

**OMB Text**

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 20 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.

**Reason for submission:**

Add Note

(Required)

- First Submission of the Annual Principal Investigator Worksheet About Local Context
- Revised Submission of the Annual Principal Investigator Worksheet About Local Context

**Signatory Institution Information**

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**Submitting User Information**

Campbell, Brian

<b>Email:</b>	bcampbell@emmes.com	<b>NCI Person ID Number:</b>	
<b>Contact Roles:</b>	Investigator, User		
<b>Address:</b>		<b>Phone:</b>	

**1. Enter Principal Investigator email address.**

Add Note

(Required)

jwalter@emmes1.com

Walter, Jay PhD

<b>Business Address:</b>	12 My Court Anyplace, CA 21701	<b>Business Phone:</b>	(215)707-3390
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If the message "Contact not found." appears, it means that this PI cannot be found in the CIRB database. Email the Helpdesk at [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com) or call 1-888-657-3711 to determine what action is required.

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**1. Enter Principal Investigator email address.**

Add Note

(Required)

If the message "Contact not found." appears, it means that this PI cannot be found in the CIRB database. Email the Helpdesk at [ncicirbcontact@emmes.com](mailto:ncicirbcontact@emmes.com) or call 1-888-657-3711 to determine what action is required.

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**2. Name of Signatory Institution**

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Test University  
12 Street  
Ste. 304  
Anyplace, CA, 21701

**Research Staff**

[Add Note](#)

**3. How many sub-investigators do you have supporting you in conducting CIRB-approved research?**

(Required)

**4. How many research nurses/CRAs do you have supporting you in conducting CIRB-approved research?**

(Required)

**5. Have you or any of your research staff reported a financial conflict of interest related to any studies on the CIRB menu that resulted in a management plan?**

(Required)

- Yes
- No

**NOTE: Principal Investigator Education, Training, and Experience**

*No additional information is required. Information pertaining to investigator education, training, and experience is captured annually through the NCI Investigator Registration.*

**Principal Investigator Resources**

[Add Note](#)

**6. How many actively accruing research studies, for which you are the PI, do you have open, including CIRB-approved and those not reviewed by the CIRB?**

(Required)

**a. List CIRB-approved studies by Study ID Number.**

[Add Note](#)

**7. How many study participants are currently receiving study intervention for studies for which you are the PI?**

(Required)

**Recruitment**

[Add Note](#)

**8. Describe how potential study participants are identified and recruited to CIRB-approved studies.**

(Required)

**If applicable, an attachment can be added here.**

[Add Note](#) [View Audit](#)

[Add Attachment](#)  
No Attachments added.

**9. Identify recruitment materials usually used:**

[Add Note](#)

(Required)

- Cooperative Group/sponsor-supplied handouts
- Locally-developed educational materials (Reminder: Study-specific material requires CIRB approval)
- Other

**Please describe.**

[Add Note](#)

### Compensation to Study Participants

[Add Note](#)

10. The CIRB is aware that there is typically no compensation provided for CIRB-approved studies to study participants. Describe any compensation/incentives provided by the Signatory Institution or others to study participants enrolled in CIRB-approved studies, for example: parking validation, cafeteria voucher, other.

(Required)

### Informed Consent Process

Answer the following questions regarding the process used to introduce a trial to a potential study participant and obtain their informed consent.

#### 11. Where does the consent discussion take place?

[Add Note](#)

(Required)

#### 12. Who is authorized to obtain consent?

[Add Note](#)

(Required)

#### 13. How long does the potential study participant have to review the consent document before a response is required, including time to take the consent document home?

[Add Note](#)

(Required)

**14. Who is available to answer questions?** Add Note

(Required)

**15. How is the potential study participant's understanding of consent assessed?** Add Note

(Required)

**16. How is the informed consent process conducted with non-English speaking potential study participants?** Add Note

(Required)

**17. Who provides consent?** Add Note

(Required)

Potential study participant *Check all that apply.*

Parent for potential pediatric study participant

Legally Authorized Representative

Other

**Please explain.** Add Note

**18. For what languages are translations routinely provided?** Add Note

(Required)

**If translations are routinely provided, what process is currently used to translate the informed consent document?** [Add Note](#)

**If applicable, an attachment can be added here.** [Add Note](#) [View Audit](#)

No Attachments added. *Reminder: Translations must be CIRB-approved prior to presenting to a potential study participant.*

**19. Describe your institution's policy regarding assent by children or impaired adults.** [Add Note](#)

*(Required)*

**If applicable, an attachment can be added here.** [Add Note](#) [View Audit](#)

No Attachments added.

**20. Describe your institution's process to receive and address concerns from study participants and others about the conduct of the research.** [Add Note](#)

*(Required)*

**Pharmacy Information** [Add Note](#)

**21. Will the drugs/agents used in the study be managed by a pharmacist?**

*(Required)*

Yes

No

[Add Note](#)

**If a pharmacist will be managing the drugs/agents used in the study, provide the name and title of the pharmacist at each practice location where research will be conducted.**

▲ ABC ▼

[Add Note](#)

**If the drugs/agents will not be managed by a pharmacist, provide the name and title of the responsible person for the drugs/agents at each practice/location where research will be conducted.**

▲ ABC ▼

[Add Note](#)

**22. How is the pharmacist/responsible person provided with a copy of the protocol at each practice location?**

*(Required)*

▲ ABC ▼

**Measures to Protect Confidentiality**

Confidentiality is defined as the study participant's understanding of, and agreement to, the ways identifiable information pertaining to them will be stored and shared. Identifiable information can be printed, electronic, or visual (such as photographs).

[Add Note](#)

**23. Check all measures that will be used to maintain the confidentiality of identifiable information.**

*(Required)*

- Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.
- Computer-based files will be available to study personnel through the use of access privileges and passwords.
- Prior to obtaining access to identifiable information, study personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.
- Whenever feasible, identifiers will be removed from study-related information.
- Other

[Add Note](#)

**Please describe.**

▲ ABC ▼

## Measures to Protect Privacy

Privacy is defined as the study's participant's ability to control how other people see, touch, or obtain information about them. Violations of privacy can involve circumstances such as being seen without clothing or partially clothed, being photographed without consent, being asked personal questions in a public setting, etc.

### 24. Check all measures that will be used to maintain the study participant's privacy.

[Add Note](#)

(Required)

- Use of drapes or other barriers to vision for subjects who are required to disrobe.
- Consent is obtained prior to collecting photographs involving study participants.
- Sensitive information is collected and used with respect to maintaining privacy.
- Individuals are not identified publicly without their consent.
- Other

Please describe.

[Add Note](#)

## Emergency Resources

[Add Note](#)

### 25. Check all resources available at the site to treat emergencies resulting from study-related procedures.

(Required)

- ACLS trained personnel and crash cart
- BCLS trained personnel
- Emergency response team within facility
- Emergency drugs and supplies to stabilize study participant until emergency personnel arrive
- Staff available to call 911
- Other

Please describe.

[Add Note](#)

## Using a Legally Authorized Representative (LAR)


[Add Note](#)

### 26. Do you plan on enrolling study participants through an LAR?

(Required)

- Yes
- No

### 27. At your institution, describe who may serve as an LAR.


[Add Note](#)

If applicable, an attachment can be added here.

[Add Note](#) [View Audit](#)

No Attachments added.

### 28. Provide a description of how you assess a potential study participant's ability to provide consent.

[Add Note](#)

If applicable, an attachment can be added here.

[Add Note](#) [View Audit](#)

No Attachments added.



## Vulnerable Populations

**Note about prisoners: The CIRB is not constituted to review research involving prisoners. If an investigator wishes to enroll prisoners in a study, IRB review must be conducted by the local IRB.**

**29. Check all vulnerable populations from which you intend to enroll.**

[Add Note](#)

- Children
- Pregnant women
- Economically disadvantaged
- Educationally disabled
- Physically disabled
- Other

**Please describe.**

[Add Note](#)

**For each vulnerable population checked, indicate safeguards.**

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## Safeguards for Children

[Add Note](#)

**Check all safeguards you use for children. (Required)**

- Youth Information Sheets
- Assent
- Extra Monitoring
- Researchers credentialed in pediatrics
- Other health professionals with pediatrics experience
- Other

**Please describe.**

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## Safeguards for Pregnant Women

Add Note

Check all safeguards you use for pregnant women. (Required)

- Inclusion is scientifically appropriate based on preclinical studies
- Information is provided pertaining to how study intervention could impact the woman and the fetus
- Other

Please describe.

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## Safeguards for Economically Disadvantaged

Add Note

Check all safeguards you use for the economically disadvantaged. (Required)

- Cost burden is fully explained
- No financial incentives are provided
- Social services are available to assist study participant
- Other

Please describe.

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## Safeguards for Educationally Disabled

Add Note

Check all safeguards you use for the educationally disabled. (Required)

- Verbal explanation of the research is provided in lay language
- Extra time is available to answer questions
- At the potential study participant's request, family members/significant others can participate in informed consent process
- Caregiver to assist with medications and identifying adverse events
- Translations are available, if needed
- Other

Please describe.

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## Safeguards for Physically Disabled

[Add Note](#)

Check all safeguards you use for the physically disabled. *(Required)*

- Treatment facility is accessible
- Assistance is available, as needed
- Witness to consent is available, as needed
- Other

Please describe.

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## Other Vulnerable Populations

[Add Note](#)

Describe all safeguards you use for 'Other' vulnerable populations.

*(Required)*

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**Additional Confirmations When Investigator Intends to Enroll Pregnant Women [45 CFR 46.204 (h), (i), (j)]**

Confirm the following statements by choosing 'Yes'.

**30. No inducements will be offered to terminate a pregnancy.**

[Add Note](#)

(Required)

Yes

No

**31. Research team will have no part in decisions related to the timing, method, or procedures used to terminate the pregnancy.**

[Add Note](#)

(Required)

Yes

No

**32. Research team will have no part in determining the viability of a neonate.**

[Add Note](#)

(Required)

Yes

No

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**You've completed the form. You can now either save the form for later revision, or submit it.**

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[Submit](#)