MUSC
Medical University of South Carolina

# IRB Reviewer Checklist
# Informed Consent Document

Reviewer: PRO # PI:

| | | | | |
|---|---|---|---|---|
| **Document contains an understandable description of:** | | | | |
| All basic required elements as listed on the "Informed Consent" Guidance Poster (HRPP Program Guide Section 2.5 Appendix A) and IRB Committee Members website and 45 CFR 46.109, 45 21 CFR 50.25 21 CFR 56.109(b). | | | | |
| 1. | Explanation of research purpose/reason for selection. | ◯ Yes | ◯ No | |
| 2. | Adequate description of all procedures/activities. | ◯ Yes | ◯ No | |
| 3. | An explanation of the expected duration of the subject's participation. | ◯ Yes | ◯ No | |
| 4. | Description of reasonably foreseeable risks/discomforts. | ◯ Yes | ◯ No | |
| 5. | Description of anticipated benefits to subjects or others. | ◯ Yes | ◯ No | |
| 6. | Description of all alternative courses of treatment. | ◯ Yes | ◯ No | |
| 7. | Description of all costs of participation and any additional costs to subjects resulting from research participation. | ◯ Yes | ◯ No | |
| 8 | Information on subject compensation, amount, and payment schedule. | ◯ Yes | ◯ No | |
| 9. | Identification of all experimental procedures/test articles. | ◯ Yes | ◯ No | |
| 10. | Data sharing statement that de-identified information or biospecimens may be used for future research or that they will never be used for this purpose. | ◯ Yes | ◯ No | |
| 11. | For tests articles (regulated by the FDA), a statement that "the purpose of the study includes evaluation of both the safety and the effectiveness of the test article". | ◯ Yes | ◯ No | ◯ NA |
| 12. | Clearly separates research component from any concurrent medical treatment. | ◯ Yes | ◯ No | ◯ NA |
| 13. | A statement that subject will be notified of significant new findings during the course of the study. | ◯ Yes | ◯ No | ◯ NA |
| **Additional elements of disclosure, when appropriate:** | | | | |
| 14. | A statement that the particular treatment or procedure might involve risks to the participant, which are currently unforeseeable. | ◯ Yes | ◯ No | ◯ NA |
| 15. | A statement that if the participant is or becomes pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which are currently unforeseeable. | ◯ Yes | ◯ No | ◯ NA |
| 16. | Anticipated circumstances under which the participant's participation might be terminated by the investigator without regard to the participant's consent. | ◯ Yes | ◯ No | ◯ NA |
| 17. | The consequences of a participant's decision to withdraw from the research. | ◯ Yes | ◯ No | ◯ NA |
| 18. | Procedures for the orderly termination of participation by the participant. | ◯ Yes | ◯ No | ◯ NA |
| 19. | The approximate number of participants involved in the study. | ◯ Yes | ◯ No | ◯ NA |

| | | | | |
|---|---|---|---|---|
| 20. | A statement that the subject's biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit. | ◯ Yes | ◯ No | ◯ NA |
| 21. | A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. | ◯ Yes | ◯ No | ◯ NA |
| 22. | For research involving biospecimens, whether the research will or might include whole genome sequencing. | ◯ Yes | ◯ No | ◯ NA |
| **Vulnerable population requirements:** | | | | |
| 23. | Does the study involve cognitively impaired participants? If yes, complete the checklist for Cognitively Impaired Persons. | | ◯ Yes | ◯ No |
| 24. | Does the study involve children? If yes, complete the checklist for Children. | | ◯ Yes | ◯ No |
| **Standard Paragraphs included stating:** | | | | |
| 25. | A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained | | ◯ Yes | ◯ No |
| 26. | An explanation of whom to contact for answers to pertinent questions about the research. | | ◯ Yes | ◯ No |
| 27. | An explanation of whom to contact for answers to pertinent questions about the research participants rights. | | ◯ Yes | ◯ No |
| 28. | An explanation of whom to contact in the event of a research-related injury to the participant. | | ◯ Yes | ◯ No |
| 29. | Contact information for the research team for questions, comments, concerns or complaints. | | ◯ Yes | ◯ No |
| 30. | Contact information for someone independent of the research team for problems, concerns, questions, information or input. | | ◯ Yes | ◯ No |
| 31. | A statement that participation is voluntary. | | ◯ Yes | ◯ No |
| 32. | A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. | | ◯ Yes | ◯ No |
| 33. | A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. | | ◯ Yes | ◯ No |
| **VA-Funded Research** | | | | |
| 34. | Informed Consent is on VA Form 10-1086 | | ◯ Yes | ◯ No |
| 35. | Informed Consent includes a statement that in the event of a research-related injury the VA will provide necessary medical treatment to a participant injured by participation. | | ◯ Yes | ◯ No |
| 36. | Informed Consent includes a statement that a veteran-participant does not have to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans have to pay co-payments for medical care and services provided by the VA. | | ◯ Yes | ◯ No |
| 37. | As appropriate, the VA standard consent language is included for (check as applicable):<br>☐ Commercial Products<br>☐ Future use of data<br>☐ Payment for participation in the study | | ◯ Yes | ◯ No |

| | | | |
|---|---|---|---|
| | ☐ Photographs, voice and/or video recording (including use of VA Form 10-3203)<br>☐ Future use of specimens<br>☐ Re-contact<br>☐ Disclosure of results | | |
| **FDA-Regulated Research** | | | |
| 38. | A statement that notes the possibility that the Food and Drug Administration may inspect the records. | ◯ Yes | ◯ No |
| **Research Involving More than Minimal Risk** | | | |
| 39. | An explanation of whether any compensation is available if injury occurs. | ◯ Yes | ◯ No |
| 40. | If compensation is available if injury occurs, what it consists of, or where further information may be obtained. | ◯ Yes | ◯ No |
| 41. | An explanation as to whether any medical treatments are available if injury occurs. | ◯ Yes | ◯ No |
| 42. | If medical treatments are available if injury occurs, what it consists of, or where further information may be obtained. | ◯ Yes | ◯ No |