# Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback"

**OMB # 0925-0642, exp., date 05/31/2020**

**TITLE OF INFORMATION COLLECTION:** CTSU Multi-Group Audit (MGA) Feedback Surveys

**PURPOSE:** The purpose of this information collection is to obtain feedback from individuals who are involved in Multi-Group Audits (MGAs), wherein sites are audited by more than one NCI Clinical Trials Research Network (NCTN) Group at the same time/visit (as opposed to being conducted at separate times/visits). MGAs are being implemented as part of a three-year pilot program led by the Clinical Trials Monitoring Branch (CTMB) and coordinated by the Cancer Trials Support Unit (CTSU). Based on early planning and budgeting, we anticipate conducting up to **125** MGAs over the three years of the pilot.

The surveys will request feedback from two types of MGA participants (site staff and auditor staff) regarding their experiences with the MGAs, and will be used to better service delivery.

The MGA feedback survey for sites will be used to collect feedback from staff members at clinical sites that have recently undergone an MGA, including investigators, clinical research coordinators, regulatory specialists, and pharmacists. The MGA feedback survey for auditor staff will be used to collect feedback from auditors and associated audit staff who have recently participated in an MGA. All feedback will be used to better service delivery of the MGAs.

**DESCRIPTION OF RESPONDENTS**: There are two main categories of respondents for this survey, both receiving similar questions: Site staff members from the sites that undergo MGAs, and auditor staff who conduct the MGAs.

Site staff members include investigators, clinical research coordinators, regulatory specialists, data managers, pharmacists, and other staff who are involved in the conduct of NCI-funded NCTN and/or National Community Oncology Research Program (NCORP) trials at their sites. There are expected to be anywhere from 5-30 site staff involved with each MGA, depending on the size and organization of the site (a figure of 15 was used for the calculations below). We are estimating that two of these staff members/site will be investigators (i.e., physicians).

Auditors are individuals who represent the various NCTN Groups (either as direct employees, i.e, staff auditors, or as volunteer/ad hoc auditors) and conduct site visits on behalf of the Groups to document the accuracy of data submitted to the Groups and to verify investigator compliance with protocol and regulatory requirements. Associated auditor staff members work in the NCTN Group audit offices and are involved in various aspects of the audits, but do not attend the audit visits themselves. Auditors are a mix of physician and non-physicians, with the latter being more numerous; it is estimated that approximately 33% of auditors are physicians.

**TYPE OF COLLECTION:** (Check one)

[ ] Customer Comment Card/Complaint Form     [X] Customer Satisfaction Survey
[ ] Usability Testing (e.g., Website or Software     [ ] Small Discussion Group
[ ] Focus Group     [ ] Other:_

**CERTIFICATION:**

I certify the following true:
1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does <u>not</u> raise issues of concern to other federal agencies.
4. The results of the website survey are <u>not</u> intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of <u>substantially</u> informing <u>influential</u> policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name:  Gary Smith, Branch Chief, CTMB

To assist review, please provide answers to the following question:

**Personally Identifiable Information:**
1. Is personally identifiable information (PII) collected?  [  ] Yes  [X]  No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974?   [  ] Yes [X] No
3. If Applicable, has a System or Records Notice been published?  [  ] Yes  [X] No

**Gifts or Payments:**
Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants?  [ ] Yes [ X ] No

**ESTIMATED BURDEN HOURS and COSTS**

| Category of Respondent | Instrument | No. of Respondents | No. of Responses per Respondent | Time per Response (in hours) | Total Burden Hours |
|---|---|---|---|---|---|
| Individual | Multi-Group Audit (MGA) Feedback Survey – Site Staff | 1875 | 1 | 10/60 | 313 |
| Individual | Multi-Group Audit (MGA) Feedback Survey – Audit Staff | 625 | 1 | 10/60 | 104 |
| **Total** | | **2500** | **2500** | | **417** |

| Category of Respondent | Total Burden Hours | Wage Rate* | Total Burden Cost |
|---|---|---|---|
| Individuals | 417 | $67.66 | $28,212.14 |
| **Totals** | | | $28,212.14 |

*Wage estimates are an average based upon a generic category of Health Care Practitioner at a median  hourly wage rate of $35.83 per hour for allied health professionals (code 29-1199) and $99.48 per hour for Physicians and Surgeons, All Other (code 29-0169) for collections limited to physicians.  Information is provided by the Bureau of Labor Statistics website at http://www.bls.gov/oes/current/oes290000.htm.

**FEDERAL COST:**  The estimated annual cost to the Federal government is $15,726

| Staff | Grade/Step | Salary | % of Effort | Fringe (if applicable) | Total Cost to Gov't |
|---|---|---|---|---|---|
| **Federal Oversight** | | | | | |
| CTMB Branch Chief | 15/8 | $164,200 | 1% over 3 years | | $4,926.00 |
| **Contractor Cost** | | | | | |
| Data collection | | | | | $10,800.00 |
| **Travel** | | | | | 0 |
| **Other Cost** | | | | | 0 |
| **Total Cost** | | | | | $15,726 |

**If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**

**The selection of your targeted respondents**
1.  Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?
                                                              [X] Yes          [ ] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)?   If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Potential respondents will be drawn from site staff at the sites participating in the MGAs as well as the auditors and audit staff involved with the conduct of the MGAs.  With respect to site staff, aside from the primary investigator and coordinator contacts for each site (obtained from the auditing Groups and the CTSU's Regulatory Support System (RSS) database), other site staff who were involved with the MGA will be asked to provide their names and contact information at each of the NCTN Group "exit interviews" during the MGA visit; this will provide a broad selection of site staff to request feedback from.

Auditor staff participating in MGAs will be known from the official assignments made during the MGA planning and scheduling process; their contact information can be obtained from the auditing Groups and/or RSS.

The surveys will be sent out on a rolling basis within two weeks following each MGA visit. MGA participants (site staff and audit staff) will receive an email invitation to participate in one of the two online MGA feedback surveys.  This invitation will describe the purpose of the survey and approximate burden time.  A link to the survey in Survey Monkey will be included in the email, whereby the individual will access the survey landing page.

The project team will review the survey data over time to identify:
- The common benefits of MGAs as noted by the site staff and audit staff (and if any differences by respondent role)
- The common challenges of MGAs as noted by the site staff and audit staff (and if any differences by respondent role)
- Potential process/procedure improvements to address the findings noted above.
- Stated preferences for participating in MGAs in the future vs. going back to the standard single-Group audits (and if any differences by respondent role)


**Administration of the Instrument**
1. How will you collect the information? (Check all that apply)
     [X] Web-based or other forms of Social Media
     [ ] Telephone
     [ ] In-person
     [ ] Mail
     [ ] Other, Explain
2. Will interviewers or facilitators be used?  [ ] Yes [X] No

**Please make sure that all instruments, instructions, and scripts are submitted with the request.**