Contact PD/PI:(b)(6)

## Obtained via FOIA by Judicial Watch, Inc.

The current version of the consent form provides opportunity for the patient to also allow donation of maternal blood and urine to the HSTB. Although all of the tissue will be collected from one hospital site, all of the 18 UPMC hospitals are linked by a common laboratory information system. This vast system allows access to information on the maternal medical record and de-identified information related to the demographics will be available to the successful GUDMAP Atlas projects.

Procedures for Collecting, Processing and Distributing Specimens: All fetal tissue is collected through a collaborative process including Family Planning, Obstetrics and Pathology, All patients are consented for the procedure and tissue donation separately by the Family Planning and Obstetrics staff. Furthermore, patients are consented 24-hours in advance, allowing notice of potential cases for the following day. Once a patient has agreed to donate fetal tissues for research purposes, the HSTB is alerted and subsequently Pathology is involved. The HSTB acts as a courier and delivers the material to Pathology for gross examination and dissection. After pickup from the procedure area, the tissue-banking technician brings the specimen to the surgical pathology gross room area. The clinical pathology staff assigned to that bench performs immediate gross pathology assessment. The pathologist (b)(6) co-I) is involved at this stage in the clinical evaluation and subsequent harvesting of the specimen to ensure quality control at the level of gross evaluation. All specimens are grossly evaluated for mechanical disruption. After appropriate materials have been obtained for histologic evaluation for clinical diagnosis, the genitourinary tissue will then be rapidly triaged for GUDMAP Atlas projects. Pathology has snap freezing capabilities as well as the appropriate materials to preserve specimens via other required methods. In addition, the tissue banking space is in close proximity to the gross room. The samples will then be taken to the validation laboratories (b)(6) further assessment of the tissue prior to distribution; this transfer system is already established based on the existing collaboration.

We have extensive experience and the requisite staff to ensure adherence to the yet to be defined GUDMAP Atlas projects criteria as proven by successful contributions made to TCGA, caHUB and CPTAC. HSTB has in place the infrastructure to provide adequate support for all the elements needed for the GUDMAP project. The Tissue Resource was the only core facility rated "outstanding" in the NCI review of the Cancer Center in 2010 and again in 2015, with an overall impact score of 20 (core PI: [D)(E) P30 CA047904). We have the infrastructure in place as well as the experience to procure and process the required tissue and biological materials for the various GUDMAP projects. In addition the HSTB has extensive experience in running and maintaining a viable CAP accredited tissue resource. The current facilities consist of 45 ultra-low mechanical freezers and 7 liquid nitrogen storage vessels. The HSTB has adequate space for the long-term storage of specimens collected for the GUDMAP project.

The HSTB has an online request tool in place to streamline investigator driven research projects. This online tool allows researchers to submit all contact information, project specific requirements and necessary regulatory documents to the project manager of HSTB. We are in the process of working with our information technology department to generate a secure link for GUDMAP investigators. Once the Project Manager has reviewed and approved the request, the project is assigned to a staff member for appropriate actions. This electronic request site creates a centralized hub where HSTB staff and the requesting investigator can all access the project, provide appropriate documentation, see relevant information and communicate via project updates and email.

HSTB fetal tissue collection: The Fetal Tissue IRB has been in existence since 2005. Since 2010, the numbers of consents and collections has been steadily increasing (**Table 2**) and we are in an excellent position to expand our services to include the needs of the GUDMAP Atlas projects. Accrual of tissues less than 16 weeks only began in the middle of 2015, and we have already collected over 20 cases. Based on the demand of the Atlas projects we can ramp up the accrual for these early cases, since consent efforts to date are based on current needs and most women were not asked to donate.

Table 2: Number of cases, active projects and disbursements per year for fetal tissues

Year	No. of cases	No. of active projects	No. of disbursements
2010	(b)(4)	**************************************	
2011	П		
2012	П		
2013	Ţ		
2014	T		1
2015	Ti .		

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