OMB#: 0925 – 0625
Expiry Date: 01/31/2014

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NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0625). Do not return the completed form to this address.

Locally-Developed Material Submission Form

Submit this form with the participant-directed materials to the CIRB via email at localcontextcirb@emmes.com. One study per form.)

Section A: General Information

1. Name of Signatory Institution: _____
2. Principal Investigator Name: _____
3. Name of Person Completing the Report if other than the PI: _____

    a. Email Address: _____
    b. Phone Number: _____

4. Study Number Associated with Materials: _____

    a. Study Title: _____
    b. Protocol Version Date: _____

5. The materials being submitted are:

- ☐ Recruitment and/or Educational Materials (complete Section B)
- ☐ Translated Materials (complete Section C)
- ☐ Both (complete Sections B and C)

Section B: Locally-Developed Participant-Directed Materials

NOTE: PIs are encouraged to submit drafts for CIRB review to avoid incurring expenses related to the production of materials that might be revised by the CIRB.

1. Identify the recruitment and/or educational materials that are being submitted at this time:

☐ Newspaper Ad	☐ Recruitment Letter	☐ Informational Article
☐ Poster/Flyer	☐ Website/Internet Posting	☐ Phone Screening Script
☐ Brochure	☐ Radio/Media Script	☐ Other:_____

2. Please choose one option:

☐ This material is new and has not yet been IRB-approved.

☐ This IRB-approved material is being submitted to the CIRB with modifications as outlined below:

_____

NOTE: A track changes version and a clean version of the material must be included with the submission.

Section C: Translated Materials

In order for the CIRB to review and approve translated documents, the English language version of the document must already have CIRB approval.

1. CIRB review and approval of the following translated study-specific documents is requested.

   Check all that apply:

   ☐ Informed Consent Document (ICD). If the study has multiple ICDs, list ICD titles below:
   1. _____
   2. _____
   3. _____
   4. _____

   ☐ Other documents (list below):
   1. _____
   2. _____
   3. _____
   4. _____

2. The following documents are required (Check off below when document is attached):

   ☐ CIRB-approved English language document(s) corresponding to the translated document

   ☐ Translated version(s) of the CIRB-approved English language document

☐ Translator's Certificate(s) of Accuracy or equivalent document(s)

If you have any questions regarding the completion of this request, please contact the CIRB Helpdesk at 888-657-3711 or ncicirbcontact@emmes.com.