**Human Subjects Research Assessment Survey**

**VA Ann Arbor Healthcare System**

* **The VA ACOS/ Research and/ or the IRB Coordinator will assist investigators to determine if their proposed activity must be reviewed by the VA IRB.**
* **The VA IRB maintains the authority to determine when human subject research may qualify for exemption from IRB review at the VAAAHS.**

**Once you have determined that your project constitutes research (**[**decision tree**](/ANNARBORRESEARCH/docs/IsMyProjectResearch.pdf)**) the following questions will help you determine if it needs to be reviewed by the AAVAHS IRB.**

**Step 1: Is it Human Research?**

Yes,  No Does the research involve collecting information about living persons?  
 **If Yes, go to Step 2.**   
 If No, the activity is not human subjects research as defined by DHHS. **Go To Step 3!**

**Step 2: Is the activity DHHS-Regulated Research on Human Subjects?**   
  Yes,  No (a) Does the research involve collecting data through intervention (physical procedures or   
 manipulations) or interactions (communications or personal contact) with the individuals?   
  Yes,  No (b) Does the research involve collecting individually identifiable private information (such as protected   
 health information) about living persons)?   
  Yes  No (c) Does the activity involves a retrospective chart review of outcomes of patients on a certain drug or   
 device in the course of medical practice?  
  Yes  No (d) Does the activity involves a prospective study of the outcomes of patients who were prescribed a drug   
 or device by their personal physicians, or compares the diagnostic results of scans or tests ordered by their personal   
 physicians?

**If you answered Yes to (a) or (b) or (c) or (d), the activity is “DHHS-Regulated Research on Human Subjects”.   
 (Continue to Step 4.)**

**Step 3: Is the activity FDA-Regulated Research on Human Subjects?**

Yes  No (a) Does the activity involve the use of a drug, other than the use of an approved drug in the course of standard medical practice? (Including record/image/chart reviews of patients who received FDA regulated products or controls, not in course of medical practice.)

Drugs Including: a substance recognized by an official pharmacopoeia or formulary; a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; a substance (other than food) intended to affect the structure or any function of the body; a substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device; a biologic product (any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product) applicable to the prevention, treatment, or cure of diseases or injuries. *(A Dietary supplement for which the activity involves a disease claim will be treated as a drug.)*

Yes  No (b) Does the activity involve the use of a medical device, other than the use of an approved medical device in the course of medical practice.

Medical Devices Including: an instrument, apparatus, implement, machine, contrivance, implant, software, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Yes  No (c) Will the results of the activity be submitted to the FDA or held for inspection by the FDA.

Yes  No (d) Will tissue specimens be used to test the effectiveness of a medical device and will the information be submitted to the FDA for FDA approval of the device (even if data/tissue is anonymized).

**If you checked No to (a) and (b) and (c) and (d), the research activity is not FDA-Regulated. Skip to Step 5**

**IF you checked Yes to (a) or (b) or (c) or (d) then continue below:**

Yes  No (e) Does the activity involve individual who is or becomes a participant in research, either as a recipient of an FDA regulated product (approved or experimental) or as a control, as directed by a research protocol and not by medical practice?

Yes  No (f) Does the activity involve an individual who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control?

**If you checked Yes to (e) or (f) then the research activity is “FDA-Regulated Research on Human Subjects”**

*• The consent process must disclose that the FDA may inspect the study records;*

*• Consent documents must be dated (all VA Consent Forms must be dated)*

*• Consent cannot be waived under emergency regulations (per VA); and*

*• Consent documentation may only be waived if the activity is minimal risk and documentation of consent is not ordinarily required outside the research context.*

**Step 4: Does the study require Ann Arbor VA review?**

**A. VA IRB Review is required for Human Subjects Research Conducted at Ann Arbor VAMC**

You must submit a VA Human Studies Research Application if **any** of the following activities **will take place at the Ann Arbor VA Healthcare System** or other VA sites associated with it.

1. Human research subjects will be recruited

2. Human research subjects will participate in research (DHHS or FDA)

3. Human research samples will be analyzed

4. VA medical records will be accessed for research

5. Human research data (with identifiers) will be managed and /or stored

## Please download the most recent version of the Ann Arbor VA IRB Application at this web-site [**http://www.annarbor.research.va.gov/**](http://www.annarbor.research.va.gov/)

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**B. Exclusion from Human Subjects Research Review**

(If you cannot check all boxes 1-5, then please go back to Section A.)

1. No human research subjects will be recruited at the Ann Arbor VAMC or other VAMC Sites**(1)**

2. No human research samples will be tested at the Ann Arbor VAMC or other VAMC Sites**(1)**

3. No medical records will be accessed for research at the Ann Arbor VAMC or other VAMC Sites**(1)**

4. No human research data will be managed or stored at the Ann Arbor VAMC   
or other VAMC Sites**(1)**

*(1) Other VA Sites = Battle Creek VAMC, Saginaw VAMC, Toledo VAMC, Flint VA CBOC, Jackson VA CBOC and Intensive Psychiatric Community Care Clinic (Ann Arbor)*