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?

- ☐ minors (under 18 years)
- ☐ pregnant women
- ☐ people with disabilities
- ☐ people who cannot read
- ☐ educationally disadvantaged
- ☐ serious or life threatening illness
- ☐ prisoners
- ☐ non-English speakers
- ☐ economically disadvantaged
- ☐ 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 date
or other organizational representative

_____
printed name

_____
title