Duke | OFFICE of AUDIT, RISK & COMPLIANCE

Internal-Review Study Personnel Questionnaire

Quality Assurance/Peer Review Materials: Confidential and Privileged Under North Carolina Law
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Protocol #: _____
Protocol Title: _____
Principal Investigator (PI): _____
Co-PI(s): _____
Primary Study Coordinator(s): _____
Clinical Research Unit: _____
Sponsor: _____

Please complete all portions of this form prior to the scheduled Human Subject Research Compliance (HSRC) review of this protocol and return to the OARC office (OARC-RCA@duke.edu or fax 919.684.6105).

Section 1

This portion of the questionnaire should be completed by the Principal Investigator (PI).

1. Do you (the Principal Investigator) have experience with audits/HSRC reviews?
   ☐ No, I have no experience with audits/HSRC reviews.
   ☐ Yes, I have some experience with audits/HSRC reviews
   ☐ FDA ☐ Internal ☐ Sponsor Audit ☐ Other*

   * If other, please provide brief description in this space.

2. Has this study had one or more of the above stated audits/reviews (including a Human Subject Research Compliance (HSRC) review)?

   If so please list type of audit/review and date_____

3. How many years have you been employed at Duke (in a research capacity)?
   ☐ years ☐ months

4. How many years have you been involved in research?
   ☐ years ☐ months

5. How many current studies are you involved in?

   ☐ as Principal Investigator

   ☐ as Co-PI

   ☐ as Sub Investigator

   ☐ as other Key Personnel

   ☐ studies being conducted at other sites

6. Do you currently hold the Investigational New Drug (IND) or Investigational Device Exemption (IDE) for any study, including the protocol being reviewed?
   ☐ No, I have no INDs/IDEs.
   ☐ Yes, I hold the following INDs/IDEs*:
   [* If yes, please provide the IRB number and IND/IDE number for all below.]

7. Are most subjects that you enroll (on all studies) also your patients?
   ☐ No*
   ☐ Yes*
   [* Please feel free to provide any information you feel would help to clarify.]

8. Please provide a list of all areas in which you are board certified.

9. Which statement best describes your feeling regarding your initial training in conducting research:
   ☐ I did not receive any training; it has been learn as you go
   ☐ I was given the basics, but have learned from my mistakes
   ☐ It was excellent and robust

Section 2

This portion of the questionnaire refers to the specific protocol being reviewed.

Please be as accurate as possible. Please provide the name and e-mail of person completing this portion.

Name: _____ e-mail: _____
Role: _____

1. Is this protocol being conducted at other sites?
   - ☐ Yes
   - ☐ No

2. Who is the author of the protocol?
   - ☐ PI Only
   - ☐ Collaborative effort includes PI
   - ☐ Industry sponsor
   - ☐ Other: _____

3. Does the PI have final say regarding the eligibility of subjects?
   - ☐ Yes
   - ☐ No

4. What duties has the PI delegated? (Please mark all that apply)
   - ☐ Physical exams and/or evaluation of subject
   - ☐ Dispensing and inventory of test article and/or directly involved in treatment of subject
   - ☐ Obtain and document informed consent
   - ☐ Prepare regulatory documents
   - ☐ Complete or correct case report forms (CRFs)
   - ☐ Monitor study
   - ☐ Report adverse event/serious adverse event (AE/SAE)
   - ☐ Protocol deviation reports/notes to file
   - ☐ Recruit subjects
   - ☐ Prepare IRB submissions
   - ☐ Other: Please describe in space below

5. Do Case Report Form (CRFs or eCRFs) exist for this study?
   - ☐ Yes
   - ☐ No

6. Does the PI review and sign (Please mark all that apply):
   - ☐ CRFs
   - ☐ Consent form
   - ☐ Lab reports
   - ☐ IRB submissions
   - ☐ AE reports

7. Is there an electronic database for this study?
   - ☐ Yes
   - ☐ No

   If yes, what database is being used, is it password protected and who has access to it?

   _____

8. Who initially describes the study to the potential subject?
   - ☐ PI
   - ☐ Coordinator
   - ☐ Staff Nurse or Resident
   - ☐ Other: (Please specify) _____

9. How is initial contact made?
   - ☐ Phone call
   - ☐ In person
   - ☐ Letter
   - ☐ Other: _____

10. Who generally obtains consent from subject?
    - ☐ PI
    - ☐ Coordinator
    - ☐ Staff Nurse or Resident
    - ☐ Other: (Please specify) _____

11. Does this study recruit healthy volunteers?
    - ☐ Yes
    - ☐ No

12. Are healthy controls/ Non-Duke Subjects given a copy of the Duke Health Enterprise Notice of Privacy Practices brochure at the time of consent?
    - ☐ Yes
    - ☐ No

13. Is the subject given a copy of the signed consent form?
    - ☐ Yes
    - ☐ No

14. Is a copy of the consent form placed in the medical record?
    - ☐ Yes
    - ☐ No

15. Is the process documented with a note stating that no protocol-related procedures occurred prior to obtaining consent?
    - ☐ Yes
    - ☐ No

16. Were all of the subject's questions and concerns addressed prior to the subject signing consent?
    - ☐ Yes
    - ☐ No

17. Dispensing of study test article (i.e., study drug or device):

	By Prescription	By Coordinator/ Research Team	By Investigational Drug Services	Other - Please describe
How is test article dispensed?				

18. If the study is blinded, who holds the randomization code?
    - ☐ PI
    - ☐ IDS
    - ☐ Sponsor
    - ☐ Third party (Please describe): _____

19. Is there a Test Article Accountability Log?
    - ☐ Yes
    - ☐ No

20. Is the Duke Laboratory used for all test analysis?
    - ☐ Yes
    - ☐ No

    If no, please note lab(s) being used. _____

21. Subject enrollment:

Date if initial IRB approval
Date of 1st Human Subject Contact at Duke:
Total # of subjects in study (signed consent):
Total # of subjects approved by the IRB:
Total # of screen failures:
Total # of subjects lost to follow-up:
Total # completed:
Total # of active subjects:
Total# of subject entered on enrollment log
Total # of early withdrawals:
Enrollment end date:

22. How are subjects recruited? (Please mark all that apply)
    - ☐ Advertisements
    - ☐ Flyers
    - ☐ Web posting
    - ☐ Letters
    - ☐ Others: _____

23. Have there been any staff changes since the last IRB renewal?
    - ☐ Yes
    - ☐ No

Section 3

This portion of the questionnaire should be completed by the primary study coordinator(s).

1. How many years have you been employed at Duke (in a research capacity)?

    ☐ years ☐ months

2. How many years have you been involved in research? Please answer as accurately as possible; however, we realize you may have to estimate.

   ☐ years ☐ months

3. How many current studies are you involved in?

   ☐ as study coordinator

   ☐ as key personnel

4. Are you approved by Duke to perform phlebotomy for this study?
   - ☐ Yes
   - ☐ No

5. What duties have been delegated to you by the PI?
   - ☐ Physical exams and/or evaluation of subject
   - ☐ Dispensing and inventorying of test article and/or directly involved in treatment of subject
   - ☐ Obtain and document informed consent
   - ☐ Prepare regulatory documents
   - ☐ Complete or correct CRFs
   - ☐ Monitor study
   - ☐ Report AE/SAE
   - ☐ Protocol deviation reports/notes to file
   - ☐ Recruit subjects
   - ☐ Prepare IRB submissions
   - ☐ Other: Please describe in space below
   - ☐ NA

6. Study subject encounter visit documentation is found in what form?
   - ☐ Paper
   - ☐ Electronic
   - ☐ Both

7. Do you question and collect Adverse Event (AE) information at each visit?
   - ☐ Yes
   - ☐ No

8. Do you check subject's concomitant medication at each visit?
   - ☐ Yes
   - ☐ No

9. Do you provide training to subjects on any special aspects of the study (diaries, diet, taking test article, etc.) and remind them of their next visit?
   - ☐ Yes
   - ☐ No