OMB #0925-xxxx
Expiration Date: xx/xx/xxxx

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 5469

To: Montello, Michael
NCI
EPN - Executive Plaza North, 7024

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Though data is being collected by the CIRB, there is no intent to use this information for research in any form. The data being collected is for the sole purpose of fulfilling the mission o the Central Institutional Review Board (CIRB). The dat available is not intended in any use other than to conduct IRB review of studies. Therefore, data are not being collected on human subject participants as part of the CIRB Initiative. The CIRB improves access to NCI-sponsored Cooperative Group clinical trials for potential study participants and

Original Request Received in OHSR on: 10/19/2010

Responsible NIH Research Investigator(s): Michael Montello, NCI

OHSR review of your request dated Thu, Oct 14, 2010 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person SPC Admin Assist. CB

Note:

Charlotte Holden, JD — Acting Director, OHSR — 10/25/2010

Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#5469

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: October 14, 2010

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Mike Montello 10/15/10
(Signature)

Through: Steve Friedman
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Protocol Title: NCI Central Institution Review Board (CIRB)
Name of NIH Principal Investigator(s): Mike Montello, PharmD, MBA

IC: NCI/NIH Laboratory/Branch CIB/CTEP/DCTD
Building & Room No.: EPN, Rm 7036_ Tel. No: 301-435-9206 FAX No.: 301-480-4663

Is the Principal Investigator an NIH employee? X Yes No
If no, please explain:

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):
Though data is being collected by the CIRB, there is no intent to use this information for research in any form. The data being collected is for the sole purpose of fulfilling the mission of the Central Institutional Review Board (CIRB). The data available is not intended for any use other than to conduct IRB review of studies. Therefore, data are not being collected on human subject participants as part of the CIRB Initiative.

The CIRB improves access to NCI-sponsored Cooperative Group clinical trials for potential study participants and their physicians by enabling local IRBs to rapidly approve clinical trials through the use of a facilitated review process. The NCI Central Institutional Review Board (CIRB) Initiative reviews protocol, informed consent document(s), completed CIRB application(s); and when appropriate, an investigator drug brochure. The CIRB reduces the administrative burden on local IRB's and investigators.

2. If applicable, list your non-NIH Collaborating Investigator(s).
Name Institution Address Tel. # FAX #

_____

_____

3. Proposed start date of your research __Research is not being conducted.
[The Adult CIRB began meeting January 2001; The Pediatric CIRB began meeting November 2004.]

Proposed completion date? There is no research being conducted.

4. Will you be _____these samples or data?

Collecting Yes/No
Receiving Yes/No
Sending Yes/No

5. Do the samples or data:
(a) Already exist?___Yes __X_No
(b) Or are they being collected for the express purpose of this study?
___Yes __X__No
If "yes," please describe:_____
(c) Or a combination of (a) and (b)? ___ Yes _____No

6. What role will you have in this research project? (Check all that apply)

___ Analyze samples/data only.
___ Consultant/advisor to collaborator(s) listed above.
___ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).
___ Co-authorship on publication(s)/manuscript(s) pertaining to this research.
___ You or NIH hold an IND for this research.
___ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.
____ Other (If necessary, use this space to describe your role in this research).

***We are not conducting a research project. The CIRB improves access to NCI-sponsored Cooperative Group clinical trials for potential study participants and their physicians by enabling local IRBs to rapidly approve clinical trials through the use of a facilitated review process.

7. Where are the subjects of this research activity located?

Though data is being collected by the CIRB, there is no intent to use this information for research in any form. The data being collected is for the sole purpose of fulfilling the mission of the CIRB. The data available is not intended for any use other than to conduct IRB review of studies. Therefore, data are not being collected on human subject participants as part of the CIRB Initiative.

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8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ___Yes ____ No

* no human subjects

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?

The NCI uses various information collection tools to support CIRB activities, though none of them are being collected for research purposes. These include forms requiring completion by a site conducting a clinical trial eligible for review by the CIRB, as well as forms completed by the CIRB members themselves.

There are 6 general areas in which forms are completed and data are collected. These include:

1. CIRB Helpdesk survey: collects customer feedback pertaining to the use of the CIRB helpdesk.
2. CIRB Institution Enrollment Forms: Enrollment documents collect information on the institutions interested in enrolling or having already enrolled in the CIRB Initiative.
3. CIRB Membership Information: Membership documents collect information on CIRB members. Information requested includes: name, degree, college and/or university attended, graduation year, bio sketch, headshot, title, place of employment, address, email address, telephone number, and picture. This is public accessible information.
4. Direct Deposit Form: This is an optional form for CIRB Members to complete should they choose to receive honoraria via direct deposit.
5. IRB Application Forms: The application forms are required to be submitted to the CIRB in order to complete a submission for review.
6. CIRB Reviewer Forms: Theses forms are completed by the Board Members when they submit reviews.

The CIRB Helpdesk Survey seeks to collect information that can be used by the CIRB in a systematic fashion to improve operations and enhance reviewer satisfaction with the initiative. The remaining forms are necessary in order to facilitate a complete review of protocols by the CIRB with the absence of conflict of interest in place.

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10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes _x_ No

(b) Pathological waste ___ Yes __x_ No

(c) Autopsy material ___ Yes __x_ No

(d) Publicly available source ___Yes _X_ No

(e) Other__

Cooperative Groups, Board Members, and Institutions supply a variety of information for the conduct of the CIRB, though none of the data collected is for the intent of research.

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) ____ Samples and/or data will be anonym zed/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) ___ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) ___ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?

_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

<u>There is no research being conducted.</u> <u>This project is Exempt. The reason for the exemption would be as cited in 45 CFR 46.101(b) (4): (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these</u>

sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

_____ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for **each** IRB):

_____ Name of institution that provided the review
_____ Address of reviewing institution
_____ Name of PI for the IRB approved protocol
_____ Title of IRB approved protocol and protocol #
_____ Federal Wide Assurance (FWA) number**

___ No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance***, have conflicts of interest by NIH employees, if any, been resolved?
_x_ Yes _____No

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

Brentin, Christine (NIH/OD) [E]

From: Jennifer Dugan [jdugan@emmes.com]
Sent: Tuesday, October 19, 2010 10:07 AM
To: OHSR (NIH/DDIR); Pursley-Crotteau, Suzanne (NIH/OD) [E]
Cc: Montello, Mike (NIH/NCI) [E]; Friedman, Steve (NIH/NCI) [E]; Adler, Jeanne (NIH/NCI) [E]; Valmonte, Claudine; Goldberg, Jacquelyn (NIH/NCI) [E]
Subject: OHSR Application
Follow Up Flag: Follow up
Flag Status: Red
Attachments: OHSR App_101510.pdf

Dear OHSR,

Please review the attached CIRB Application.

Per instruction, signatures were obtain in advance and hopefully any remaining items can be resolved via email.

Thanks,

Jennifer

Jennifer L. Dugan, MS
Project Manager
NCI CIRB Operations Office
The EMMES Corporation
401 N. Washington Street, Suite 700
Rockville, MD 20850
Phone: 301-251-1161 x2827
Fax: 301-251-1355
jdugan@emmes.com
www.emmes.com

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Tuesday, October 19, 2010 2:35 PM
To: Montello, Mike (NIH/NCI) [E]
Cc: 'jdugan@emmes.com'
Subject: Request for Review Rec'd-OHSRP 5469

Good afternoon Dr. Montello,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as **OHSRP #5469.** Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: NCI Central Institution Review Board (CIRB)

Thank you.

Sincerely,

OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


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