

GTEx biospecimens access policy – October 24, 2013

The most current version of this policy can be found at <http://www.gtexportal.org/home?page=sampleForms>

Overview

The NIH Common Fund Genotype-Tissue Expression (GTEx) project is a resource for the general scientific community. In addition to primary data and analyses available through dbGaP and other venues, banked GTEx biospecimens will also be made available to scientists. The goal of this policy is to facilitate the efficient use of this valuable resource. All GTEx samples, whether renewable (e.g. fibroblast and lymphoblastoid cell lines) or non-renewable (e.g. DNA, RNA, Tissues, etc.), are subject to this policy.

GTEx Access Committee (GTEx-AC)

The GTEx-AC is composed of Program Directors from NIH lead Institutes and the Common Fund. This committee will meet once a month to review requests. You can reach the GTEx-AC at nhgrigtex@mail.nih.gov; the chair of this committee is Dr. Simona Volpi.

Step 1 – Determine the tissue access mechanism (see Appendices A-C)

The mechanism for requesting use of GTEx biospecimens depends on the scope of the request and whether funding is needed for the proposed study.

1) *Funding is needed.*

- a. Applicants may apply to a Funding Opportunity Announcement (FOAs) designed specifically for GTEx or related sample resources. See, for example, <http://grants.nih.gov/grants/guide/rfa-files/rfa-rm-12-009.html>. Future FOAs will be announced at <http://commonfund.nih.gov/GTEx/grants.aspx>. Instructions for requesting sample availability and access will be included in the FOA. NIH Institutes, Centers, or programs interested in issuing their own RFA/PA that would involve access to the GTEx resource or to provide co-funding for an RFA/PA are encouraged to coordinate with GTEx program staff.
- b. Applicants are encouraged to propose use of GTEx samples when applying for NIH research project grants (e.g., R01) or similar peer reviewed grants (NSF, Wellcome Trust, etc.). Although not guaranteed, awarded R01 (and similar) grantees will have priority use of GTEx biospecimens, assuming they received written documentation of sample availability through a “Short Sample Availability/Access Request” (SSAR) submitted to gtex_sample_reqs@broadinstitute.org. Applicants must contact the GTEx-AC at least 3 months before submission deadlines in order to obtain a sample availability letter and provisional approval of the project.

- 2) **Funding is NOT needed.** There are two mechanisms for accessing samples by applicants who have their own funding. Before samples are distributed, documentation of adequate funding is required.
- a. Streamlined Process: submit a “Short Sample Availability/Access Request” (SSAR) directly to gtex_sample_reqs@broadinstitute.org. Streamlined access requests are appropriate in any of the following situations:
 1. Technical feasibility studies that will require $N \leq 24$ of a given sample type and will use $\leq 1/10$ th of the material available.
 2. Studies involving exclusively renewable resources (e.g., cell lines), no matter the number of samples.
 3. Studies involving work that is within scope of an existing funded, peer-reviewed grant (NIH R01/U01 or equivalent, e.g. NSF, MRC-UK) or contract. The funded grant or contract does not have to have specified use of GTEx samples in the original application, but the proposed assays must be within scope of the peer reviewed grant and GTEx samples are an appropriate choice for the given scientific question. The determination of whether the proposed work is within scope will be determined by the GTEx-AC, with input from external *ad hoc* reviewers and the program officer for the grant\contract. If the work is determined not to be within scope, a full sample access request must be submitted (see below)
 - b. Full Process: submit a “Full Sample Availability/Access Request” (FSAR) directly to gtex_sample_reqs@broadinstitute.org. Full access requests are required when investigators do not have an existing, NIH (or similar) peer-reviewed grant in which use of GTEx samples would be considered within scope. This situation will apply to many for-profit entities, NIH intramural investigators, PIs with institutional support, etc.
 - c. X01 Process: an X01 Resource Access Program may be developed in the future (http://grants.nih.gov/grants/funding/funding_program.htm). This mechanism involves NIH peer review of applications whereby access to biospecimens is granted, but with no specific financial support to perform assays or analyses.

Both Short and Full Sample Availability/Access Requests will be accepted on a continuing basis and should be sent by email to gtex_sample_reqs@broadinstitute.org. A GTEx representative will acknowledge receipt. The Broad Institute, as the Data Coordinating Center for GTEx, will administer this process and perform searches of the sample inventory to document availability, but the name of the requestor and the scientific aims will only be available to GTEx program staff until a request is approved. All questions about the access policy and procedures should be directed to GTEx program staff at nhgrigtex@mail.nih.gov.

Investigators interested in using GTEx samples are encouraged to contact the GTEx-AC at nhgrigtex@mail.nih.gov as early in the process as possible in order to become familiar with this resource and access policies.

Step 2 - Review of Access Requests by the GTEx-AC (See Appendix C)

All the information requested in the SSAR or FSAR must be complete in order to be considered by the GTEx-AC.

Short Sample Availability/Access Requests will be reviewed at least once a month by the GTEx-AC, supplemented by additional *ad hoc* reviewers, as required. Decisions are expected within 4 weeks in most cases.

Full Sample Availability/Access Requests will be reviewed at least once a month by the GTEx-AC and additional *ad hoc* reviewers. Decisions are expected within 8 weeks in most cases.

After review by the GTEx-AC, recommendations are presented to the NIH GTEx Working Group (GTEx-WG), a committee comprised of GTEx program directors or designees from each supporting Institute/Center. The GTEx-WG makes the final decision about which projects are approved. Investigators will be notified by email of the decision. This decision is final and there is no appeal process. Investigators may submit revised requests.

An appropriate Program Officer will be assigned as the primary point of contact for each approved request.

An abstract for all approved uses will be publicly available at :
<http://www.gtexportal.org/home?page=sampleForms>

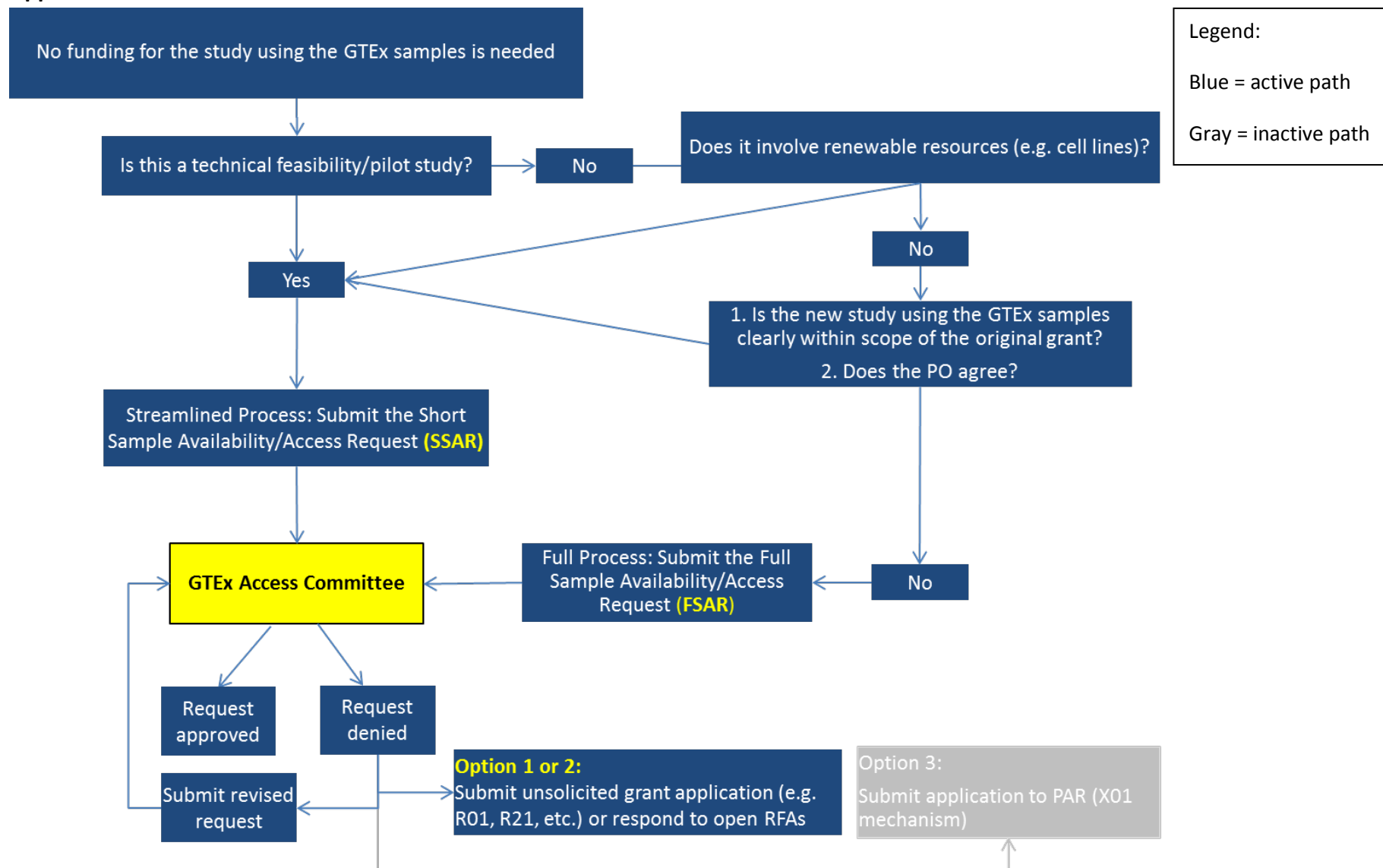
Step 3 - MTA and Sample shipment

A “Material Transfer Agreement (MTA)” is required and needs to be in place before delivery of the samples. The current version of the MTA may be found at:
<http://www.gtexportal.org/home?page=sampleForms>. Once executed, the GTEx-AC will provide the approved investigator with information to coordinate shipment of biospecimens. Investigators must take delivery of samples within 6 months from the time they are ready for shipment by the Biorepository, or they will be returned to the inventory for use by others.

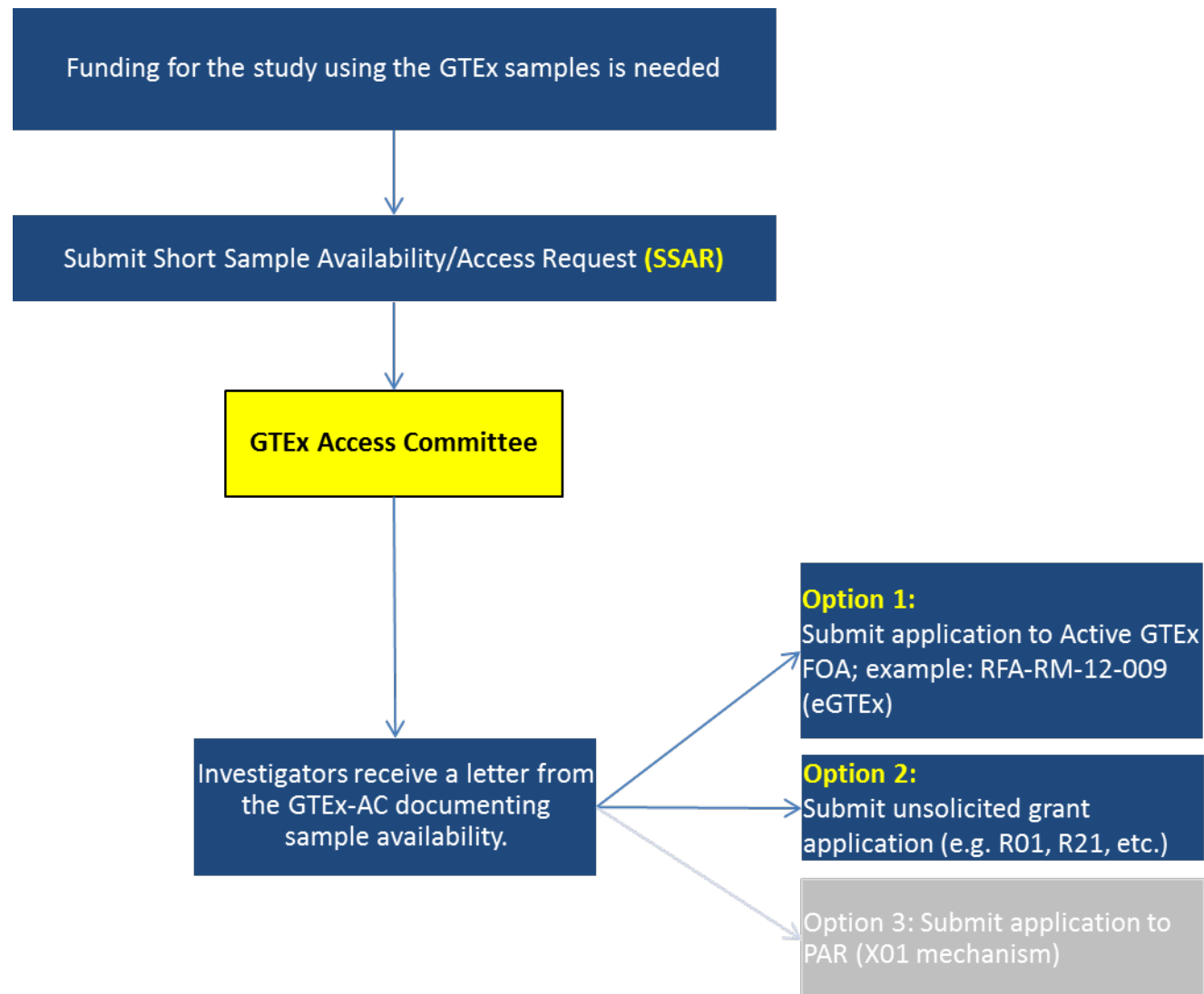
Step 4 - Post-shipment Requirements

Investigators must follow the data analysis and sharing plan agreed to in the Sample Availability/Access Request and periodically report on progress. The format and frequency of reporting will be agreed upon in collaboration with the assigned Program Officer.

Appendix A



Appendix B



Appendix C - GTEx Tissue Access Mechanism Table

Funds needed	Mechanism	Sample Access Process	Review of Access Request	Timeframe/Review Dates
Yes	RFA (example) <ul style="list-style-type: none"> RFA-RM-12-009 (eGTEx) 	Short Sample Availability/Access Request (SSAR) [prior to submission of RFA application]	GTEx-AC; external <i>ad hoc</i> reviewers, if required [prior to NIH study section review of application]	SSAR must be received at least 3 months prior to application deadline
Yes	R01, R21, U01 etc.	Short Sample Availability/Access Request (SSAR) [prior to submission of R01, etc. application]		
No	Small Technical Feasibility Study (n ≤ 24 samples) or exclusively uses renewable resource (e.g. cell lines)	Streamlined Process: Short Sample Availability/Access Request (SSAR)	GTEx AC; external <i>ad hoc</i> reviewers, if required	Accepted on a continuing basis - decision in 4 weeks
No	PIs with a peer-reviewed grant (NIH R01/U01 or equivalent, e.g. NSF, MRC-UK) and research plans “within scope” of existing grant			Accepted on a continuing basis - decision in 4 weeks, unless external review needed (up to 8 weeks)
No	PIs without an existing peer-reviewed, “within scope” grant (most for-profit entities, NIH intramural, PIs with institutional support, etc.)	Full Process: Full Sample Availability/Access Request (FSAR)	GTEx AC & external <i>ad hoc</i> reviewers	Accepted on a continuing basis - decision in 8 weeks

GTEx-AC GTEx Sample Access Committee - trans-NIH group of Program Officers

External reviewers - content experts convened on an *ad hoc* or regular/standing basis

In all cases, secondary review of applications could be obtained from the relevant Institute Advisory Committee and/or the GTEx External Scientific Panel.