**VA INFORMED CONSENT PROCESS CHECKLIST**

**\*Complete this checklist for each consent obtained and file with the original informed consent document\***

**RESEARCH STUDY IDENTIFICATION (Required information)**

STUDY TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ROLE OF STUDY TEAM MEMBER OBTAINING CONSENT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

RESEARCH SUBJECT IDENTIFICATION: (Required information)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |   |   |  | | | |  / /  |

Last Name First Name Mid. Init. Last-4 SSN Todays Date (mm/dd/yy)

|  |  |
| --- | --- |
| **A.** | Date ALL required SIGNATURES (Subject, Witness (If required by IRB) and Person Obtaining Consent), their PRINTED NAMES and the DATES they signed the informed consent document (ICD) have been Checked and Verified Accurate and appear in the proper location |
| **B.** | DATE AND TIME THE CONSENT FORM WAS REVIEWED AND DEEMED COMPLETE\*\*Must be prior to date/time of Subject’s First Study Activity\*\* |
| **C.** | DATE AND TIME OF THE SUBJECT’S FIRST STUDY ACTIVITY OR STUDY INVOLVEMENT  |
|  | Verify and Initial each requirement below. |
| **1.**  | Informed consent and HIPAA Authorization, if required by VA-IRB (or another IRB) was obtained from this subject prior to study participation.  |
| **2.** | A VA Scope of Practice Form has been signed by the PI and approved by the VA IRB which designates me as an authorized agent of the PI and qualified to obtain consent for this study.  |
| **3.** | This prospective subject was given adequate time necessary to carefully and fully read the Informed consent document (ICD) and all questions were answered to his/her satisfaction.  |
| 4. | All aspects of this subject’s study involvement, including the purpose of the study, known and potential risks, possible benefits and alternatives to study participation were explained and discussed prior to subject signing the ICD or agreeing to participate in the research.  |
| 5. | If required, a scanned image of the Research Enrollment Note, Consent Form and/or HIPAA Authorization will be entered into the subject’s electronic medical record (CPRS). |
| 6. | Subject has been consented using the most recently approved, VA date-stamped version of the consent form (VA Form 10-1086) and HIPAA Authorization Form (VA Form 10-0493).  |
| 7. | A copy of the informed consent document has been issued to this subject and the subject was instructed to retain that copy for reference and to ask any and all questions that might arise throughout their study involvement.  |
| 8. | The subject has been shown where in the ICD to locate study team phone number(s) and the phone number of the VAAAHS IRB Coordinator. The subject has been reminded to call with any questions or concerns. Cathy Kaczmarek @ 734.845.3439 |
| 9. | The subject has been informed that participation is entirely voluntary and that they may withdraw their participation at any time and for any reason.  |
| 10. | Original ICDs and all copies are printed and issued as single-sided documents and that the original signed ICD must be kept in the investigator’s project files on VA property. |
| 11. | Upon completion of the Informed Consent Process, this subject’s name was added to the Master List of All Subjects. [Per revised VHA Handbook 1200.05 (11/12/14) a MLS is no longer required, but a list of all enrolled participants is considered good research practice.] |
| 12. | I know I can contact the VAAAHS IRB Coordinator at 734.845.3439 or the Research Compliance Officer at 734.845.4013 if I have questions or concerns regarding the consent of this or any individual considering study participation. |

ORIGINAL FORM VERSION: 4/15/09. REVISIONS: 9/17/09, 10/30/09, 11/30/09, 12/07/11, 2/27/12, 10/7/13

2/19/14, 4/1/14, 6/18/14, 12/19/14, 4/27/15, 11/26/19