**Madison VA Research Checklist for Non-Exempt Research for Studies Under the Revised Common Rule**

**Version Date: May 1, 2019**

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| 1. **Determination of whether the study falls under VA purview** | | | |
| 1. Are any personnel engaged in human subjects research under their VA appointment? | Yes  *The study falls under VA purview. Go to next question.* | No  *Go the next question.* | |
| 1. Does this study enroll, use specimens obtained from, or use medical records of Madison VA patients? | Yes  *The study falls under VA purview. Go to next question.* | No  *Go the next question.* | |
| 1. Is the protocol supported by VA funds? | Yes  *The study falls under VA purview. Go to next question.* | No  *If the answer to all questions in this section is no, the study does not fall under VA purview. This checklist does not need to be completed.* | |
| 1. Has the study team uploaded a completed VA Privacy Officer/Information Security Officer Checklist? | Yes  *Ensure the checklist is complete. Go to next section.* | No  *Request the study team upload a completed checklist in ARROW.* | |
| Section notes, if applicable: Click here to enter text. | | | |
| 1. **Involvement of non-veterans in VA research** | | | |
| 1. Does this study enroll, use specimens obtained from, or use medical records of individuals ***IN ADDITION TO*** Madison VA patients? | Yes  *Go to next question.* | No  *Go the next section.* | Not applicable – *the study only includes VA employees.*  *Go the next section.* |
| 1. Do any of the following apply?    1. VA funds will be used to support activities involving non-VA subjects.    2. Study team members will interact or intervene while under their VA appointments with non-VA subjects.   *NOTE: The IRB must document in the IRB minutes or IRB protocol file its determinations regarding participation of non-veterans in the study. Non-veterans may only be entered into a VA research study when the investigator can present a compelling argument to the IRB for the inclusion of non-veterans (e.g., insufficient number of veterans; survey of VA employees; study of active duty military; study involving veterans’ family members), and the research is relevant to the care of veterans or active duty military personnel. Non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the investigators.* | Yes  *All non-VA participants are to be considered VA subjects under VA purview and all VA research requirements will apply to them. Further, the study team is required to provide justification for inclusion of the non-veterans per the note at left.* | No  *A separate IRB application is required to cover the research involving the non-VA subjects.* | |
| Section notes, if applicable: Click here to enter text. | | | |

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| 1. **Madison VA-prohibited or –restricted research** | | |
| 1. Does this study involve any of the following?  * Prisoners * Classified research * Planned emergency research | Yes  *Consult with the Madison VA Research Compliance Officer. A researcher generally cannot conduct the research involving the populations/procedures at left under his/her Madison VA appointment.* | No  *Go the next question.* |
| 1. Does this study involve pregnant women? | Yes  *Women who are known to be pregnant and/or their fetuses may be involved in VA research if all of the requirements of 45 CFR 46.204 are met AND the Madison VA Hospital Director certifies the Madison VA Hospital has sufficient expertise in women’s health to conduct the proposed research. Ensure the study meets the requirements of 45 CFR 46.204 and the study team provides signoff from the Madison VA Hospital Director. The VA R&D Committee will be responsible for working with the Madison VA Hospital Director to obtain any required signoff.* | No  *Go the next question.* |
| 1. Does this study involve either:    * The use of human embryo(s) or    * Creation of human embryos solely for research purposes or research? | Yes  *Ensure research does not involve: 1) the creation of human embryo(s) for research purposes; or 2) or a situation where the embryo(s) used in the research are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498B of the Public Health Service Act (42 U.S.C. 289g(b)).* | No  *Go the next question.* |
| 1. Does this study involve neonates?   *Note: If the study involves neonates document that the research is limited to prospective observational or retrospective record review studies that involve neonates or neonatal outcomes.* | ☐ Yes  *A researcher cannot conduct research involving neonates under his/her Madison VA appointment unless it is limited to prospective observational or retrospective record review studies that involve neonates or neonatal outcomes.* | ☐ No  *Go the next question.* |
| 1. Does this study involve children, including samples, images, or data that are derived from children? | ☐ Yes  *A researcher generally cannot conduct research involving children under his/her Madison VA appointment unless the research a) is relevant to the VA, b) does not pose more than minimal risk to subjects, and c) meets the requirements of 45 CFR 46.401-404 and 408. In addition, the Madison VA Hospital Director must approve participation in any proposed research involving children. Ensure the study meets the requirements of 45 CFR 46.401-408. The VA R&D Committee will be responsible for working with the Madison VA Hospital Director to obtain any required signoff.* | No  *Go the next question.* |
| 1. Will the research study be conducted at international sites (i.e., sites not within the United States, its territories, or Commonwealths) or involve biological specimens or human data originating from international sites?   *Note: This requirement applies to multi-site trials if the study is sponsored by the VA, the VA functions as the coordinating center, the VA subcontracts to an international site, or the principal investigator for the overall project is a VA investigator* | Yes  *The Madison VA does not allow the conduct of international research for investigators under their purview. Have the Madison VA study team confirm that they will not participate in any activities conducted at international sites. NOTE: Other sites not under Madison VA purview may participate in international research.* | No  *Go the next section.* |
| Section notes, if applicable: Click here to enter text. | | |
| 1. **Student and Trainee Research** | | |
| 1. Is a student or trainee identified as a member of the VA study team? | Yes  *Students and trainees can participate in Madison VA research as study team members if they are 1) enrolled in an institution with an educational affiliation agreement with the Madison VA facility (i.e., the UW-Madison) or 2) directly appointed to a VA training program that has no external institutional sponsorship (e.g., VA Advanced Fellowship). Have the study team confirm that the student and/or trainee meets at least one of these two criteria.* | No  *Go the next section.* |

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| 1. **Data retention and de-identification** | | |
| 1. Do the study documents include a timeframe regarding when data will be destroyed or de-identified? | Yes  *Ensure documents reflect the current VA requirement to retain study records between 6-7 years after the close of the study.* | No  *Request the study team revise the application and applicable consent documents to reflect that the researcher will retain the records between 6-7 years after the close of the study.* |
| Section notes, if applicable: | | |
| 1. **Use or creation of data banks/repositories, tissue collection, and tissue banks** | | |
| 1. Does the protocol involve the creation of a VA data bank/repository (i.e., data kept at the VA for future research purposes, including a recruitment contact list) or providing data to a VA repository or VA tissue bank? | Yes  *May require an additional IRB application to cover the bank/repository.* | No  *Go the next question.* |
| 1. Does the study involve the collection or use of tissue or specimens? | Yes  *If the investigator believes that the human biologic specimens obtained could be part of, or lead to the development of, a commercially valuable product, this should be described in the consent form.* | No  *Skip to the next section.* |
| 1. Will the tissue or specimens be stored for this specific study at a non-academic, for-profit institution for more than 90 days? This does not refer to tissue banking for unspecified future use.   *NOTE: If the answer to this question is “yes”, the protocol and/or IRB application provide the following assurances:*   * *Only the analyses/tests listed in the protocol and consent form can be performed (see below for additional requirements related to tissue banking)* * *The code will be maintained at the VA until the samples are de-identified* * *DNA/RNA will not be analyzed* * *The company will inform the investigator in writing when the samples are destroyed* * *Case reports will not contain initials if they leave the VA* * *Specimens will be destroyed upon request of the subject* * *Before company personnel view files at the VA, they must complete VA security and privacy training* * *Specimens will be destroyed within 1 year of the study completion date* | Yes  *A waiver from the VA Office of Research & Development (ORD) will be required and the IRB application must contain the assurances detailed to the left. The VA R&D Committee will be responsible for obtaining any waivers from ORD..* | No  *Go the next question.* |
| 1. Does the study involve banking tissue or specimens for unspecified future use? | Yes  *Go the next question.* | No  *Go the next section.* |
| 1. Is the tissue banked at one of the following:  * Madison VA Hospital * Another VA site * NCI (e.g., Alliance, ECOG-ACRIN, SWOG) * Other site approved by central VA specifically for this study | Yes  *Go to next question.* | No  *Tissue banking unlikely allowed; consult with the VA Research Compliance Officer or VA Research Office.* |
| 1. Does the consent form include language that addresses **all** of the following?  * The types of specimens that will be stored and name and location of the biorepository/tissue bank. * Whether the tissue/specimen will be used for future research and, if so, what kind of research (e.g., research specified in the consent form; research conducted by the PI only; research conducted by other investigators; research related to specific diseases) * Whether the tissue/specimen will be used to generate a cell line or for genetic testing * Whether the tissue/specimen will be stored without any identifiers (i.e., “deidentified”) – if coded, the consent form must state that the specimen will be labeled with a code that does not contain any personal identifiers (i.e., PHI as defined by HIPAA) * Whether the research results will be conveyed to the subject, subject’s family, and/or health care provider and, if so, under what conditions – note that in order for the results of the testing to be released, the laboratory conducting the tests must be CLIA-certified * Whether the tissue/specimen and all links to clinical data will be destroyed or removed from the bank upon the subject’s request * Whether the subject will be contacted after completion of the original study * Any potential conflict of interest or financial gains for the investigator or participating institution | Yes  *Go to next section.* | No  *The consent form must be revised to include the missing element(s).* |
| Section notes, if applicable: Click here to enter text. | | |

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| 1. **Social Security Numbers** | | | |
| 1. Will real Social Security Numbers (SSNs), scrambled SSNs, or the last four digits of SSNs be used in the study?   *NOTE: This does not include the use of partial SSNs on the informed consent form or HIPAA authorization.* | Yes  *Consult with the VA Privacy Officer regarding the acceptability of using real SSNs, scrambled SSNs, or last 4 digits of SSNs. Go to next question.* | No  *Skip to next section.* | |
| 1. Will real SSNs be collected solely to pay subjects? | Yes  *Ensure the consent form describes the collection of SSNs and any other information (e.g., bank account) to facilitate payment and is clear that the SSNs are only collected for payment purposes. Recommended consent form language: To receive payment for your participation in this study, you may be required to provide your social security number and bank account information. This information will be used by the VA to pay you for this study and will not be kept by the study team.* | No  *Investigators may obtain and use real SSNs only when real SSNs are required to meet the specific aims of the research protocol.*  *Ensure:*   1. *the consent form describes collection of SSNs; and* 2. *the justification provided for the use of SSNs and security measures in place to protect the SSNs are documented in the IRB application Privacy & Confidentiality section and/or protocol and meeting minutes.* | |
| 1. Are study team members requesting SSNs by telephone? | Yes  *Study teams are prohibited from requesting SSNs by telephone. Ensure IRB documents are revised to eliminate this method of collecting SSNs.* | No  *Go to next section.* | |
| Section notes, if applicable: Click here to enter text. | | | |
| 1. **Subject identification and recruitment** | | | |
| 1. Will the research team access or use medical records or other data repositories to identify or recruit potential subjects for the research study?   *NOTE: The VA employs a stricter definition of preparatory to research than the University of Wisconsin-Madison. Only activities prior to the submission of a study to the IRB fall under the preparatory to research provision. Review of records for subject identification or recruitment or screening activities do not qualify as preparatory to research activities under VA policy.* | Yes  *Such access or use requires a partial waiver of authorization but NOT a waiver of informed consent under VA rules. Ensure waivers of authorization for this activity are documented in the IRB application and minutes.* | No  *Go to next section.* | |
| 1. Will the initial contact with potential research subjects occur via telephone as the first contact?   *NOTE: With the exceptions noted at right where a study team may have obtained permission from subjects for additional contact, initial contact with potential research participants must be made in person or via letter to avoid cold contact. The initial contact for potential research subjects must be made in accordance with the most recent VHA and VHA memoranda or guidance regarding this issue (available at* [*www.research.va.gov*](http://www.research.va.gov)*).* | Yes  *The VA does not allow initial contact with potential subjects to occur via telephone unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study (e.g., the study team obtained permission to re-contact them for future research). Ask the study team to revise IRB materials to eliminate this type of contact or provide documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study. NOTE that under VA requirements retaining subject contact information for future research opportunities likely constitutes a data repository and triggers those requirements. Consult with the VA Research Compliance Officer as needed.* | No  *Go to next section.* | |
| Section notes, if applicable: Click here to enter text. | | | |
| 1. **Consent form & authorization form requirements** | | | |
| 1. Does this study qualify for a waiver of informed consent for the entire study?  * *Note that waivers of informed consent cannot be granted for studies involving the use of photographs, voice recordings, or video recordings.* | Yes  *Skip to the next section.* | No  *Go to next question.* | |
| 1. Does this study qualify for a waiver of documentation of informed consent for the entire study? | Yes  *Use the Informed Consent Checklist to document how the study meets the criteria for a waiver of documentation of informed consent. Skip to question 8.* | No  *Go to next question.* | |
| 1. In addition to the elements of consent required under the Common Rule and, if applicable, the FDA regulations, are the following VA-specific requirements met by the consent documents?  * Use of the Madison VA consent form template * The name of the PI * The name of the study * The sponsor of the study (including the VA), if applicable * Inclusion of VA patient relations number:   *For information on the rights of research subjects, please contact the VA hospital patient relations representative at (608) 280-7078.*   * Inclusion of number to verify if the study is a VA study:   *If you want to confirm this is a valid VA study, please call the VA Research Office at (608) 280-7007.*   * Inclusion of VA compensation for injury language:   *In the event you sustain physical injury as a result of participation in this investigation, all necessary and appropriate care will be provided. However, the VA may not pay for the costs of treatment for injuries that result from your non-compliance with study procedures.*   * Inclusion of payment for care language:   *Veteran-subjects, or non-Veteran subjects participating in this VA study, will not be required to pay for care received as a subject in a VA research project. Some veterans are required to pay co-payments for medical care and services provided at the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.*   * Inclusion of distinction between risks related to the research versus those associated solely with usual care provided by the subject’s health care provider. The informed consent process is to include language advising subjects to review the risks of the latter with their health care providers. * Inclusion of language describing the plan or potential to re-contact subjects if the subjects will be re-contacted for future research whether within VA or outside VA. NOTE: This constitutes a data repository and VHA research data repository requirements would apply. | Yes  *Go to next question.* | No  *Ask the study team to revise documents to include missing elements.* | |
| 1. Will VA subjects undergo any procedures at the UW? | Yes  *Ensure the following compensation for injury language is included in the consent document in addition to the VA compensation for injury language: In the event that you are physically injured as a result of participating in this research at a UW Health facility, emergency care will be available. There is no commitment by UW-Madison, UW Medical Foundation or UW Hospital to provide any compensation for research-related injury. The VA Hospital will reimburse UW-Madison, UW Medical Foundation or UW Hospital for any charges that may result from emergency care at the UW Health facility. You have not released UW-Madison, UW Medical Foundation or UW Hospital from liability for negligence. Please contact the investigator, (name) at (phone number) if you are injured or for further information.* | No  *Go to next question.* | |
| 1. Will photographs be taken or voice or video recordings made of subjects for research purposes?   *NOTE: The IRB cannot waive informed consent for the use of photographs, voice recordings, or video recordings.* | Yes  *The informed consent form for research must include a discussion of why photographs, or voice or video recordings are being taken for the research, who will have access to them, whether they will be disclosed outside of the VA, and what their disposition will be after the research is completed.* | No  *Go to next question.* | |
| 1. Does the consent document(s) include a signature and date line for the subject? | Yes  *Go to next question.* | No  *Ask the study team to revise the consent form(s) to include a subject signature line.* | |
| 1. Does the consent form(s) include a signature and date line for the person obtaining consent? | Yes  *Go to next question.* | No  *Ask the study team to revise the consent form to include the relevant signature line or document that the IRB waived the requirement for the signature of the person obtaining consent because there is no physical contact with the subject (e.g., the only contact with the subject is by telephone or mail).* | |
| 1. Does the signature page include a line to capture the final four digits of the subjects’ SSNs? | Yes  *Go to next question.* | No  *Ask the study team to revise the consent form(s) to include a line to capture the last for digits of the subjects’ SSN.* | |
| 1. Are individuals with impaired decision-making capacity being enrolled? | Yes  *Ensure the consent form has a line for legally authorized representative to sign and date.* | No  *Ensure the consent form does NOT include a line for legally authorized representative to sign and date.* | |
| 1. Is a short form being used or does the IRB require a witness to the consent process or signing of the consent form? | Yes  *Ensure the consent form has a line for a witness to sign and date.* | No  *Ensure the consent form does NOT include a line for a witness to sign and date if written consent is being obtained.* | |
| 1. Has a VA-specific HIPAA authorization form, separate from the consent form, been provided? | Yes  *Go to next question.* | No  *The VA requires separation of the HIPAA authorization form from the consent form; request a separate authorization form.* | Not applicable -  *No protected health information is being used or disclosed for this study.* |
| 1. Does the study use and/or disclose any of the following information about patient treatment for the research study:  * HIV * Sickle cell anemia * Drug abuse * Alcohol abuse | Yes  *Ensure this language is specifically referenced in the HIPAA authorization form.* | No  *Ensure the collection of this information has been removed from the draft HIPAA authorization form.* | Not applicable -  *No patient information is being used or disclosed for this study.* |
| 1. Is the HIPAA form consistent with the consent form and other IRB materials?   *NOTE: The IRB does not approve the HIPAA form but instead ensures it is consistent with the consent form and other IRB materials.* | Yes  *Go to the next question.* | No  *Ask the study team to revise the form or documentation so that they are consistent.* | Not applicable -  *No protected health information is being used or disclosed for this study.* |
| 1. Will any PHI be disclosed to a non-VA entity? | Yes  *Ensure the HIPAA authorization form identifies such disclosure.* | No  *Go to the next question.* | Not applicable -  *No protected health information is being used or disclosed for this study.* |
| 1. Does the study team need to request a waiver of authorization or altered authorization for the research? | Yes  *Ensure the study team completes and uploads in ARROW the “Application for IRB Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule for Protocols Conducted by VA Researchers” form.* | No  *Go to the section K.* | |
| Section notes, if applicable: Click here to enter text. | | | |

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| 1. **Waiver or alteration of HIPAA authorization** | | |
| 1. Did the study team request a waiver of informed consent for the entire study (as opposed to a component of the study, such as screening)? | Yes  *Go to next question.* | No  *Skip to the next section.* |
| 1. Does the study team need a waiver of authorization or altered authorization for the research? | Yes  *Ensure the study team completes and uploads in ARROW the “Application for IRB Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule for Protocols Conducted by VA Researchers” form.* | No  *Go to the next section.* |
| Section notes, if applicable: Click here to enter text. | | |

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| 1. **Subjects who lack decision-making capacity** | | |
| 1. Will patients who lack decision-making capacity be enrolled in this study? | Yes  *Go to next question.* | No  *Skip to the next section.* |
| 1. Does the IRB application and/or protocol describe how the research team will determine when surrogate consent is obtained?   *NOTE*   1. *In general, the research staff must perform or obtain and document a clinical assessment of decision-making capacity for any subject suspected of lacking decision-making capacity.* 2. *Individuals ruled incompetent by a court of law are considered to lack decision-making capacity.* | Yes  *Ensure the method is acceptable. Go to next question.* | No  *Have study team revise application to provide this information.* |
| 1. Has the investigator provided one of the following justifications to include subjects with impaired decision-making capacity:    1. The proposed research entails:       1. No greater than minimal risk to the subject; OR       2. Presents a greater probability of direct benefit to the subject than harm to the subject; OR       3. Greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject’s disorder or condition that is of vital importance for the understanding or amelioration of the subject’s disorder or condition.   AND   * 1. The research cannot be performed solely with persons who possess decision-making capacity and the focus of the research is the disorder leading to the subjects’ lack of decision-making capacity, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke); OR   2. The subject of the research is not directly related to the subjects’ lack of decision-making capacity but the investigator has presented a compelling argument for including such subjects (e.g., transmission of methicillin-resistant staphylococcus aureus infections in a nursing home where both individuals with and without decision-making capacity are affected). | Yes  *Go to next question.* | No  *Ask study team for additional justification.* |
| 1. Do the IRB application and/or protocol contain the following information/assurances related to surrogate consent?  * A description of the procedures to ensure that subjects’ legally authorized representatives (LARs) are well-informed regarding their roles and obligations to protect persons who lack decision-making capacity, including:   + Their obligation is to try to determine what the subjects would do if able to make an informed decision; and   + If the potential subject’s wishes cannot be determined, they must be told they are responsible for determining what is in the subjects’ best interests. * An assurance that even if their LARs agree to their participation that subject dissent or resistance will be respected and the subject will not be forced or coerced to participate in the research study. * An assurance that the information (i.e., informed consent process and HIPAA authorization) that will be provided to the subjects’ LARs is the same as would ordinarily be provided to the subjects themselves if they had decision-making capacity. * An assurance that assent will be obtained when feasible. | Yes  *See note at left.* | No  *Request revisions to the IRB application or other materials to ensure compliance with this requirement.* |
| 1. Does the IRB application and/or protocol describe the order of LARs for surrogate consent as follows?  * Health care agent (i.e., an individual named by the individual in a Durable Power of Attorney for Health Care) * Legal guardian or special guardian * Next of kin in this order: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or * Close friend   NOTE: *An individual who is qualified as a LAR to provide informed consent on behalf of a prospective research subject may not always qualify as a personal representative for purposes of consent to use or disclose a human subject’s PHI (i.e., signing a HIPAA authorization). Therefore, in circumstances involving authorization for use or disclosure of a human subject’s PHI, the investigator must ensure the LAR meets the requirements of a personal representative (legal guardian or power of attorney) in HIPAA and the Privacy Act of 1974 prior to the LAR’s signing a HIPAA authorization.* | Yes  *Go to next question.* | No  *Request revisions to the IRB application or other materials to ensure compliance with this requirement.* |
| Section notes, if applicable: Click here to enter text. | | |

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| 1. **VA R&D endorsement/approval** | | |
| 1. Has the VA R&D committee issued an endorsement of the study? | Yes  *The IRB approval must include an administrative hold and consent documents cannot be released until VA R&D committee* ***approval*** *is issued. Ensure the notice generated in ARROW identifies the need for VA R&D committee* ***approval*** *before the administrative hold can be lifted.* | No  *Do not schedule for IRB review and forward to the VA R&D Committee for review and endorsement.* |
| Section notes, if applicable: Click here to enter text. | | |