2 - Annual PI Worksheet About Local Context -- PI Information OMB Text OMB#: 0925 - 0625 Expiry Date: 01/31/2014 Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of your participation in the NCI CIRB is protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the NCI CIRB at any time. Refusal to participate will not affect your benefits in any way. The information collected will be kept private to the extent provided by Jaw. Names and other identifiers will not appear in any report of the NCI CIRB. Information provided will be combined for all participants and reported as summaries. You are being requested to complete this instrument so that we can conduct activities involved with the operations of NCI CIRB Initiative. 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. Add Note Reason for submission: First Submission of the Annual Principal Investigator Worksheet About Local Context Revised Submission of the Annual Principal Investigator Worksheet About Local Context View Audit Signatory Institution Information **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. (Reauired) If the message "Contact not found." appears, it means that this PI cannot be found in the CIRB database. Email the Helpdesk at jwalter@emmes1.com ncicirbcontact@emmes.com or call 1-888-657-3711 to determine what action is required. Walter, Jay PhD Business (215)707-3390 Business 12 My Court Address: Anyplace, CA Phone: 21701 Previous | Next | Save for Later | PDF 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.

Previous Next Save for Later PDF

Annual PI Worksheet About Local Context -- Information

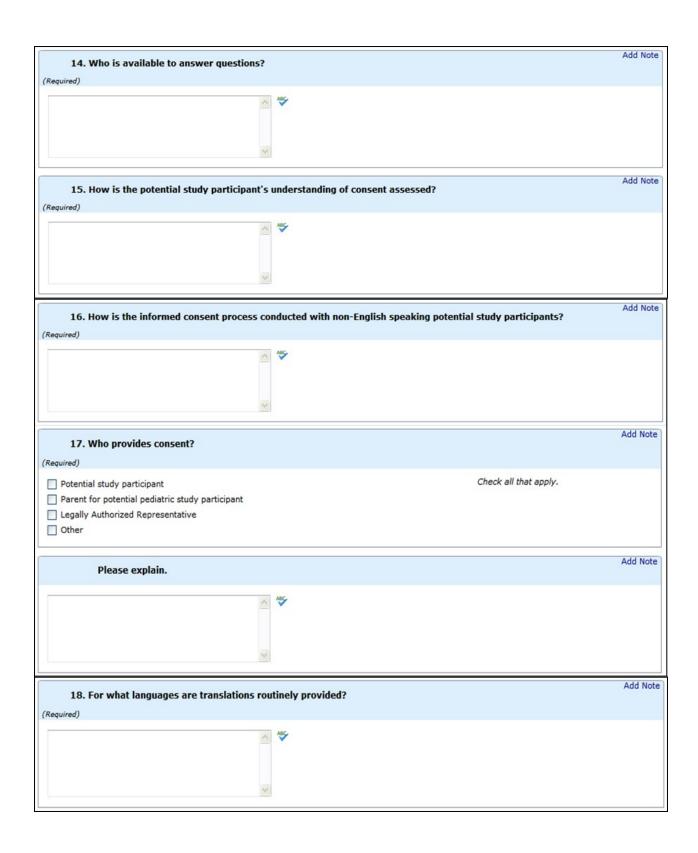
2. Name of Signatory Institution

View Audit

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)	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)	Add Note
O Yes O 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 (Required)	CIRB?
a. List CIRB-approved studies by Study ID Number.	Add Note
^ *	
	Add Note
7. How many study participants are currently receiving study intervention for studies for which you are the PI? (Required)	Add Note
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: (Required)	Add Note
Cooperative Group/sponsor-supplied handouts Locally-developed educational materials (Reminder: Study-specific material requires CIRB approval)	
Other	
Please describe.	dd Note
ABS ABS	
w.	

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 the informed consent.	ir
	Add Note
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? (Required)	Add Note

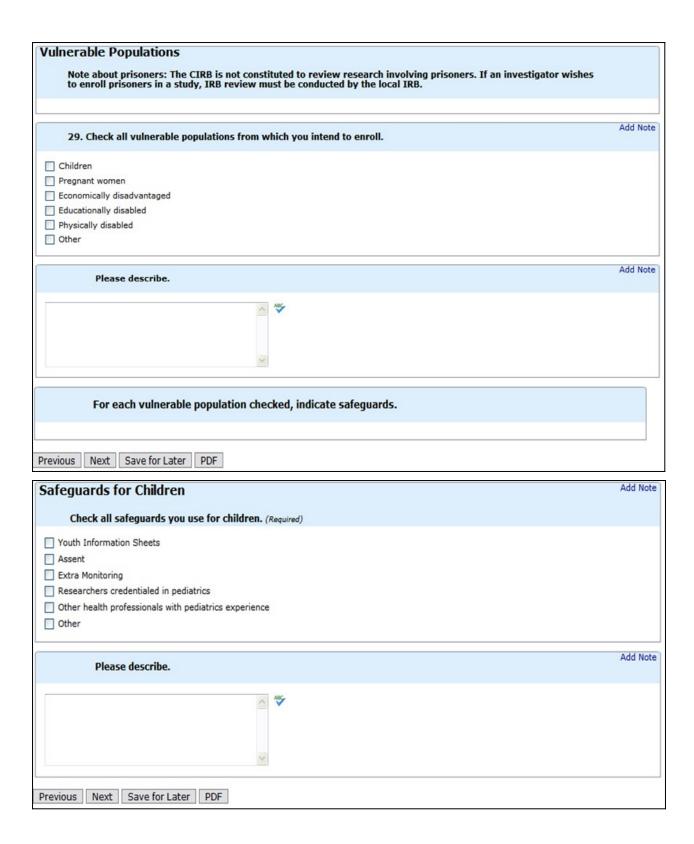


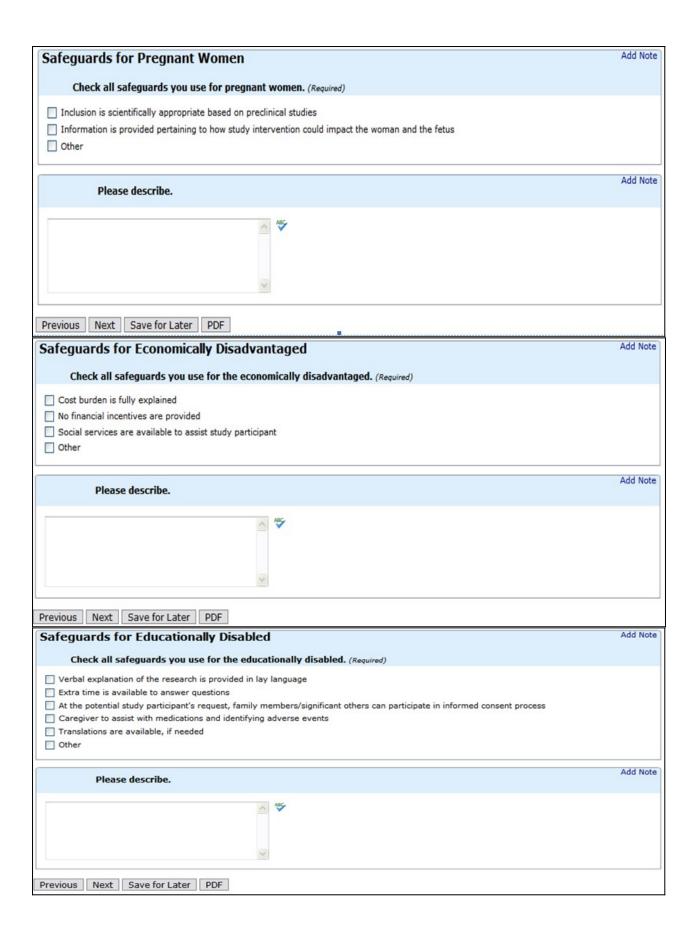
If translations are routinely provided, what process is currently used to translate the informed consent document?	Add Note
ABC	
Add No	te View Audit
If applicable, an attachment can be added here.	te view Addit
Add Attachment No Attachments added. Reminder: Translations must be CIRB-approved prior to presenting to a potential study page 1.	articipant.
19. Describe your institution's policy regarding assent by children or impaired adults. (Required)	Add Note
ABC	
Add M	te View Audit
If applicable, an attachment can be added here.	ite view Audit
Add Attachment 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)	
ABC ABC	
×	
Pharmacy Information	Add Note
21. Will the drugs/agents used in the study be managed by a pharmacist?	
(Required)	
○ Yes ○ No	

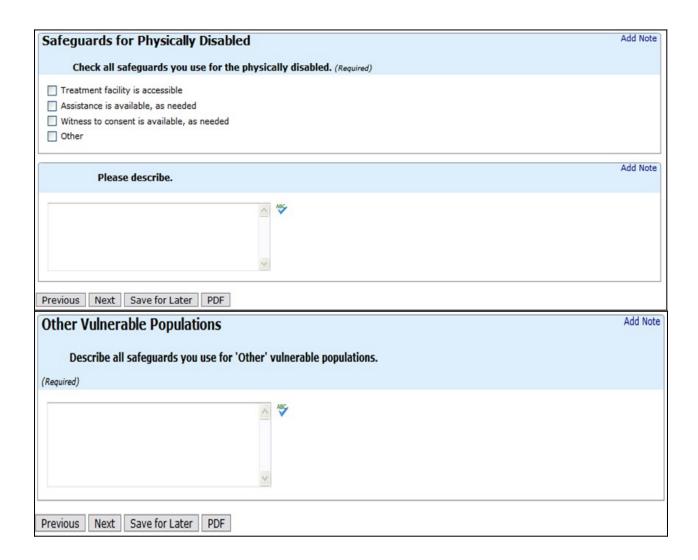
	Add Note
If a pharmacist will be managing the drugs/agents used in the study, provide the name and title of the pharmacist at each practice location where research will be conducted.	
<u>△</u>	
If the drugs/agents will not be managed by a pharmacist, provide the name and title of the responsible	Add Note
person for the drugs/agents at each practice/location where research will be conducted.	
<u>△</u>	
22. How is the pharmacist/responsible person provided with a copy of the protocol at each practice location?	Add Note
(Required)	
<u>^</u>	
w.	
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).	
23. Check all measures that will be used to maintain the confidentiality of identifiable information. (Required)	Add Note
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 	
Please describe.	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.	
24. Check all measures that will be used to maintain the study participant's privacy. (Required)	Add Note
 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
ASS V	
Emergency Resources 25. Check all resources available at the site to treat emergencies resulting from study-related procedures. (Required)	Add Note
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
ABC V	

Using a Legally Authorized Representative (LAR)		Add Note
26. Do you plan on enrolling study participants through an LAR? (Required)		
YesNo		
27. At your institution, describe who may serve as an LAR.		Add Note
ABS		
	Add Note	View Audit
If applicable, an attachment can be added here.		
Add Attachment No Attachments added.		
28. Provide a description of how you assess a potential study participant's ability to provide consent.		Add Note
ABS		
If applicable, an attachment can be added here.	Add Note	View Audit
Add Attachment No Attachments added.		







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		
Previous Next Save for Later PDF		
You've completed the form. You can now either save the form for later revision, or it.	submit	
Save for Later Print Submit		