SELF-ASSESSMENT CHECKLIST

SECTION 1: <u>REGULATORY DOCUMENTATION</u>

Staff Documentation

	YES	NO	NA
1. Are all versions of the IRB approved protocol on file (including most recent)?	☐	☐	☐
2. Are there CVs/biosketches of PI, Co-Is, and all study staff on file?	☐	☐	☐
3. Are CVs updated within the past two years?	☐	☐	☐
4. Are CVs signed and dated?	☐	☐	☐
5. Is valid medical licensure on file for all applicable IRB approved staff members (e.g. nurses and MD's)?	☐	☐	☐
6. Is there a staff signature/delegation of responsibility log on file?	☐	☐	☐
7. Does the signature/delegation of responsibility log reflect current and previous IRB approved staff?	☐	☐	☐

SECTION 1.1: <u>DATA AND SAFETY MONITORING</u>

	YES	NO	NA
8. Is there a Data Safety Monitoring Plan (DSMP) for this study?	☐	☐	☐
9. Has the DSMP been followed in accordance with the IRB approved protocol?	☐	☐	☐
10. Is there a Data Safety Monitoring Board (DSMB) for this study?	☐	☐	☐
11. Have all DSMB reports been submitted to the IRB?	☐	☐	☐

SECTION 1.2: <u>INVESTIGATIONAL PRODUCTS</u>

Please note this section may not apply to your study if you are not using an investigational product.

For Clinical Investigators[1]

	YES	NO	NA
12. Is an IND[2] being used for this study?	☐	☐	☐
13. For IND studies, is there a signed *FDA 1572* on file?	☐	☐	☐
14. Is an IDE[3] being used for this study?	☐	☐	☐
15. For IDE studies, is an Investigator Statement on file for each investigator involved in the study?	☐	☐	☐
16. Are all staff listed on the 1572 or who have signed an Investigator Agreement IRB approved?	☐	☐	☐
17. Is a Financial Disclosure form on file for each investigator listed on the 1572 or who have signed an Investigator Agreement)?	☐	☐	☐
18. Are all correspondences to and from the sponsor on file?	☐	☐	☐
19. Is there a copy of the Investigator Brochure or Device Manual on file?	☐	☐	☐
20. If the product is already marketed, is there package insert/product information on file?	☐	☐	☐
21. Is the PI a sponsor-investigator (i.e. IND/IDE holder)? If yes complete Sponsor-Investigator section.	☐	☐	☐

[1] **Clinical Investigator** is the individual who actually conducts a clinical investigation. He/She is responsible for how the test article is administered and/or dispensed and in the event that an investigation is conducted by a team of individuals, he/she is the responsible leader of that team.

[2] **Investigational New Drug (IND)** application is the process through which a drug sponsor alerts the FDA of its intentions to conduct clinical studies with an investigational drug. An IND is required for any significant changes in labeling, dose, administration or study population.

[3] **Investigational Device Exemption (IDE)** allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Pre-market approval (PMA) or Pre-market Notification 510K submission to FDA.

FOR SPONSOR-INVESTIGATORS[4] ONLY

	YES	NO	NA
22. Is there a signed FDA 3674 – Certification of Registration to ClinTrials.gov on file? A 3674 should be on file for each applicable study.	☐	☐	☐
23. Is the complete IND/IDE application to the FDA on file?	☐	☐	☐
24. IND: Is the FDA letter of no objection on file? Please note that the FDA does not always send a letter of no objection for IND studies. If no letter is received, the IND study may start 30 days after it is received by the FDA.	☐	☐	☐
25. IDE: Is the FDA approval letter on file?	☐	☐	☐
26. Are Amendments to the IND/IDE on file?	☐	☐	☐
27. Are annual reports to the IND/IDE on file?	☐	☐	☐
28. Are safety reports to the IND/IDE on file?	☐	☐	☐
29. Are general correspondences with the FDA on file?	☐	☐	☐
30. For IND studies, is there a *FDA 1571* on file to accompany all of the above FDA correspondence?	☐	☐	☐
31. Is there a monitor[5] for this study?	☐	☐	☐

SECTION 2: IRB DOCUMENTATION[6]

	YES	NO	NA
32. Are all IRB submissions (including electronic submission confirmation sheets) on file?	☐	☐	☐

[4] **Sponsor-Investigator** is the individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A Sponsor-Investigator is required to fulfill the responsibilities of both the Investigator and Sponsor.

[5] Individual monitoring the study for subject safety and protocol adherence according to the protocol's data and safety monitoring plan. For IND Studies - Individual listed as the *monitor* in section 14 of the FDA form 1571. For IDE studies - individual identified in the investigational plan.

[6] Copies of correspondences may be retained in hardcopy or electronic format (e.g. shared folder space)
Note: eIRB correspondences do not substitute for the original documents.

SECTION 2: IRB DOCUMENTATION

	YES	NO	NA
33. Are all notifications of IRB requires modification/deferral or disapproval on file?	☐	☐	☐
34. Are all PI responses to the IRB notification(s) on file?	☐	☐	☐
35. Are all IRB notifications of approval on file?	☐	☐	☐
36. Are all adverse event submissions on file?	☐	☐	☐
37. Are all other event submissions (e.g. protocol deviation) on file?	☐	☐	☐

SECTION 3: SUBJECT RECRUITMENT PROCEDURES

	YES	NO	NA
38. Are recruitment methods described in the IRB approved protocol?	☐	☐	☐
39. Is the approved recruitment method being adhered to?	☐	☐	☐
40. Have all recruitment materials (e.g. ads and phone scripts) been approved by the IRB? Note: All recruitment materials must be re-approved at the time of continuing review.	☐	☐	☐
41. Are all approved recruitment materials (original and all revisions) on file?	☐	☐	☐
42. If changes were made to any recruitment materials, where these approved prior to implementation?	☐	☐	☐

SECTION 4: SUBJECT SELECTION CRITERIA

	YES	NO	NA
43. Is there an eligibility checklist containing inclusion/exclusion criteria for all enrolled subjects?	☐	☐	☐
44. Is there source documentation to verify inclusion/exclusion criteria?	☐	☐	☐
45. Does the eligibility criteria checklist for each subject include dated signature/initials of the person obtaining the information?	☐	☐	☐

SECTION 4: SUBJECT SELECTION CRITERIA

	YES	NO	NA
46. For any enrolled subjects that did not meet eligibility criteria, was a request for a protocol exception submitted to the IRB prior to enrollment?	☐	☐	☐
47. For subjects who did not meet eligibility (e.g. screen-failures), was identifiable information destroyed or authorization obtained to keep the subject's identifiable information?	☐	☐	☐

SECTION 5: INFORMED CONSENT PROCESS[7]

	YES	NO	NA
48. Was informed consent obtained from each subject prior to the start of any study procedure(s), including screening procedures to determine eligibility?	☐	☐	☐
49. Are there valid signed and dated consent forms on file for all enrolled subjects?	☐	☐	☐
50. Is there written documentation of the informed consent process for all enrolled subjects?	☐	☐	☐
51. If surrogate consent was obtained, does the IRB protocol include surrogate consent?	☐	☐	☐
52. Was the consent process conducted in adherence with the IRB-approved protocol?	☐	☐	☐
53. Were non-English speaking subjects enrolled?	☐	☐	☐
54. If non-English speaking subjects were enrolled was the IRB-approved process for enrolling non-English subjects followed?	☐	☐	☐
55. Copy of the consent form was given to subjects	☐	☐	☐

SECTION 6: DATA COLLECTION & SOURCE DOCUMENTS

	YES	NO	NA
56. Is data collection complete/accurate for each subject as specified by protocol (e.g. no blank fields/missing data)?	☐	☐	☐
57. Is source documentation available to support data entry for each subject?	☐	☐	☐

[7] The QI **Informed Consent Checklist** is the best way to ensure that study sites are not violating the informed consent process. A copy of the checklist can be obtained at:
http://www.partners.org/phsqi/QIWeb/files/ConsentFormComplianceChecklist%202005.pdf

SECTION 6: <u>DATA COLLECTION & SOURCE DOCUMENTS</u>

	YES	NO	NA
58. Does the source documentation/CRF for each subject include dated signature/initials of the person obtaining the information for each subject?	☐	☐	☐
59. Are changes/cross-outs, additional comments (if any) in subject files routinely initialed and dated?	☐	☐	☐
60. For any changes/cross-outs being made, is the original entry still legible? (e.g. use of white-out or pencil erased entries is not acceptable)	☐	☐	☐

SECTION 7: <u>DRUG/DEVICE DISPENSING ACCOUNTABILITY</u>

Who is responsible for drug/device accountability?

☐ Study Site ☐ Research Pharmacy ☐ Other _____ ☐ N/A

If **study site** is responsible for drug/device accountability, complete the section below.

	YES	NO	NA
61. Is there documentation of investigational product receipt on file?	☐	☐	☐
62. Is there documentation of drug/biologic/device use for each subject (e.g. drug accountability log, study file notation)?	☐	☐	☐
63. Is there documentation for the return of drug/biologic/device from the subject back to the study site?	☐	☐	☐
64. Is there documentation for the return (back to drug sponsor/manufacturing company/research pharmacy) or destruction of drug/biologic/device?	☐	☐	☐
65. Have there been any other events (e.g. drug/biologic dosing errors or device malfunctions to date?	☐	☐	☐
66. Have these events been reported to the IRB as unanticipated problems?	☐	☐	☐

SECTION 8: Laboratory <u>Documentation</u>

	YES	NO	NA
67. Is Lab Certification (CLIA/CAP) current, and on file?	☐	☐	☐
68. Are laboratory reference ranges (normal values) on file?	☐	☐	☐
69. Have all lab reports been reviewed and signed/dated by a licensed physician investigator?	☐	☐	☐

SECTION 8: Laboratory <u>Documentation</u>

	YES	NO	NA
70. Are all out-of-range lab values marked as to their clinical significance?	☐	☐	☐

General Note: If any of the above essential documents are stored in any place other than the regulatory binder, please add a note-to-file giving exact location. If documents are stored electronically, note-to-file should give the pathway (e.g., my network places/shared drive/ protocol 2011P123456/IRB documentation)

Note:
If 'No' is answered to any of the questions above, make correction and, if applicable, report deviation to IRB according to policy and add a note to file.

Contact the QI Program if you have further questions
humanresearchqi@partners.org