2 - Annual PI Worksheet About Local Context -- PI Information

OMB Text

OMB#: 0925 – 0625

Expiry Date: 01/31/2014

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Add Note

Reason for submission:

(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

View Audit

Submitting User Information

Campbell, Brian

Email:	bcampbell@emmes.com	**NCI Person ID Number:**	
Contact Roles	Investigator, User		
Address:		**Phone:**	

Add Note

1. Enter Principal Investigator email address.

(Required)

jwalter@emmes1.com

Walter, Jay PhD

Business Address:	12 My Court Anyplace, CA 21701	**Business Phone:**	(215)707-3390

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 or call 1-888-657-3711 to determine what action is required.

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Add Note

1. Enter Principal Investigator email address.

(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 or call 1-888-657-3711 to determine what action is required.

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Annual PI Worksheet About Local Context -- Information

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2. Name of Signatory Institution

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)

Add Note

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

(Required)

Add Note

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)

Add Note

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)

Add Note View Audit

If applicable, an attachment can be added here.

Add Attachment

No Attachments added.

Add Note

9. Identify recruitment materials usually used:

(Required)

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

Add Note

Please describe.

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 SignatoryInstitution 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.

Add Note

11. Where does the consent discussion take place?

(Required)

Add Note

12. Who is authorized to obtain consent?

(Required)

Add Note

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?

(Required)

Add Note

14. Who is available to answer questions?

(Required)

Add Note

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

(Required)

Add Note

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

(Required)

Add Note

17. Who provides consent?

(Required)

Check all that apply.

- [ ] Potential study participant
- [ ] Parent for potential pediatric study participant
- [ ] Legally Authorized Representative
- [ ] Other

Add Note

Please explain.

Add Note

18. For what languages are translations routinely provided?

(Required)

Add Note

If translations are routinely provided, what process is currently used to translate the informed consent document?

Add Note View Audit

If applicable, an attachment can be added here.

Add Attachment
No Attachments added.

Reminder: Translations must be CIRB-approved prior to presenting to a potential study participant.

Add Note

19. Describe your institution's policy regarding assent by children or impaired adults.

(Required)

Add Note View Audit

If applicable, an attachment can be added here.

Add Attachment
No Attachments added.

Add Note

20. Describe your institution's process to receive and address concerns from study participants and others about the conduct of the research.

(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.

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.

Add Note

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

(Required)

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.

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.

Add Note

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

(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

Add Note

Please describe.

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

Add Note

Please describe.

Using a Legally Authorized Representative (LAR)

Add Note

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

(Required)

- Yes
- No

Add Note

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

Add Note View Audit

If applicable, an attachment can be added here.

Add Attachment

No Attachments added.

Add Note

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

Add Note View Audit

If applicable, an attachment can be added here.

Add Attachment

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.

Add Note

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

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

Add Note

Please describe.

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

Add Note

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

Add Note

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

Add Note

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

Add Note

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

Add Note

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'.

Add Note

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

(Required)

- ○ Yes
- ○ No

Add Note

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

(Required)

- ○ Yes
- ○ No

Add Note

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

(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.

Save for Later | Print | Submit