

United States Food and Drug Administration
Generic Clearance: Collection of Qualitative Feedback on FDA Service Delivery
OMB Control Number 0910-0697
Gen IC Request for Approval

Title of Gen IC: Strengthening Interactions Between CBER's Office of Tissues and Advanced Therapies (OTAT) and Cell and Gene Therapy (CGT) Sponsors

1. Statement of Need:

The mission of the Center for Biologics Evaluation and Research (CBER) is to ensure the safety, purity, potency, and effectiveness of biological products including vaccines, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury. Through its mission, CBER also helps to defend the public against the threats of emerging infectious diseases and bioterrorism.

The Office of Tissues and Advanced Therapies (OTAT) leads and coordinates the Center's diverse activities pertaining to products falling within its regulatory jurisdiction, including gene therapy, tumor vaccines, xenotransplantation, stem cells, human tissue for transplantation, plasma protein therapeutics, combination products, bioengineered tissues and certain medical devices. Through the course of its regulatory work, OTAT interfaces with sponsors (companies, individuals, or other entities responsible for initiating and managing a clinical trial) of cell and gene therapy (CGT) products at numerous points in the development and post-marketing process, including review of formal submissions (e.g., INDs or BLAs), response to meeting requests, and other, less formal interactions.

CGT is a rapidly growing and evolving field with an increasingly complex array of product modalities. The increasing workload volume (e.g., >50% increase in CGT INDs between 2016-19) and complexity associated with clinical trials for CGT products has placed significant demands on OTAT and could continue to do so in the future, with potential implications for the effectiveness of the interaction model between CBER/OTAT and CGT sponsors. FDA is seeking to identify existing areas of strength as well as potential areas for improvement in OTAT-CGT sponsor interactions throughout the product lifecycle and across relevant types of interactions (e.g., formal meetings, submissions, etc.). This research is focused on understanding the CGT sponsor perspective, as one of many sources of input for this important effort.

2. Intended Use of the Information:

The information collected during these individual interviews will help inform an internal operational diagnostic of OTAT's communications processes to identify areas where future process or systems changes might facilitate better collaboration and communication with sponsors while, where possible, simultaneously easing the demands on OTAT staff. Furthermore, insights gained from interviews may be further refined and validated in future listening sessions/focus groups with a larger group of sponsors.

The desired impact is ultimately to strengthen OTAT's CGT sponsor engagement model as a means to further progress innovation in the CGT fields and advance CBER's patient-driven mission, while also easing the demands on OTAT staff.

3. Description of Respondents:

Participants in the individual interviews will be CGT sponsors with some experience interacting or communicating with OTAT in the recent past (<5 years). Respondents will be drawn from:

- Large biopharma companies;
- Small biotechs; and
- Academic principal investigators; and
- Other groups as deemed necessary.

4. Type of Collection: (Check one box below. If you are requesting approval of other instruments under the generic clearance, complete this justification for each instrument.)

- Customer Comment Card/Complaint Form Customer Satisfaction Survey
 Usability Testing (e.g., Website or Software) Small Discussion Group
 Focus Group Other: Interview Guide

Given the ongoing COVID-19 public health emergency, all data will be collected from participants via web and telephone interviews.

Please find attached as appendices the following materials:

- (a) Invitation email to be sent to sponsors
- (b) Interview guide

5. Confidentiality of Respondents:

The following will be provided both in the email invitation to participate as well as through the interview script: “Your participation or non-participation is completely voluntary, and your responses will not have an effect on your eligibility for receipt of any FDA services. Your input will be blinded and aggregated by a third party contractor prior to being shared with CBER/OTAT. In instances where respondent identity is needed (e.g., for follow-up), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.”

6. Amount and Justification for Proposed Incentive:

Is an incentive (e.g., stipend, reimbursement of expenses, token of appreciation) provided to participants? Yes No

7. Questions of a Sensitive Nature:

This information collection does not involve questions of a sensitive nature.

8. Description of Statistical Methods

This is a qualitative study using a convenience sample. It does not entail the use of any statistical methods. A third party contractor will organize and facilitate the individual interviews. For the individual interviews, invitations to known sponsors would be sent by email. No screening will be

necessary, as individuals are known to the FDA. The interviewer will follow a structured interview guide. Up to 30 individual interviews will be scheduled, along with follow up interviews with up to half of these respondents.

The information gathered will be qualitative in nature, focusing on the expectations, needs, opinions, and utility of the experiences with OTAT. Open-ended questions will allow us to gather more qualitative information to have a better understanding of the Sponsor’s needs and develop more specific recommendations for the operational diagnostic as well as a potential future listening sessions/focus groups project. These will be followed by more structured questions which will allow the third party contractor to aggregate thematic findings from the interviews.

9. **Burden:** [Complete the table below.]

Burden Hour Computation -- (Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours).

Example:

Type of information collection/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Sponsor Interviews (Private Sector)	30	75	37.5
Follow up Interviews (Private Sector)*	15	30	7.5
Total			45

**Burden assumption is that half of the interviewees will require a follow up, so of up to 30 primary interviews, FDA expects there will be 15 follow up interviews*

10. **Federal Cost:**

There is NO estimated annual cost to the Federal government.

11. **Date(s) to be Conducted:**

March 22, 2021 – June 30, 2021

12. **Requested Approval Date:** March 22, 2021.

13. **FDA Contacts:**

Program Office Contact	FDA PRA Contact
Anne Taylor Center for Biologics Evaluation and Research Anne.Taylor@fda.hhs.gov 240-402-5683	Ila S. Mizrachi FDA Paperwork Reduction Act Ila.Mizrachi@fda.hhs.gov 301-796-7726

14. **Certification:** In submitting this request, I certify the following to be true:

- a) The collections are voluntary;
- b) The collections are low-burden for participants and are low-cost for both the participants and the Federal Government;
- c) The collections are noncontroversial;
- d) Personally identifiable information (PII) is collected only to the extent necessary and is not retained; and
- e) Information gathered will not be used for the purpose of substantially informing influential policy decisions.