

VAMHCS Office of Research Compliance

**INVESTIGATOR/STAFF INTERVIEW CHECKLIST
SELF-ASSESSMENT TOOL**

GENERAL INFORMATION

Principal Investigator		
E-mail Address		
Sub-Investigator(s)		
Key Personnel/Function	Personnel	Function
IRB Panel		
IRB Protocol Number		
Study Title		
School/Center/Institution <i>Please check one:</i>	<input type="checkbox"/> SOM <input type="checkbox"/> Dental <input type="checkbox"/> Pharm <input type="checkbox"/> Nursing <input type="checkbox"/> SW <input type="checkbox"/> CVD <input type="checkbox"/> MPRC <input type="checkbox"/> IHV <input type="checkbox"/> GCC <input type="checkbox"/> GCRC	
Subject Population <i>Please check all that apply:</i>	<input type="checkbox"/> Geriatric <input type="checkbox"/> Pregnant Women <input type="checkbox"/> Pediatric <input type="checkbox"/> Prisoner <input type="checkbox"/> Psychiatric <input type="checkbox"/> Mentally Disabled <input type="checkbox"/> Handicapped <input type="checkbox"/> Veteran <input type="checkbox"/> Employee/Student <input type="checkbox"/> Community	
Sponsor <i>Please check one:</i>	<input type="checkbox"/> Industry <input type="checkbox"/> Government <input type="checkbox"/> Internal/Department <input type="checkbox"/> Foundation <input type="checkbox"/> Other: _____	
Funding Source <i>Please check one:</i>	<input type="checkbox"/> Industry <input type="checkbox"/> Government <input type="checkbox"/> Internal/Department <input type="checkbox"/> Foundation <input type="checkbox"/> Other: _____	
Person Completing Checklist		
Date Checklist Completed		

Investigator Name

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I. Workload/Conduct of the Study

- A. Describe a typical workday at this office/practice.
- B. How much of your time is dedicated to research studies?
- C. How many studies are you currently conducting?
- D. How many active subjects are participating in all currently ongoing studies?
- E. How many physician sub-investigators do you have on staff?
- F. What is the average workload (# of subjects) per physician?
- G. How many study coordinators do you have on staff?
- H. What is the average workload (# of subjects) per study coordinator?
- I. How many studies are you conducting for this indication?
- J. If there are studies that have competing objectives/eligibility criteria, how do you determine which trial is offered /assigned to potential subjects?
- K. Approximately how many subjects with this indication/condition do you see per day? per week? per month?
- L. Please explain the procedure for a subject to be considered for participation in a research trial.
- M. If there is more than one physician working on the study, how do you determine who sees the subject? Does the same physician see the subject throughout the trial?

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- N. How long have you worked with:
- The sub-investigator(s)?
 - The study coordinator(s)?
 - The research nurse(s)?
 - The data manager(s)?
- O. Describe the delegation of roles and responsibilities at this site and at any satellite sites.
- P. Who screens the subjects?
- Q. Who conducts the informed consent process?
- R. Who documents the informed consent process (enrollment note and Research Subject Clinical Warning) in CPRS?
- S. Who takes medical histories?
- T. Who performs physical exams?
- U. Who evaluates out-of-range lab values?
- V. Who assigns causality of AEs?
- W. Who records SAEs?
- X. Who writes in the subjects' charts?
- Y. Who completes the CRFs?
- Z. Who responds to queries? Are the responses reviewed by the PI?

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II. Clinical Tests

- A. Are any other facilities used outside of this hospital/clinic?
- B. Who draws blood samples?
- C. How are they processed?
- D. Who reviews the results of laboratory tests?

III. Training

- A. Do you have SOPs? If yes, for which processes?
- B. Do you and your staff have any regulatory/compliance training?
- C. Describe the study-specific training you and your staff received (e.g. investigators' meeting, in-service by sponsor/funding source).
- D. What is the training process for you and your staff? Do you document the type of training, when it was given, and by whom?

IV. Study Protocol

- A. Did you have an opportunity to influence the design of the protocol?
- B. Are there any areas where you do not agree with the protocol design?
- C. Is the protocol clearly written?
- D. Are there any difficulties regarding inclusion/exclusion criteria?

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- E. Are there any difficulties in assessing primary efficacy/safety parameters?
 - F. Do you find the protocol difficult to follow? If yes, why?
- V. CRF
- A. Who captures key efficacy parameters on the CRF?
 - B. What is the correction process?
 - C. Who is permitted to sign the CRFs?
 - D. Is the CRF clearly written
 - E. Is the CRF 'user friendly'?
 - F. Do you have any additional comments on the CRF?
- VI. IRB
- A. What is your relationship with the IRB?
 - B. Are you, or any of your staff, a member of the IRB?
 - C. Are there any other committees involved in the review and approval of the study (e.g. radiation safety)?
 - D. Do you have any comments or suggestions to improve the IRB review process and/or your relationship with the IRB?

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VII. Subject Recruitment

- A. Are subjects recruited from your private practice or are they referrals?
- B. Do you advertise for subjects?
- C. Have recruitment materials been reviewed and approved by the IRB?
- D. How do you inform the subject's PCP or referring physician that the subject is taking part in the study? If a letter is sent, please provide a copy.
- E. How are medical histories checked/confirmed?

VIII. Subject Information/Informed Consent

- A. How are subjects made aware that they are taking part in a clinical study?
- B. What are they told?
- C. Who informs them?
- D. Is written information (other than the informed consent form) given to the subjects? If so, please provide a copy.
- E. When is informed consent obtained in relation to the first contact/visit?
- F. Describe the informed consent process.
- G. Do you give the subject a copy of the information sheet? A copy of the signed consent form?

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- H. Do you have an Enrollment Note template and is an enrollment note consistently entered into CPRS as soon as a participant signs consent?
 - I. Do you have a Research Subject Clinical Warning Note template and is an RSCW consistently entered into CPRS as soon as a participant signs consent?
 - J. Has new information about the drug/device become available to you? If so, have the study subjects been informed?
 - K. Have you been advised of any new safety information about the drug/device? If so, was the consent form revised? How were past (completed/withdrawn) study subjects informed?
- IX. Records
- A. How is paperwork handled in your office practice (e.g. correspondence, completion of source documents, progress notes, CRFs, consent forms, regulatory documents)?
 - B. What is the process for the first recording of study data (i.e. what is the source document for each study-related procedure/parameter)?
 - C. Where do you keep study documents?
 - D. Are archives available? On-site? Off-site?
 - E. Are records protected from fire and water damage?
 - F. Are electronic records kept behind the VA firewall?
 - G. Are all records stored and used according to VA policies on privacy and data security?
 - H. Has the study monitor reviewed record retention requirements with you?

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- I. Describe your record retention policy.

- X. Randomization
 - A. Describe the process for randomizing subjects into the study.

- XI. Study Drug/Device
 - A. Who receives the study drug/device shipments?

 - B. Have there been any problems with any of the shipments? If yes, please describe.

 - C. Where is the drug/device stored? Is it secure? Is the temperature monitored?

 - D. Who dispenses the study drug/device?

 - E. Was this delegation of responsibility documented?

 - F. What are your drug accountability procedures?

 - G. Is the study drug/device dispensed directly to the subjects?

 - H. Where are unused supplies (returned from subjects) stored?

 - I. What are the destruction/return-to-sponsor procedures for unused supplies?

 - J. If you and the pharmacy are both recording study drug/device dispensing and return, are you periodically comparing your records to ensure that they are consistent with each other?

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XII. SAEs

- A. Are the SAE definitions clear?
- B. How have you handled SAE occurrences to date?
- C. Are treatment codes revealed?
- D. How are SAEs reported to the IRB? to the sponsor/funding source?

XIII. Data Safety Monitoring Plan

- A. Have you been able to follow the DSMP you described in your IRB submission?
- B. If not, have you reported this to the HRPO and made a modification request if necessary?
- C. How do you send information to your DSMP/DSMB?
- D. How do you receive reports from the DSMP/DSMP?
- E. How do you report to the IRB?

XIV. Complaints or Suggestions

- A. Have you received any complaints or suggestions from participants or their families or advocates? From your staff?
- B. If yes, have the complaints/suggestions led to any changes/improvements in your study procedures?

XV. Collaboration with Sponsor/Funding Source

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- A. Have you worked with this sponsor/funding source previously?
- B. How is your relationship with the CRO, if applicable?
- C. How is your relationship with the study monitor?
- D. Are your questions answered in a timely manner?
- E. Did you attend an investigators' meeting for this study? If so, was it beneficial?
- F. What additional training would you have liked to receive
 - o At the meeting?
 - o Prior to study initiation?
 - o During the conduct of the study?
- G. Have there been any sponsor audits of this study? If so,
 - o Are the reports available for review?
 - o Were there any observations related to the protection of human subjects?
 - o Were there any observations related to compliance with human research subject regulations?
 - o Is documentation available to verify the implementation of corrective actions taken in response to noted deficiencies?
- H. Would you work with this sponsor/funding source again?

XVI. Other

- A. Has any regulatory authority inspected your site? If so, when, and what was the outcome?