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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: NCEH/DEEHS/Healthy Homes and Lead Poisoning Prevention Program (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: Lead Poisoning Prevention: Childhood Lead Poisoning Prevention

_____

Name of CIO Project Officer/Program Official:

Kimball F. Credle
EEHS/Healthy Homes and Lead Poisoning Prevention Program

Telephone Number: 770-488-3643

Mailstop: F-58

1. Are there definite research plans? ☐ Yes ☒ No
   If no, state specific reasons below, and skip to signatures:
   This is a prevention grant for state/local health department designed primarily to identify high-risk areas, ensure testing of children less than 6 years of age, and reporting of data associated with testing.
2. Will the grantee conduct human subject research in the next funding cycle? ☐ Yes ☐ No
   If no, state specific reasons above, and skip to signatures.

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? ☐ 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: _____

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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: Kimball Credle -S Digitally signed by Kimball Credle -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, cn=Kimball Credle -S, 0.9.2342.19200300.100.1.1=1000689221 Date: 2017.01.31 08:47:28 -05'00'	01/31/2017	
Branch Chief or Branch ADS: Sheila R. Stevens -S Digitally signed by Sheila R. Stevens -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000277259, cn=Sheila R. Stevens -S Date: 2017.01.31 12:01:04 -05'00'	01/31/2017	
Division ADS or Human Subjects Contact: Stephanie I. Davis -S Digitally signed by Stephanie I. Davis -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1001232781, cn=Stephanie I. Davis -S Date: 2017.01.31 12:47:24 -05'00' Stephanie Davis, on behalf of Helen Schurz-Rogers	01/31/2017	
CIO (Human Subjects Contact): Padmaja Vempaty Digitally signed by Padmaja Vempaty DN: cn=Padmaja Vempaty, o=CDC/ATSDR, ou=NCEH/ATSDR, email=dmy6@cdc.gov, c=US Date: 2017.01.31 13:02:52 -05'00'	01/31/2017	

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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:

_____

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