

A. BACKGROUND AND SIGNIFICANCE

1. The University of Pittsburgh Health Science Tissue Bank (HSTB) is an established fetal tissue core

Biological research specimen collection at the University of Pittsburgh is centralized through the Health Sciences Tissue Bank (HSTB). The workflow and expertise that is already in place will be leveraged to generate the GUDMAP Tissue Hub and we will also act as the primary tissue collection site. The HSTB has over 18 years of experience of prospectively procuring tissues and biological materials for researchers. The HSTB has a tissue procurement site at (b)(4); (b)(6)

(b)(4) which is part of a multi-hospital chain, consisting of (b)(4) (b)(4) We have been collecting fetal tissue for over 10 years with an established IRB (b)(6) (b)(6) co-I). Currently the HSTB has numerous researchers acquiring fetal tissue for various projects from 6-24 weeks of gestation. The tissue collections include liver, heart, gonads, legs, brain, genitourinary, and placenta (b)(6) (b)(6) co-I) has been utilizing the HSTB to procure genitourinary tissues including kidneys, ureters and bladders.

2. The HSTB has a strict consenting protocol

We have an established consenting protocol in line with the best practices recommendations from the NIH. All patients who present to obstetrics and family planning who wish to undergo an elective abortion, or have experienced a spontaneous abortion, are asked by a registered nurse (not involved with the procurement) to give consent for tissue procurement and banking. There is a 24-hour waiting period after the consent process and the initial registered nurse is not involved with the tissue procurement. This consent form also gives permission for tracking of patient progression, gathering of patient demographics and collection of clinically relevant information to be included in the database as well as an option for the donation of maternal blood, urine and amniotic fluid. The consent form related to research on tissue from an elective abortion (less than 24 weeks gestation) has been designed with extensive input from clinical colleagues and the Institutional Review Board of the University of Pittsburgh to ensure compliance with all Pennsylvania state and federal laws.

3. The proposed GUDMAP Tissue Hub (HUB) and collection site has significant infrastructure

The proposed HUB will leverage the resources of the current HSTB, which has a physical footprint in 4 hospitals of UPMC, which includes space and technical staff. The current organization consists of 16 staff members, which includes: a Medical Director (b)(6) PI), an Assistant Director (b)(6), a Project Manager (b)(6), Quality Assurance Manager (b)(6), lead technicians, supervisors, and technical staff. In addition the HUB will include a fetal pathologist (b)(6) co-I), a pediatric clinician (b)(6) co-I) and a classically trained human anatomist (b)(6) co-I) (b)(6) will spearhead this initiative. He is a clinician scientist with intimate knowledge of tissue banks [9-16] and the genitourinary system [17-19]. (b)(6) is a perinatal pathologist who has extensive knowledge and experience related to identification and quality control of fetal specimens [20-22]. Both (b)(6) are developmental biologists with successful research programs related to development of the genitourinary system [23-28]. This team is uniquely qualified to run, quality control and distribute samples to the successful GUDMAP Atlas projects. The HSTB has approximately 1000 sq. ft. of space at each of the flagship hospitals. This reflects significant institutional commitment and support to this research support facility (**see letters from**

(b)(6)

(b)(6) We have a strong Informatics backbone with our flagship and community hospitals linked through a common laboratory information system. In addition we have a variety of web-based tools to streamline the biological specimen procurement activities and extensively annotate the accrued specimens.

4. The proposed HUB and collection site has protocols for rigorous quality control

To keep up to date with the needs of the ever-growing area of tissue banking, the University of Pittsburgh is an institutional member of the International Society for Biological and Environmental Repositories (ISBER; <http://www.isber.org>). This is the organization responsible for establishing and disseminating best practices for biorepositories. ISBER works very closely with the National Cancer Institute (NCI) and the NCI's Biorepositories and Biospecimen Research Branch. A unique attribute of ISBER is that it represents repository organizations, users, as well as companies that develop the myriad collection of items and services that sustain repositories. In 2005, the organization published the "best practices for repositories" (ISBER, 2005) [29], a document containing a thorough and comprehensive treatise on repository management and