# INVESTIGATOR/STAFF INTERVIEW CHECKLIST

## SELF-ASSESSMENT TOOL

## GENERAL INFORMATION

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>E-mail Address</th>
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<table>
<thead>
<tr>
<th>Sub-Investigator(s)</th>
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<thead>
<tr>
<th>Key Personnel/Function</th>
<th>Personnel</th>
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<th>IRB Panel</th>
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<table>
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<tr>
<th>IRB Protocol Number</th>
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<table>
<thead>
<tr>
<th>Study Title</th>
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<table>
<thead>
<tr>
<th>School/Center/Institution</th>
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<tbody>
<tr>
<td>Please check one: SOM Dental Pharm Nursing SW CVD MPRC IHV GCC GCRC</td>
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<tr>
<th>Subject Population</th>
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<tbody>
<tr>
<td>Please check all that apply: Geriatric Pregnant Women Pediatric Prisoner Psychiatric Mentally Disabled Handicapped Veteran Employee/Student Community</td>
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<th>Sponsor</th>
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<tr>
<td>Please check one: Industry Government Internal/Department Foundation Other:</td>
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<th>Funding Source</th>
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<td>Please check one: Industry Government Internal/Department Foundation Other:</td>
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<tr>
<th>Person Completing Checklist</th>
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<tr>
<td>Date Checklist Completed</td>
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1/19/05
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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:
   o The sub-investigator(s)?
   o The study coordinator(s)?
   o The research nurse(s)?
   o 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?
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?
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?
Investigator Name

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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?
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/DSMB?

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
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
   - At the meeting?
   - Prior to study initiation?
   - During the conduct of the study?

G. Have there been any sponsor audits of this study? If so,
   - Are the reports available for review?
     - Were there any observations related to the protection of human subjects?
     - Were there any observations related to compliance with human research subject regulations?
     - 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?