

## INFORMED CONSENT COMPLIANCE CHECKLIST

| ITEM |  | ✓ | CORRECTIVE ACTION   |
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| 1.   | Was informed consent obtained from each subject?   |   | Report this violation to the IRB.   |
| 2.   | Is a consent form on file for each subject consented?  |   | <ul style="list-style-type: none"> <li>▪ Report this violation to the IRB.</li> <li>▪ Write a signed and dated note to file explaining when and by who consent was obtained.</li> </ul>   |
| 3.   | Is the consent form on file for each subject an original?  |   | <ul style="list-style-type: none"> <li>▪ Write a signed and dated note to file, explaining why only a photocopy is available.</li> </ul>  |
| 4.   | Are all pages of the consent form on file for each subject?  |   | <ul style="list-style-type: none"> <li>▪ Report this violation to the IRB</li> <li>▪ Write a signed and dated note to file confirming that all information was presented to the subject, and if possible, explain why pages are missing.</li> </ul>   |
| 5.   | Was consent obtained from each subject prior to performing any screening procedures to determine eligibility?        |   | Report this violation to the IRB.   |
| 6.   | Did all subjects receive a copy of the signed and dated consent form?  |   | Report this violation to the IRB.   |
| 7.   | Is there documentation to support that subject's received a copy of the signed and dated consent form?               |   | <ul style="list-style-type: none"> <li>▪ Write a signed and dated note to file indicating that subjects were given a copy of the consent form but it was not documented.</li> <li>▪ For all future subjects enrolled, document (e.g. in progress notes or on an enrollment log) that each subject was given a copy of the signed and dated consent form.</li> </ul> |
| 8.   | Is subject identification (written or imprinted with hospital card) on all pages of the consent form?                |   | <ul style="list-style-type: none"> <li>▪ Ensure that identification is on all pages of consent form for future subjects.</li> <li>▪ If possible, add subject's identification to all existing consent forms.</li> </ul>   |
| 9.   | Did each subject sign and date the consent form for him/herself? (excluding IRB approved surrogate/parental consent) |   | <ul style="list-style-type: none"> <li>▪ Report this violation to the IRB.</li> <li>▪ Write a signed a dated note to file explaining any missing signature/date; or explaining who signed and dated for subject.</li> </ul>   |
| 10.  | Did an IRB approved study representative obtain consent for all subjects?  |   | <ul style="list-style-type: none"> <li>▪ Report this violation to the IRB.</li> <li>▪ Check the initial approval to verify who is IRB-approved to obtain consent.</li> </ul>  |
| 11.  | Did the IRB-approved study representative obtaining consent sign and date for him/herself?                           |   | Write a signed and dated note to file explaining who signed/dated for the study representative or if it was an omission, explain how and when consent was obtained.   |
| 12.  | Are there any discrepancies between the dates the subject and the study representative signed the consent form?      |   | Write a signed and dated note to file clarifying when consent was obtained.   |
| 13.  | Are there any changes/handwritten corrections (e.g. contact telephone number) to any of the consent forms used?      |   | <ul style="list-style-type: none"> <li>▪ Report this violation to the IRB</li> <li>▪ Submit an amendment to the IRB updating the consent form.</li> </ul>   |
| 14.  | Are original copies of all IRB approved consent forms on file?   |   | Obtain missing versions of the IRB approved consent forms from the protocol administrator.  |

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| 15. | Was a valid (IRB approval stamp on the bottom) consent form used to consent each subject?                            | <ul style="list-style-type: none"> <li>▪ Report this violation to the IRB.</li> <li>▪ If possible, re-consent the subject on a valid consent form.</li> </ul>  |
| 16. | Are yes/no or similar options on the consent form (if applicable) complete for all subjects?                         | Assume the subject “does not” agree to the option unless the subject can complete the information at a later time.   |
| 16. | Is the number of subjects who have signed the consent form less than the target enrollment goal approved by the IRB? | <ul style="list-style-type: none"> <li>▪ Report this over-enrollment to the IRB.</li> <li>▪ Submit an amendment to the IRB requesting an increase in the enrollment goal.</li> </ul>   |
| 17. | Is there a signed authorization form on file for all subjects enrolled on or after April 14, 2003?                   | <ul style="list-style-type: none"> <li>▪ Send an authorization form to each subject and request that they sign and return it to the study site.</li> <li>▪ Ask each subject to indicate that the authorization is retroactive to the time of enrollment</li> </ul> |

Submit all violations using the appropriate form which can be found at <http://healthcare.partners.org/phsirb/forms.htm>.