INSTRUCTIONS FOR COMPLETING THE VA CONSENT FORM 10-1086

 [B] = Basic Element (required in all forms) [A] = Additional Element (must include when appropriate)

PURPOSE OF RESEARCH STUDY

[ ] Include a statement that the study involves research. [B]

[ ] Explain the purpose of the study. [B]

DESCRIPTION
[ ] Must describe all research procedures in the study; must identify which procedures are experimental. [B]
[ ] Must describe the expected duration of subject's participation. [B]

[ ] Must identify any procedures that are experimental. [B]
[ ] State the approximate total number of subjects to be involved in the study. [A]

Required Information:

* Who can take part in this study? How will subjects be selected?
* Give a step by step description of the procedures from selection of patients through follow-up. Identify phases, if appropriate.
* Identify and discuss all experimental procedures. Be sure to include invasive techniques, restriction of normal activities, long term follow-up, and possibility of receiving inactive materials.
* Make a clear distinction between procedures which are necessary because of the study and those which would be required as part of the subject’s usual care. This includes increases in time, complexity, discomfort, and/or prolongation of hospitalization or hospitalization entirely for research purposes.
* If the study involves random assignment, the nature and probability of group assignment must be specified:
 *“Using a procedure similar to flipping a coin, you will have a 1 in chance of receiving a sugar pill instead of .”*
* If the subject and/or treating physician are to be kept blind to group assignment, this fact must be included.
* When appropriate, the subject’s approximate time of involvement in the study shall be indicated.
* The number of times a procedure is repeated shall be noted.
* The duration of all lengthy procedures, including questionnaires, should be indicated. This may be summarized for procedures done as a group.
* If blood is withdrawn, both the frequency of the procedure and the total amount of blood should be indicated in metric measures, followed by teaspoons, tablespoons, ounces, pints, etc., as appropriate. For studies involving a large number of samples to be drawn over an extended time interval, an estimate can be given. The IRB will usually not allow withdrawal of more than 450 ml of blood during a 3 month period.
* For women of child-bearing age: If pregnant subjects are to be excluded, this must be noted in the Consent Form.

BANKED SPECIMENS FOR FUTURE RESEARCH

The Consent Form must clearly address the following concerns:

1) The types of specimens that will be stored and the location of the tissue bank and the types of future research that the sample will be used for.

2) Will the specimen be shared with other researchers for approved research protocols?

3) The length of time the specimen will be stored. What will be the disposition of the specimen after completion of the study or at the end of the banking period (how long)?

4) Will the specimen will be labeled with a code that doesn’t contain any personal identifiers (i.e., protected health information as defined by HIPAA). Will the subject’s clinical data be linked to the specimen?

5) When and under what conditions research results will be conveyed to the subject, the subject’s family, or the subject’s physician. Note: Laboratories that test human specimens cannot report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients unless the laboratory is Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified.

6) Will the specimen be used to generate a cell line or for genetic testing?

7) Will the human subject be contacted after the completion of the original study?

8) Will the specimens and all links to clinical data be destroyed or removed upon the subject’s request?

9) Any potential conflict of interest or financial gains for the investigators or the participating institution?

RISKS
[ ] Must include this statement “There may be other risks that are unforeseeable at this time.”
[ ] May include a statement that a particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable. [A]

Required Information:

* State any known risks, inconveniences, or side effects (including physical, emotional, social or economic), with at least a rough estimate of number per 100, 1000, etc. of likelihood for severe events such as, loss of limb, coma, death, hemorrhage, etc.
* If blood is to be drawn, include the following statement.
*"The risks of simple blood drawing commonly include: the occurrence of discomfort and/or bruising at the site of puncture; and less commonly, the formation of a small blood clot or swelling of the surrounding area, and bleeding from the puncture site. Rarely, fainting and local infection may occur.”*
* Include the effects these occurrences will have on the person’s health as a result of participating in the research study.
* Include a statement describing the extent, if any of the risk of possible loss of confidentiality.

BENEFITS
[ ] Describe the benefits to the subject and benefits to society; not payments to subjects. [B]

* If there are no clear benefits to this subject, include the following statement.
*"You are not likely to benefit by participating in this study."*
* Payments or reimbursements must be listed under COMPENSATION and not under BENEFITS.

ALTERNATE COURSES OF ACTION

[ ] Include a statement that participation in the study is voluntary [B]

  *“You do not have to participate in this study. You may drop out of the study at any time without penalty. By doing so, you will not lose any benefits that you may be entitled to.”*

[ ] Include a statement that refusal to participate will involve no penalty or loss of benefits to which the
 subject is otherwise entitled [B]

[ ] Briefly describe alternate accepted courses of therapy or diagnostic procedures, as well as the potential
 harms and benefits [B]

[ ] Include a statement about any risks from not participating in the study [B]

[ ] Include a statement that the subject may discontinue participation at any time, the consequences,
and the procedures for orderly termination of participation [A]
*"In case you decide to withdraw from the study, you may be harmed in the following ways\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_:"*

STATEMENT OF RESEARCH RESULTS

[ ] Describe how subject confidentiality will be protected with specific details of privacy & security [B]

* Include a statement to describe who will have possession and access to research data (including medical record data, surveys, questionnaires, videos, audio cassettes).
* Describe how these items will be coded and how they will be secured. Describe how investigator access to these items will be terminated.

[ ] State subjects will not be identified in publications. [B]

*“If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.”
“No information by which you can be identified will be released or published unless required by law.”*

[ ] State that significant new findings developed during the course of the research that may affect the subject's willingness to continue participation will be provided to the subject. [A]

*“We will let you and your physician know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.”*

[ ] If the study includes surveys which may elicit information concerning suicidal intent, depression, or other major clinical findings, indicate the conditions when the primary physician will be notified.

 [ ] State “Federal Oversight agencies and offices may have access to your records.” [B] - Added 12/19/14

SPECIAL CIRCUMSTANCES

[ ] Indicate there will not be any costs for any additional care received as a participant in the research study. [A]

*“There will be not be any costs to you for any additional care that you receive as a participant in this research study.”*

[ ] Include a statement about the circumstances under which the investigators may terminate the participation of the subject without regard to the subject's consent (must include when appropriate). [A]

# *"The investigators of this study may have to end your participation in this study for the following reasons\_\_\_\_\_\_:"*

[ ] There should not be 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

[ ] Use this statement if non-veterans will be recruited as research subjects. *“Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.”*

[ ] When appropriate, add the appropriate statements
 *“The sponsor funds the VA Medical Center based on the number of research subjects enrolled.”
 “The sponsor provides a fixed payment to the VA Medical Center for performing the study.”*

 [ ] When appropriate, add the following statement:

 *“The particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, it he subject is or becomes pregnant) that are currently unforeseeable.”*

COMPENSATION

[ ] Must include a statement about payments to subjects (or state none) [B]
*Describe any payments or reimbursements and the schedule of payments*

[ ] Describe the form of payments *including cash, coupons, phone cards or gift items)* and how payments will be made. [A]

* The VA IRB will not allow excessive payments to research subjects that may be a coercive influence on the subject’s decision to participate in the research study

PATIENT AUTHORIZATION FOR ACCESS TO PHI
[ ] If the research study is FDA regulated, must state that the FDA may inspect the research records [B]
 (See item 8 in the standard boilerplate list of required statements)

SUBJECTS RIGHT’S PAGE
[ ] Investigators are not allowed to change the mandatory boilerplate text on this page.
[ ] The contact persons and phone numbers must be accurate and up to date

 \*This page includes all required explanations for research involving more than minimal risk:

* An explanation as to whether any compensation was available if injury occurred.
* If compensation was available when injury occurred, an explanation as to what it consisted of or where further information may be obtained.
* An explanation as to whether any medical treatments were available if injury occurred.
* If medical treatments are available when injury occurs, an explanation as to what it consists of or where further information may be obtained.

VA Ann Arbor Healthcare System
RESEARCH PARTICIPANT OUTREACH PROGRAM

[This is no longer a requirement per new VHA Handbook 1200.05 – Nov. 12, 2014]

VA investigators MAY distribute the informational brochure, “Volunteering in Research – Here are some things you need to know,” to potential research participants in settings where participants may be recruited (e.g., clinic waiting areas), and to each prospective participant when that individual is approached to take part in a project. [But this is no longer a requirement per new VHA Handbook 1200.05 – Nov. 12, 2014]

Color copies of this brochure are available in the VA R&D Office (X53766) and on-line at this link:

<http://www.research.va.gov/programs/pride/veterans/Volunteering-in-Research.pdf>

During the informed consent process, VA investigators should remind research participants that the last page of the VA Consent Form has contact phone numbers for communication with research project investigators and with the VA IRB Coordinator (who is independent of the research project in question).

VA investigators should always inform research participants and their designated representatives that they may consult with staff in the VA R&D Office at any time to obtain information, discuss their questions and concerns, and offer their input.

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)

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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 (ICD) WAS REVIEWED AND DEEMED COMPLETE AND VALID\*\*Must be prior to date/time of Subject’s First Study Activity\*\* |
| C. | DATE AND TIME OF THE SUBJECT’S FIRST STUDY ACTIVITY OR INVOLVEMENT  |
|  | Verify and Initial each requirement below. |
| 1.  | Informed consent and HIPAA Authorization, if required by VA-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.  |
| 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 completed and signed, original 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

PURPOSE OF RESEARCH STUDY:

RESEARCH SUBJECT IDENTIFICATION: (Required information)

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|  |  |   |  | | | |  / /  |

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

DESCRIPTION:

RISKS:

BENEFITS:

ALTERNATE COURSES OF ACTION:

STATEMENT OF RESEARCH RESULTS:

SPECIAL CIRCUMSTANCES:

COMPENSATION:

|  |
| --- |
| RESEARCH SUBJECT’S RIGHTS:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has explained this research study and answered all questions. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply for VA care and services that are not part of this study. Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. Participants may withdraw from this study at any time without penalty or loss of VA or other benefits. VA will provide treatment for research related injury in accordance with applicable federal regulations. The VA will provide necessary medical treatment should you be injured by participation in this study.  You will be treated for the injury at no cost to you, but no provisions have been made for additional compensation.  No reimbursement, compensation or free medical care is offered by (name of any non-VA project sponsor here).  You may be among the veterans required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.In case there are medical problems, an injury, or if you have questions, concerns or complaints about the research study, you can contact member(s) of the research study team: \_\_\_\_\_\_\_ can be called at \_\_\_\_\_\_\_ during the day and \_\_\_\_\_\_\_ can be contacted at \_\_\_\_\_\_\_ after hours. The sponsor of this research study is \_\_\_\_\_\_\_\_\_\_\_\_\_ *(or state none)*You may contact the VA Human Studies coordinator at 734-845-3440 to ask questions about your rights as a research subject and to verify this study is reviewed and approved by the VA. You may also call when research study staff are not available or to discuss your questions or concerns with someone other than study staff. You may learn more about research at the VA Ann Arbor Healthcare System at [www.annarbor.research.va.gov](http://www.annarbor.research.va.gov)I have been informed about my rights as a research subject, and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form. |
| x\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | x\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | x\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature of Subject | (Print Name) | Todays Date (mm/dd/yy) |
| x\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | x\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | x\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature of Legally Authorized Representative | (Print Name) Todays Date (mm/dd/yy) |
| (Durable Power of Attorney for Health Care, Court Appointed Guardian, spouse, adult child, parent, adult sibling, grandparent, adult grandchild, adult close friend (must be ≥18) |
| [MUST DELETE THIS BLOCK IF NOT APPROVED BY VA IRB] [MUST DELETE THIS BLOCK IF NOT APPROVED BY VA IRB] |
| x\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | x\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | x\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature of person obtaining consent (Study personnel must be approved by VA IRB) | (Print Name) | Todays Date (mm/dd/yy) |
|  |

IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086) MUST BE CONSECUTIVELY NUMBERED.

You must use the new HIPAA Authorization Form found at this link –

<http://www.annarbor.research.va.gov/ANNARBORRESEARCH/resappforms.asp>

VA Form 10-0493 - Dated May 2014

\*\*\*Use of VA Form 10-3203 is no longer required. However, the consent form must include information describing any photographs, video, and/or audio recordings that will be obtained for research purposes.