

## Argus IRB Site Questionnaire: Investigator

Protocol: # \_\_\_\_\_  
Is this the first submission to an IRB?  yes  no **If “no,” please explain below, and attach a letter from your local IRB, if an existing one is delegating responsibility to Argus.**

Principal Investigator: \_\_\_\_\_

Study site (complete a separate form for each site):

Name \_\_\_\_\_

Street or P.O. address: \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ e-mail \_\_\_\_\_

1. How many years has the Principal Investigator been doing clinical research? \_\_\_\_\_

2. How many studies has the PI carried out in the area of expertise for this study? \_\_\_\_\_

3. Which categories below describe your site?

University  Hospital  Clinic  Research Facility  Private Practice

Other \_\_\_\_\_

4. What emergency facilities are in place at your site? Check all that apply:

Crash cart  911 CPR certification  Emergency medication

Other \_\_\_\_\_

5. Emergency phone numbers, including 24-hour call: \_\_\_\_\_  
\_\_\_\_\_

6. Nearest emergency facility/hospital: \_\_\_\_\_

How far away in miles? \_\_\_\_\_

7. Audits and/or actions by the FDA, NIH, State Medical Board, IRB, research subject, or other agent? **If you check any actions in the list below, for the investigator or site, please attach and explain all applicable documents.**

audit?

warning notice issued?

sanctions on principal investigator or associates?

restrictions, suspension, or revocation of professional credentials or privileges?

criminal charges against PI or associates?

termination of a study?

subject seeking compensation for injury?

8. Do any state or local laws govern the conduct of research in your site community? Please consult legal counsel and/or authorized agencies to check.  yes  no

**If “yes,” attach a list of laws and provide copies.**

9. Are any known beliefs or conditions, community specific, likely to affect the conduct of this research? Examples may be: economic, religious, ethical, or ethnic.

10. Are there any group criteria that would lead you to deny participation in this research?

- |  |  |
|--|--|
| <input type="checkbox"/> minors (under 18 years)     | <input type="checkbox"/> serious or life threatening illness |
| <input type="checkbox"/> pregnant women              | <input type="checkbox"/> prisoners                           |
| <input type="checkbox"/> people with disabilities    | <input type="checkbox"/> non-English speakers                |
| <input type="checkbox"/> people who cannot read      | <input type="checkbox"/> economically disadvantaged          |
| <input type="checkbox"/> educationally disadvantaged | <input type="checkbox"/> employees at the research site      |

**(a) Please explain with attachment(s) any boxes you checked to indicate exclusion.**

**(b) If you do recruit from within any group (unchecked boxes) please attach special policies and safeguards for these people. For example, include your methods for translating Informed Consent forms, allowing extra time for persons with learning disabilities, whether or not children sign the Consent form, or an emergency phone number for people on psychoactive or other essential medications.**

11. How do you ensure that the Principal Investigator and research site staff are knowledgeable about clinical and ethical practices? **Please attach documents (certificates, schedules for in-service training sessions, instructional materials, etc.) showing that the PI and all staff have current skills and knowledge.**

12. How will you recruit subjects for this study?

- advertisements     existing patients     known subject pool     referrals  
 other \_\_\_\_\_

13. Do you pay referral fees?     yes     no

If "yes," to whom? \_\_\_\_\_

14. Who is the research coordinator for this study? name \_\_\_\_\_  
phone \_\_\_\_\_ fax \_\_\_\_\_

15. Who will discuss the informed consent with the subject?

- Principal Investigator     Research Coordinator     Other \_\_\_\_\_

**16. Please attach a summary of procedures for presenting your study to potential subjects.**

Be sure to include: (a) time given the subject to respond, (b) whether or not the entire consent is read aloud, (c) how many times, and when, the subjects is asked if he/she has any questions, (d) whether or not the consent form can be taken home before a decision must be made, (e) discussion of additional details beyond those that are summarized in the consent; e.g., Subject Instructions forms, (f) any other special discussions; e.g., bearing on the potential vulnerability of a particular subject group.

17. Who will have access to study records?

- FDA auditors       NIH auditors       authorized monitors (internal at site)
- other \_\_\_\_\_

18. Will there be compensation for subjects?       yes       no

If "yes," how much per visit? \_\_\_\_\_ Total compensation for the study? \_\_\_\_\_

19. Please complete and sign the Investigator Certification Statement that appears below.

### INVESTIGATOR CERTIFICATION STATEMENT

**I hereby certify that the responses provided in this Site Questionnaire are true, accurate, and complete. No changes will be made in the consent form, the study protocol, or other features of the research without prior approval of Argus IRB. I will report promptly to Argus IRB any unforeseen or ongoing problems with the research study that may involve risk to human subjects. I will ensure that the informed consent procedure is explained orally to each subject and includes the features described in the Site Questionnaire (including my attachments) before he or she signs the consent. I further agree that Argus IRB has the right to visit the study site, with appropriate notice.**

\_\_\_\_\_  
signature of Principal Investigator

\_\_\_\_\_  
date

\_\_\_\_\_  
printed name of Principal Investigator

*Additional signature if required by the site:*

\_\_\_\_\_  
signature of Medical Director  
or other organizational representative

\_\_\_\_\_  
date

\_\_\_\_\_  
printed name

\_\_\_\_\_  
title