical models) to reduce or replace the use of animals."⁴ [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."⁵ [Emphasis added.]

¹People 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. <u>https://www.peta.org/blog/obgyn-residents-trade-practice-live-pigs-high-tech-simulators/</u>

²People 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/

³Department of Defense. "Determination for the Use of Animals in Medical Education and Training." May 15, 2014. Accessed March 18, 2022. <u>https://www.peta.org/wp-content/uploads/2023/03/jonathan-woodson-2014.pdf</u>

⁴U.S. National Research Council 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

⁵U.S. National Research Council Committee for the *Update of the Guide for the Care and Use of Laboratory Animals*. (2011). Appendix B: U.S. government principles for the utilization and care of vertebrate animals used in testing, research, and training. <u>https://www.ncbi.nlm.nih.gov/books/NBK54048/</u>

• The federal 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."⁶ [*Emphasis added*.]

Combining the Accreditation Council for Graduate Medical Education's (ACGME) requirement for "ethical, humanistic training" that uses "simulation,"⁷ with the federal provisions that compel the minimization of animal use—and 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 Oregon Health & Science University (OHSU) to prohibit the use of animals in its OB/GYN residency training.

Anatomical Differences Between Species Restrict the 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 can't 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's vertically oriented and appears quite different from other mammals. A pig's heart, as it sits in the thorax, is rotated counterclockwise as compared to a human heart, resulting in different locations for key structures, such as the left ventricle and atrium. The vasculature of the heart and 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, by comparison with up to five in humans.⁸

⁶U.S. Department of Agriculture Animal and Plant Health Inspection Service. (2017). *USDA Animal Care: Animal Welfare Act and Animal Welfare Regulations*. U.S. Department of Agriculture Animal and Plant Health Inspection Service.

⁷American Council for Graduate Medical Education (n.d.) *ACGME Program Requirements for Graduate Medical Education in Obstetrics and Gynecology*.

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

⁸Lelovas, 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. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4181683/</u>

Differences in other organs, such as the shape and arterial supply of the spleen,⁹ orientation of the pelvis, and the shape of the liver¹⁰ limit the realism and utility of animals like pigs in surgical training. A 2016 study in the *Journal of the Royal Army Medical Corps* states 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."¹¹

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 women. Key structures, such as the cervix, vagina, and fallopian tubes, also have different lengths in pigs compared with humans. Pigs have a longer urogenital sinus that connects to the external genitalia through a common opening. However, adult women have only 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 many microscopic anatomical differences between pigs and humans within each organ.¹²

Human-Relevant OB/GYN Simulators Offer Many Benefits

Over 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 concerns 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 to computer-assisted learning software and virtual reality programs for OB/GYN training have created important new cost-effective ways to model human anatomy and physiology accurately,¹³ create

⁹Pereira-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.

¹⁰Nykonenko A, Vávra P, Zonča P. Anatomic peculiarities of pig and human liver. (2017). *Exp Clin Transplant*, 15(1), 21–26.

¹¹O'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>

¹²Lorenzen 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 ¹³Cook, 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.

immersive scenarios that mimic real-world medical cases,¹⁴ provide students with vital opportunities to repeat medical procedures until proficiency,¹⁵ improve provider confidence and transference of learned skills to clinical practice,¹⁶ and allow educators to receive objective performance feedback.¹⁷

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,¹⁸ breech vaginal delivery,¹⁹ shoulder dystocia,^{20,21} eclampsia,²² postpartum hemorrhage,²³ amniocentesis and fetal blood sampling,^{24,25} and more. A non-animal simulation curriculum has also been developed to address deficiencies in managing obstetric emergencies.²⁶

In gynecology training, simulators ranging from partial task trainers to virtual reality systems are available.²⁷ For instance, researchers have validated a cost-effective non-

¹⁴Nitsche, J., Morris, D., Shumard, K., Akoma, U. (2016). Vaginal delivery simulation in the obstetrics and gynaecology clerkship. *The Clinical Teacher*, 13(5), 343–347.

¹⁵Larsen, 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.

¹⁶Pliego, 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.

¹⁷Madsen, M.E., Konge, L., Nørgaard, L.N., Tabor, A., Ringsted, C., Klemmensen, Å.K., et. al. (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.

¹⁸Dupuis O., Moreau R., Pham M.T., Redarce T. Assessment of forceps blade orientations during their placement using an instrumented childbirth simulator. *BJOG*. 2009 Jan;116(2):327–32.

¹⁹Deering S., Brown J., Hodor J., Satin A.J.. Simulation training and resident performance of singleton vaginal breech delivery. *Obstet Gynecol*. 2006 Jan;107(1):86–9.

²⁰Fahey J.O., Mighty H.E. Shoulder dystocia: using simulation to train providers and teams. J Perinat *Neonatal Nurs*. 2008 Apr–Jun;22(2):114–22.

 ²¹Deering S., Poggi S., Macedonia C., Gherman R., Satin A.J. Improving resident competency in the management of shoulder dystocia with simulation training. *Obstet Gynecol.* 2004 Jun;103(6):1224–8.
²²Ellis D., Crofts J.F., Hunt L.P., 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.

²³Deering S.H., Chinn M., Hodor J., Benedetti T., Mandel L.S., Goff B. Use of a postpartum hemorrhage simulator for instruction and evaluation of residents. *J Grad Med Educ*. 2009 Dec;1(2):260–3.

²⁴Pittini 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.

²⁵Tongprasert 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.

²⁶Maslovitz S., Barkai G., Lessing J.B., Ziv A., Many A. Recurrent obstetric management mistakes identified by simulation. *Obstet Gynecol*. 2007 Jun;109(6):1295–300.

²⁷Hart R., Karthigasu K. The benefits of virtual reality simulator training for laparoscopic surgery. *Curr Opin Obstet Gynecol.* 2007 Aug;19(4):297–302.

animal simulation model to teach vaginal hysterectomy,²⁸ and another study found that high-fidelity simulators were "cheaper than practicing on laboratory animals" in the long term.²⁹ A low-cost, low-fidelity, animal-free simulator was also shown to have significantly improved OB/GYN trainee confidence in performing abdominal hysterectomies.³⁰ The use of pigs to teach *in utero* stenting has been described as "cumbersome," but a non-animal trainer constructed out of simple materials was concluded to be "efficient," it was "reutilised more than 30 times," and it "replicate[d] the sensation of piercing through the uterine cavity during a clinical scenario."³¹ 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.³²

A retrospective study at the Department of Obstetrics and Gynecology at the University of Texas Medical Branch at Galveston reported that "simulator-based training may play an integrative role in developing the residents' surgical skills and thus improving the surgical outcomes of hysterectomy."³³ 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 included the dV-Trainer (Mimic Technologies) for robotic surgery, the 3-Dmed Trainer platform as a laparoscopy trainer, and the Surgical Female Pelvic Trainer with Advanced Surgical Uterus (Limbs & Things) as an open surgery trainer. Furthermore, an abdominal laparotomy training curriculum using exclusively non-animal methods demonstrated construct validity and improved the performance of residents in the study.³⁴

Request for Action

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

²⁸Greer J.A., Segal S., Salva C.R., Arya L.A. Development and validation of simulation training for vaginal hysterectomy. *J Minim Invasive Gynecol*. 2014 Jan-Feb;21(1):74–82.

²⁹Van de Ven J., Houterman S., Steinweg R.A., Scherpbier A.J., Wijers W., Mol B.W., Oei S.G. 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.

³⁰Stickrath 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

³¹Codsi E., Nitsche J.F., Faksh A., et al. Op13.09: Development of a non-animal task trainer for in utero stenting. *Ultrasound in Obstetrics & Gynecology*. 2015;46:93. doi:10.1002/uog.15226

³²Kirby T.O., Numnum T.M., Kilgore L.C., Straughn J.M. A prospective evaluation of a simulator-based laparoscopic training program for gynecology residents. *J Am Coll Surg.* 2008 Feb;206(2):343–348.

³³Asoğlu M.R., Achjian T., Akbilgiç O., Borahay M.A., Kılıç G.S. 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

³⁴Greenawald 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

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 gynecology.³⁶

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

³⁶Pawlowski, 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.