INSTRUCTIONS FOR THE RESEARCHER
COMPLETING A VA FORM 10-1086 [RESEARCH INFORMED CONSENT]
Updated Template: 3/31/2011

VA Form 10-1086, Research Consent Form, must be used as the consent form for VA NYHHS human subjects research. The only exception is that a DoD informed consent form may be employed for active duty military personnel participating in VA research at DoD sites when VA-specific language is not necessary.

These instructions apply to research consent forms to be submitted to the VA NYHHS Subcommittee for Human Studies [or IRB]. It must be completed on the computer as a Microsoft Word document before submitting for review and approval. Please use the most recent version of the template that is posted on the VA NYHHS R&D website.

All required elements must be completed as well as any additional elements required by the IRB as listed in the VHA Handbook 1200.05. The informed consent form must contain a designated block for each required signature (e.g., subject, person obtaining consent, and witness when applicable) and for the date of each signature. The IRB may require a witness if the study involves an invasive intervention or an investigational drug or device. The witness is required to witness only the subject's or subject's Legally Authorized Representative's (LAR) signature unless the Sponsor requires a witness to the informed consent process. Under appropriate conditions, investigators may obtain consent from the LAR of a subject (i.e. surrogate consent) subject to IRB approval. Optional signatures include signature of Principal Investigator - if the sponsor of the study requires it in addition to the designated person obtaining consent, signature of witness to consent process – if the sponsor of the study require a witness to the consent process in addition to a witness to the subject's signature. You may add additional lines as necessary.

The template contains text in a different font color and may either be instructions (which should be **deleted** in the final version) or needs to be **completed or revised** to be protocol specific and may be deleted if not applicable. Recommended statements may be revised as applicable. Note: The instructions are in a different font color and should not be included in the final text of your consent form. If sections in the template are noted "Include if applicable", delete if it does not apply to the protocol.

Each page of the consent form should have the **title of the study**, **name of the principal investigator**, **the version date of the consent form**, and **the IRB approval date**. The first three items are found in the headers of the form template and may be edited by double-clicking on the appropriate area. At continuing review, if there is no change in the consent form, **the version date remains the same**. The IRB approval date is a preprinted box on the footer section under "IRB Use only". [See Microsoft Word Help (*View, edit*

or format a header or footer) for help]. Shortcut: To display the header, double click on the upper left corner of the header grayed-out area.

To ensure readability, the consent form should be written at an **8th grade reading level using layman's terms as often as possible**. The language in the consent should be clearly understood by persons of the full range of educational levels that will be asked to participate. Medical jargon should be clearly defined and the information should be related to everyday familiar language. For example, when referring to medical terms that are commonly abbreviated, write out the full name the first time you mention it in the text. When using statistics, indicate the number out of 100 or more, instead of a percent. When using acronyms, spell out the phrase in full the first time it is used in the document.

Consent forms should not include a timeframe for destruction. If there is language about destruction of identifiers or research records, it must only say "in accordance with the record control schedule."

Make sure to **proof read** your work (spell check, spacing) before submitting to the Research Office. If your computer has Microsoft Word set up to track changes [Ctrl+Shift+E], make sure to click "Accept All Changes" to your document **before printing** or set up Word to show "Final" only. If submitting a revision of an IRB-approved informed consent document, include an extra copy with the track changes showing only "insertions and deletions". Please do not include tracking of "comments", "Ink" and "Formatting" changes in this print out (these options are found on the menu tab "Review / Show Markup". This copy is only to aid the IRB reviewer in locating the specific changes to the document.

Digital Stamp of IRB approval:
The IRB approval is documented on the preprinted box on the footer section of the template as the date of the most recent IRB-approval of the form along with the assigned protocol-specific MIRB ID number. Submit the consent forms in Microsoft Word format via e-mail to the outlook mail distribution group VHANYH R&D IRB (smtp: VHANYNRdirb@va.gov) with the subject line "**Digital Research Informed Consent**". Attach the consent document as a file and in the body text of the e-mail indicate the location of any changes (page number and section or paragraph) as applicable. The file will be uploaded to the VA Intranet Sharepoint site. It is available to you for download, attaching to e-mail or for printing hard copies. Because of differences in printers and default settings, it is your responsibility to check the format of your print out.

Before using the consent document:

1. A consent form document must have prior **IRB** approval. This document's approval expires and must be renewed for continued use. Any change to this document requires prior IRB review and approval. Note that final approval to

initiate research activity is written notification from ACOS/R&D after IRB approval has been reported to the VA R&D Committee.

2. Subject Identification information is required to facilitate scanning of the document into the Computerized Patient Record System (CPRS) and is on the first page header section. When a research participant is consented this signed document requires the person's name and **full social security number**.
3. Your Protocol ID is a MIRB-generated 5-digit code. It is provided to you in your approval letter. This is entered in the IRB Use Only section of each page of your IRB-approved consent document.
4. A digital copy of your consent document will be available on the VA Intranet Sharepoint site under PI Name/Protocol ID. See link below:
   https://vaww.visn3.portal.va.gov/sites/NYHDocuments

Obtaining informed consent:

1. If someone other than the investigator conducts the interview and obtains consent from a patient, the investigator needs to formally delegate this responsibility, and the person so delegated must have received appropriate training to perform this activity. The person so delegated must be knowledgeable about the research to be conducted and the consenting process, and must be able to answer questions about the study. It is recommended that the PI keep a log of this task delegation.
2. An investigator must seek consent only under circumstances that:
   a) Provide the prospective subject or the subject's legally-authorized representative sufficient opportunity to consider whether or not to participate
   b) Minimize the possibility of coercion or undue influence.
3. The information that is given to the subject or the subject's representative must be in language understandable to the subject or the subject's representative.
4. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the subject's representative is made to waive or 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.
5. A signed copy of the consent document must be provided to the research participant and the original signed and dated document filed in the investigator's research file.
6. Before persons who lack decision-making capacity may be considered for participation in any VA research, the IRB must find that the proposed research meets all VA's requirements for surrogate consent (see VHA Handbook 1200.05 Paragraph 17 and 49).
7. A progress note documenting the informed consent process must be placed in the subject's medical record (CPRS) using the template Research Enrollment Note which flags the medical record, unless this requirement was waived by the IRB.

Oral Consent Form and the use of the Short Form:

A shortened written consent document stating that the elements of informed consent required by VHA Handbook 1200.05 and 38 CFR 16.116 has been presented orally to the subject or the subject's legally-authorized representative. When this method is used, there **must** be a witness to the oral presentation.

Translation Service:
For subjects whose native language is not English, informed consent must be obtained in a language that is understandable to the subject (or the subject's legally authorized representative). In accordance with this policy, the IRB requires that informed consent conferences include a reliable translator when the prospective subject does not understand the language of the person who is obtaining consent. The VA has available a phone translations service is called Language Lines Services.

Audit of Informed Consent Document:
All informed consent documents must be audited by the Research Compliance Officer (RCO) and results reported to the Office of Research Oversight (ORO) in accordance with the requirements of VA Handbook 1058.01 for reporting serious and continuing noncompliance. The following are examples of informed consent noncompliance that should be reported:

- Lack of an informed consent document signed and dated by a subject.
- Use of an unapproved, unstamped, and/or outdated informed consent document.
- Initiation of study procedures prior to obtaining informed consent (only applies to subjects accrued in the last 12 months).
- Lack of proper Health Insurance Portability and Accountability Act (HIPAA) Research Authorization.
- Informed consent obtained by a person not authorized by the PI.

Research Participant Outreach Program Requirement:
VHA Directive 2008-079 requires you to make available to all individuals approached to take part in a research project the informational brochure, "VOLUNTEERING IN RESEARCH – Here are some things you need to know" which can be obtained for free from VA Office of Research and Development, Center On Advice and Compliance Help (COACH), (To order see website below). There are also copies available at the office of the local IRB Manager. The website also provides a link to print a copy of the brochure.
Website: http://www.research.va.gov/programs/pride/resources/materials.cfm

BEFORE SUBMITTING TO IRB: Please use the Informed Consent Checklist to ensure that you have included all the regulatory requirements for an informed consent document or refer to VHA Handbook 1200.05 Par. 30 for more details.

COMMONLY USED INFORMED CONSENT LANGUAGE

1. Describing the target participants: This study will involve 200 veteran patients like you who have undergone colonoscopy at this VA Facility. Nationwide a total of 1500 veterans are expected to participate in 20 identified VA facilities. Your participation will last for 3 months after your procedure and involves only 15 minutes of your time at 3 separate occasions.
2. Describing randomization procedures (5% chance): Using a procedure like flipping a coin or drawing chances from a hat, you will have a 1–in-20 chance of receiving placebo, a substance that looks like the study drug but contains no active medication.
3. Instructions for women of child bearing age: Since this research may have bad effects on an unborn child and should not be done during pregnancy, it is necessary that a pregnancy test be done first. To your knowledge, you are not pregnant at the present time. You also agree to avoid becoming pregnant (use contraceptives, take precautions against becoming pregnant, etc.) during this study.
4. Research-related injury with no additional compensation: In the event that you sustain an injury or illness as a result of your participation in this VA approved research study, all medical treatment (emergency as well as medical treatment beyond emergency care) will be provided by the VA. You will be treated for injury at no cost to you. However, no additional compensation has been set aside.
5. Non-release of liability: No promises have been given to you since the results and risks of a research study are not always known in advance. However, every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence.
6. Reimbursement: You will be compensated for your travel expenses while participating in this research subject. You will receive $20.00 for each blood draw/ sessions that you complete. You will receive payment at the end of each blood draw/session or at the end of all 5 sessions.
7. Payment: In return for your time and inconvenience, you will be paid $100 for your participation in this study. If you do not complete the study, you will be paid $40 for each week for participation. You will be mailed a check approximately three (3) weeks after the study has ended. Note that we will require your social security number to process the check. In addition, it is VA policy that the amount you receive from this study will be reported to the Internal Revenue Service (IRS) and may be considered taxable income.