

Attachment 2. Example of Customer Satisfaction Survey

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Food and Drug Administration Amendments Act (FDAAA) Implementation at NIH

Survey of Grantees

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Introduction

This survey of NIH grantees with trials registered in ClinicalTrials.gov is to help examine NIH's **implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA;** http://grants.nih.gov/clinicaltrials_fdaaa/index.htm). The objective is to improve of the certification of compliance process and enhance grantee's understanding FDAAA's requirements throughout the lifecycle of applicable clinical trials. This is the first annual "point in time" survey to gather grantees' opinions about the certification of compliance with FDAAA. This information will be useful in assessing the changes introduced by NIH implementation of FDAAA and may be used to further improve the peer review process.

You have been **randomly selected** to participate in this survey from a pool of grantees who received NIH funds to support the conduct of clinical trials (other than Phase 1) from September 2007 to the present. We are interested in the opinions of grantees with different levels of experience with NIH-funded applicable clinical trials. Even if you have limited experience applicable clinical trials, **your opinions are very important to us.**

The survey should take approximately 15 minutes to complete. You can stop at any point and continue at another time. There are no right or wrong answers, so please give the answer that best describes your opinion. While we would like you to answer all the questions in this survey, you may skip any questions that you do not wish to answer.

Your participation is fully voluntary and non-participation will have no impact on eligibility for or receipt of future services. If you choose to complete the survey, your responses will remain **anonymous**. Your responses will **not** be linked to your name and will **not** be made known to NIH staff. Steps have been taken to ensure unbiased completion of questionnaires by use of third-party distribution and receipt by a party not directly involved in provision of the service being assessed.

Aggregate responses will be used to guide NIH management in refining its implementation of the certification of compliance with FDAAA and enhance grantee understanding of FDAAA's requirements throughout the lifecycle of an applicable clinical trial.

Your participation is greatly appreciated.

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Section A: Your Clinical Trials Experiences

1. How long have you been an NIH grantee?
 <1 year
 1-5 years
 6-10 years
 > 10 years

2. How many of the clinical trials for which you are key personnel are registered in ClinicalTrials.gov?
 1
 2-5
 6-10
 > 10

3. Were any of the clinical trials supported by your NIH funds registered in ClinicalTrials.gov (e.g. either to meet FDAAA or as a requirement for publication in the ICJME associated journals)?
 Yes (please continue to Question 3.)
 No (please continue to Section B.)

4. Did any of your NIH grants support (in whole or in part) an “applicable clinical trial”?
 Yes
 No

5. Does your Institution provide a Protocol Registration System (PRS) organizational account for you to register your trials in ClinicalTrials.gov?
 Yes
 No

6. Does your Institution provide logistical support for clinical trials data analysis and results reporting to ClinicalTrials.gov?
 Yes
 No

7. How much time do you spend each month inputting data into ClinicalTrials.gov?
 <1 hour
 1-5 hours
 6-10 hours
 > 10 hours

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Section B: Your Understanding of FDAAA

8. How helpful is your Institution in determining your responsibilities for compliance with FDAAA?

1-----2-----3-----4-----5
not at all helpful very helpful

9. How helpful is your NIH Program Official in explaining your responsibilities for NIH certification of compliance with FDAAA?

1-----2-----3-----4-----5
not at all helpful very helpful

10. Where do you acquire guidance on FDAAA and your clinical trials (check all that apply)?

- Your Institution's sponsored research office
- NIH web sites and staff
- FDA web sites and staff
- Private consulting firm
- Colleagues

11. What parts of FDAAA do you find the most challenging to understand (check all that)?

- Identifying "applicable clinical trials"
- Identifying the "responsible party"
- Identifying milestones for registration and results reporting requirements
- Inputting results
- Inputting adverse events
- Other (please describe): _____

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Section C: NIH Certificates of Compliance with FDAAA

12. Based on your understanding, which of the following require NIH certification of compliance with FDAAA in competing applications and/or progress reports submitted to the NIH?

- on-going** applicable clinical trials only
- proposed** applicable clinical trials only
- both** on-going and proposed applicable clinical trials
- neither** on-going and proposed applicable clinical trials

13. How much time do you spend each month on NIH certificates of compliance with FDAAA?

- <1 hour
- 1-4 hours
- 5-10 hours
- > 10 hours

14. Is the time spent on NIH certificates of compliance with FDAAA burdensome?

- yes
- no