

Human Subjects Tracking Form for Contracts, Purchase (Requisition) & Task Orders, Modifications to Contracts, and for New, Renewal, and Noncompeting Continuation Grants and Cooperative Agreements

Instructions:

1. Complete for each, single award.
2. For Contracts, Grants & Cooperative Agreements, Purchase (Requisition) & Task Orders, Modifications:
 - a. Complete Parts A and B.
 - b. Submit to PGO with RFC (Request for Contract), FOA (Funding Opportunity Announcement), purchase (requisition) request, task order request or modification request.
 - c. Note: Some information requested in Part B may not be available until an award is made.

Part A: Complete for each award. (Complete applicable items.)

CIO: _____ (including Division/Office)

Purchase Order (Requisition) Number, Contract Number, Grant or Cooperative Agreement number, Task Order Number (including contract number), Modification Number (including contract number): _____

Title of Project: _____

Name of CIO Project Officer/Program Official: _____ Telephone Number: _____
 Mailstop: _____

- | | | | |
|----|--|-----|----|
| 1. | Are there definite research plans?
If no, state specific reasons below, and skip to signatures:
_____ | Yes | No |
| 2. | Will the grantee conduct human subject research in the next funding cycle?
If no, state specific reasons above, and skip to signatures. | Yes | No |

Part B: Complete when award involves human subjects.

Identify each of the research activities involving human participants by title and answer each question.

(1) (Title)

- | | | | |
|----|---|-----|---------------------------|
| 1. | Have IRB approvals been received for each performance site?
If no, when is/are approval(s) anticipated to be completed for all sites? _____
(Estimated Date – MM/YYYY) | Yes | No |
| 2. | Are CDC scientists engaged in this research activity?
If yes, has the project been reviewed at CDC for human subjects' protection?
List the CDC human subject protocol number and date of expiration: | Yes | No |
| | CDC Protocol Number: _____ | | Date of Expiration: _____ |

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3. Is this activity exempt under one of the 6 exemptions in 45 CFR 46.101(b)? Yes No

If yes, provide exemption categories: _____

4. Is there more than one site engaged in the research supported under this funding mechanism? Yes No

List the funding recipient institution/organization and any additional performance sites. Please include the Name of the Organization, Federal Wide Assurance (FWA) number and expiration date and the IRB protocol identifier and expiration date for each site:

5. Is a human subjects' restriction required on the notice of award? Yes No
If yes, identify the reason for the human subjects' restriction, and the amount of funds to be restricted:

APPROVALS (Signature and Position Title):	DATE	REMARKS
Project Officer/Program Official:		
Branch Chief or Branch ADS:		
Division ADS or Human Subjects Contact:		
CIO (Human Subjects Contact):		

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Identify each of the research activities involving human participants by title and answer each question.

(2) (Title)

1. Have IRB approvals been received for each performance site? Yes No
 If no, when is/are approval(s) anticipated to be completed for all sites? _____
(Estimated Date – MM/YYYY)

2. Are CDC scientists engaged in this research activity? Yes No
 If yes, has the project been reviewed at CDC for human subjects' protection? Yes No
 List the CDC human subject protocol number and date of expiration:
 CDC Protocol Number: _____ Date of Expiration: _____

3. Is this activity exempt under one of the 6 exemptions in 45 CFR 46.101(b)? Yes No
 If yes, provide exemption categories: _____

4. Is there more than one site engaged in the research supported under this funding mechanism? Yes No
 List the funding recipient institution/organization and any additional performance sites. Please include the
 Name of the Organization, Federal Wide Assurance (FWA) number and expiration date and the IRB protocol
 identifier and expiration date for each site:

5. Is a human subjects' restriction required on the notice of award? Yes No
 If yes, identify the reason for the human subjects' restriction, and the amount of funds to be restricted:

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Identify each of the research activities involving human participants by title and answer each question.

(3) (Title)

1. Have IRB approvals been received for each performance site? Yes No
 If no, when is/are approval(s) anticipated to be completed for all sites? _____
(Estimated Date – MM/YYYY)

2. Are CDC scientists engaged in this research activity? Yes No
 If yes, has the project been reviewed at CDC for human subjects' protection? Yes No
 List the CDC human subject protocol number and date of expiration:
 CDC Protocol Number: _____ Date of Expiration: _____

3. Is this activity exempt under one of the 6 exemptions in 45 CFR 46.101(b)? Yes No
 If yes, provide exemption categories: _____

4. Is there more than one site engaged in the research supported under this funding mechanism? Yes No
 List the funding recipient institution/organization and any additional performance sites. Please include the
 Name of the Organization, Federal Wide Assurance (FWA) number and expiration date and the IRB protocol
 identifier and expiration date for each site:

5. Is a human subjects' restriction required on the notice of award? Yes No
 If yes, identify the reason for the human subjects' restriction, and the amount of funds to be restricted:

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Identify each of the research activities involving human participants by title and answer each question.

(4) (Title)

1. Have IRB approvals been received for each performance site? Yes No
 If no, when is/are approval(s) anticipated to be completed for all sites? _____
(Estimated Date – MM/YYYY)

2. Are CDC scientists engaged in this research activity? Yes No
 If yes, has the project been reviewed at CDC for human subjects' protection? Yes No
 List the CDC human subject protocol number and date of expiration:
 CDC Protocol Number: _____ Date of Expiration: _____

3. Is this activity exempt under one of the 6 exemptions in 45 CFR 46.101(b)? Yes No
 If yes, provide exemption categories: _____

4. Is there more than one site engaged in the research supported under this funding mechanism? Yes No
 List the funding recipient institution/organization and any additional performance sites. Please include the
 Name of the Organization, Federal Wide Assurance (FWA) number and expiration date and the IRB protocol
 identifier and expiration date for each site:

5. Is a human subjects' restriction required on the notice of award? Yes No
 If yes, identify the reason for the human subjects' restriction, and the amount of funds to be restricted:

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Identify each of the research activities involving human participants by title and answer each question.

(5) (Title)

1. Have IRB approvals been received for each performance site? Yes No
 If no, when is/are approval(s) anticipated to be completed for all sites? _____
(Estimated Date – MM/YYYY)

2. Are CDC scientists engaged in this research activity? Yes No
 If yes, has the project been reviewed at CDC for human subjects' protection? Yes No
 List the CDC human subject protocol number and date of expiration:
 CDC Protocol Number: _____ Date of Expiration: _____

3. Is this activity exempt under one of the 6 exemptions in 45 CFR 46.101(b)? Yes No
 If yes, provide exemption categories: _____

4. Is there more than one site engaged in the research supported under this funding mechanism? Yes No
 List the funding recipient institution/organization and any additional performance sites. Please include the
 Name of the Organization, Federal Wide Assurance (FWA) number and expiration date and the IRB protocol
 identifier and expiration date for each site:

5. Is a human subjects' restriction required on the notice of award? Yes No
 If yes, identify the reason for the human subjects' restriction, and the amount of funds to be restricted:

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Identify each of the research activities involving human participants by title and answer each question.

(6) (Title)

1. Have IRB approvals been received for each performance site? Yes No
 If no, when is/are approval(s) anticipated to be completed for all sites? _____
(Estimated Date – MM/YYYY)

2. Are CDC scientists engaged in this research activity? Yes No
 If yes, has the project been reviewed at CDC for human subjects' protection? Yes No
 List the CDC human subject protocol number and date of expiration:
 CDC Protocol Number: _____ Date of Expiration: _____

3. Is this activity exempt under one of the 6 exemptions in 45 CFR 46.101(b)? Yes No
 If yes, provide exemption categories: _____

4. Is there more than one site engaged in the research supported under this funding mechanism? Yes No
 List the funding recipient institution/organization and any additional performance sites. Please include the
 Name of the Organization, Federal Wide Assurance (FWA) number and expiration date and the IRB protocol
 identifier and expiration date for each site:

5. Is a human subjects' restriction required on the notice of award? Yes No
 If yes, identify the reason for the human subjects' restriction, and the amount of funds to be restricted:
