American Thoracic Society

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Statement to the NIH Human Fetal Tissue Research Ethics Advisory Board
On behalf of the American Thoracic Society
Delivered by Thomas J. Mariani, Ph.D.
Professor of Pediatrics (Neonatology), Biomedical Genetics and Environmental Medicine
University of Rochester
601 Elmwood Avenue, Box 703
Rochester, NY 14642
508-801-5941
Tom_mariani@urmc.rochester.edu

On behalf of the American Thoracic Society (ATS), I thank the NIH Human Fetal Tissue Research Ethics Advisory Board for the opportunity to provide public comment on the use of fetal tissue in biomedical research, including respiratory-related research. The ATS is an interdisciplinary society of over 16,000 clinicians and scientists dedicated to the prevention, treatment, and cure of pulmonary, critical care and sleep related illnesses through research, education, and patient advocacy.

The ATS recognizes the past contributions to science and medicine made possible by incorporating the use of human fetal tissues into rational and ethical research projects. Studies with human fetal tissues helped define the mechanisms for the production of pulmonary surfactant, leading to new interventional strategies to combat the leading cause of death in preterm infants, an affliction that took the life of the child of a sitting president of the United States, John F. Kennedy. Of equal importance, cell lines derived from human fetal tissues are a major resource for development of vaccines, including those for respiratory viruses similar to SARS-CoV2.

No alternate exists to currently replace the use of human fetal tissues for many contemporary research applications. The December 18, 2018 National Institute of Allergy and Infectious Diseases (NIAID) Humanized Mouse Model Workshop concluded that "human fetal tissue-derived humanized immune systems models remain the "gold standard" to which other model systems should be compared." [i] In July 2019, the ATS was among a coalition of biomedical research societies that sent a letter to the Secretary of Health and Human Services stating, "Fetal cell lines are not a substitute for fetal tissue because the lines are limited to a small number of cell types and are inadequate for studying complex interactions between cells." [ii]

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Scientists now have a promising opportunity to expand the use of recently developed tools that provide molecular insights at high resolution and can be applied to model organisms and non-fetal human tissues. Collection and dissemination of data on human fetal tissues may facilitate or expedite the development of new tools better able to replace their use in some applications.

Recent studies from groups in the United States and Europe have highlighted novel cellular and molecular features in human fetal lungs. [iii] [iv] In prominent examples of critical ongoing clinical need, severely premature (24-28 weeks of gestation) infants remain at higher risk of developing respiratory disorders, including bronchopulmonary dysplasia and asthma. Because there are no animal models for any of these conditions that fully recapitulate human disease, human fetal tissues and cells remain invaluable for assessing environmental factor exposures as well as effects of hormones, growth factors, and other agents (e.g., drugs) on lung development.[v] [vi] Beyond lung development, human fetal lung tissue has been used in studies of lung cancer and hereditary diseases such as cystic fibrosis.[vii]

Finally, we must emphasize that ethical review for research projects currently takes place at the local and regional level, following national guidelines. Institutional Review Boards (IRBs) are bodies established locally to review research projects and plans and to protect human research subjects. IRBs have the authority to approve, disapprove, modify and/or monitor research proposals, including human subjects and materials. These boards serve to ensure that research is compliant with the ethical standards and regulations governing human subject research.

The ATS urges the NIH Human Fetal Tissue Research Ethics Advisory Board to use discretion and refrain from imposing any restrictions upon the use of human fetal tissues in research studies. Any restrictions, perhaps in the realm of rare and extraordinary cases, are best considered at the local and regional level, using the Institutional Review Board process that continues to be fully functional.

The ATS thanks the Board for this opportunity.

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[i] National Institutes of Health. National Institute of Allergy and Infectious Disease. Summary of Humanized Mouse Model Workshop. https://www.niaid.nih.gov/research/humanized-mouse-model-workshop

[ii] Letter to Secretary of Health and Human Services Alex Azar. July 11, 2019. https://www.cogr.edu/sites/default/files/2019%20Coalition%20Fetal%20Tissue%20Letter%20re%20HHS%20Policy%20-%20July%2011%202019.pdf

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