

**VA Medical Center  
New York Harbor Healthcare System (NYHHS)**

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**Informed Consent Checklist**

1. A statement that the study involves research  
 Yes                       No                       N/A
2. An explanation of the purpose of the research  
 Yes                       No                       N/A
3. The expected duration of the subject's participation  
 Yes                       No                       N/A
4. A description of the procedures to be followed  
 Yes                       No                       N/A
5. Identification of any experimental procedures vs standard care  
 Yes                       No                       N/A
6. A description of any reasonably foreseeable risks or discomforts to the subject including for example, privacy risks (legal, employment and social)  
 Yes                       No                       N/A
7. A description of any benefits to the subject or to others, which may reasonably be expected from research  
 Yes                       No                       N/A
8. A disclosure of appropriate alternative procedures or courses of treatment (if any) that might be advantageous to the subject  
 Yes                       No                       N/A
9. A statement describing the extent (if any) to which confidentiality of records identifying the subject will be maintained  
 Yes                       No                       N/A
10. If appropriate, a statement that Federal agencies such as the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP) and the Government Accounting Office (GAO) may have access to the records. [VHA Handbook 1200.5 App. C]If an FDA-regulated test article is involved, the FDA requires a statement that the FDA may choose to inspect research records that include the subject's individual medical records. [21 CFR 50.25 (1) (5)]  
 Yes                       No                       N/A
11. For research involving more than minimal risk, an explanation as to whether any compensation exists if injury occurs  
 Yes                       No                       N/A

12. For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained and an explanation of whom to contact in the event of a research-related injury to the subject [38 CFR 17.85]  
 Yes                       No                       N/A
13. An explanation of whom to contact for answers to pertinent questions about research and research subjects' rights  
 Yes                       No                       N/A
14. A statement that participation is voluntary  
 Yes                       No                       N/A
15. A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled  
 Yes                       No                       N/A
16. A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled  
 Yes                       No                       N/A
17. Include information concerning the amount of payment to subjects  
 Yes                       No                       N/A
18. Include information concerning the schedule of payments to subjects  
 Yes                       No                       N/A
19. Do not include any exculpatory language through which the subject or the subject's legally authorized representative is made to waive or to appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence  
 Yes                       No                       N/A
20. \* If appropriate, a statement that the particular treatment or procedure may involve risks to the subjects (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable  
 Yes                       No                       N/A
21. \* Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent if appropriate  
 Yes                       No                       N/A
22. \* Any additional costs to the subject that may result from participation in the research, consistent with the Federal laws concerning veteran's eligibility for medical care and treatment  
 Yes                       No                       N/A
23. \* The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject  
 Yes                       No                       N/A

24. \* A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject  
 Yes                       No                       N/A
25. \* The approximate number of subjects involved in the study  
 Yes                       No                       N/A
26. A statement that a veteran-subject will not be required to pay for care received as a subject in a VA research project except as follows:  
(a) those veterans who are required to pay co-payments for medical care and services provided by VA [38 USC 1710 (f) and (g)]  
(b) Investigators need to note charges will not be made for medical services, including transportation, furnished as part of a VA-approved research study [38 CFR 17.102]  
 Yes                       No                       N/A
27. \* If the investigators believe that the human biologic specimens obtained could be part of, or lead to the development of a commercially valuable product, or if the specimens are to be retained after the end of the study, current VA policy and Veterans Health Administration (VHA) regulations must be followed.  
NOTE: If genetic testing is to be done, VA requirements pertaining to genetic testing must also be met.  
 Yes                       No                       N/A

\* Additional elements of informed consent when applicable.