



Focus on Health Equity and Action Quality Improvement and Research: How to Leverage These Two Processes to Achieve Health Equity

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VA IRB Network Director



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Learning Objectives

At the end of this presentation, participants will be able to:

1. Provide examples of non-generalizable and research activities
2. Have a basic understanding of the categories of exempt and non-exempt research
3. Define procedures to determine the status of a research project
4. Describe how the use of VAEDA can support and improve efficiencies in the research determination process



Acknowledgement

- This presentation is an adaptation of talks provided by Drs. Molly Klote and Karen Jeans



VHA Directive 1200.05(2), Paragraph 3. cc.:

cc: “Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this directive, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research for purposes of this directive. . . .”

Source: VHA Directive 1200.05(2): Requirements for the Protection of Human Subjects in Research (January 7, 2019; amended January 8, 2021).



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VHA Directive 1200.05(2), Paragraph 3. cc.:

cc: “Research means *a systematic investigation*, including research development, testing and evaluation, *designed to develop or contribute to generalizable knowledge*. Activities that meet this definition constitute research for purposes of this directive, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. *Clinical investigations, including clinical investigations as defined under FDA regulations in 21 CFR 50.3, 312.3(b), and 812.3(h), are considered research for purposes of this directive. . . .*”

Source: VHA Directive 1200.05(2): Requirements for the Protection of Human Subjects in Research (January 7, 2019; amended January 8, 2021).



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- **Systematic investigation:**

- An activity that is planned in advance and that uses data collection and analysis to answer a question. Although research must include systematic investigation, non-research operations activities also include systematic investigation to ensure reliable outcomes. Systematic investigation does not, in and of itself, define research.

- Source: VHA Program Guide 1200.21, Paragraph 4.e.

- **Generalizable knowledge:**

- Information that expands the knowledge base of a scientific discipline or other scholarly field of study. Systematic investigations designed to develop or contribute to generalizable knowledge constitute research.

- Source: VHA Program Guide 1200.21, Paragraph 4.a.



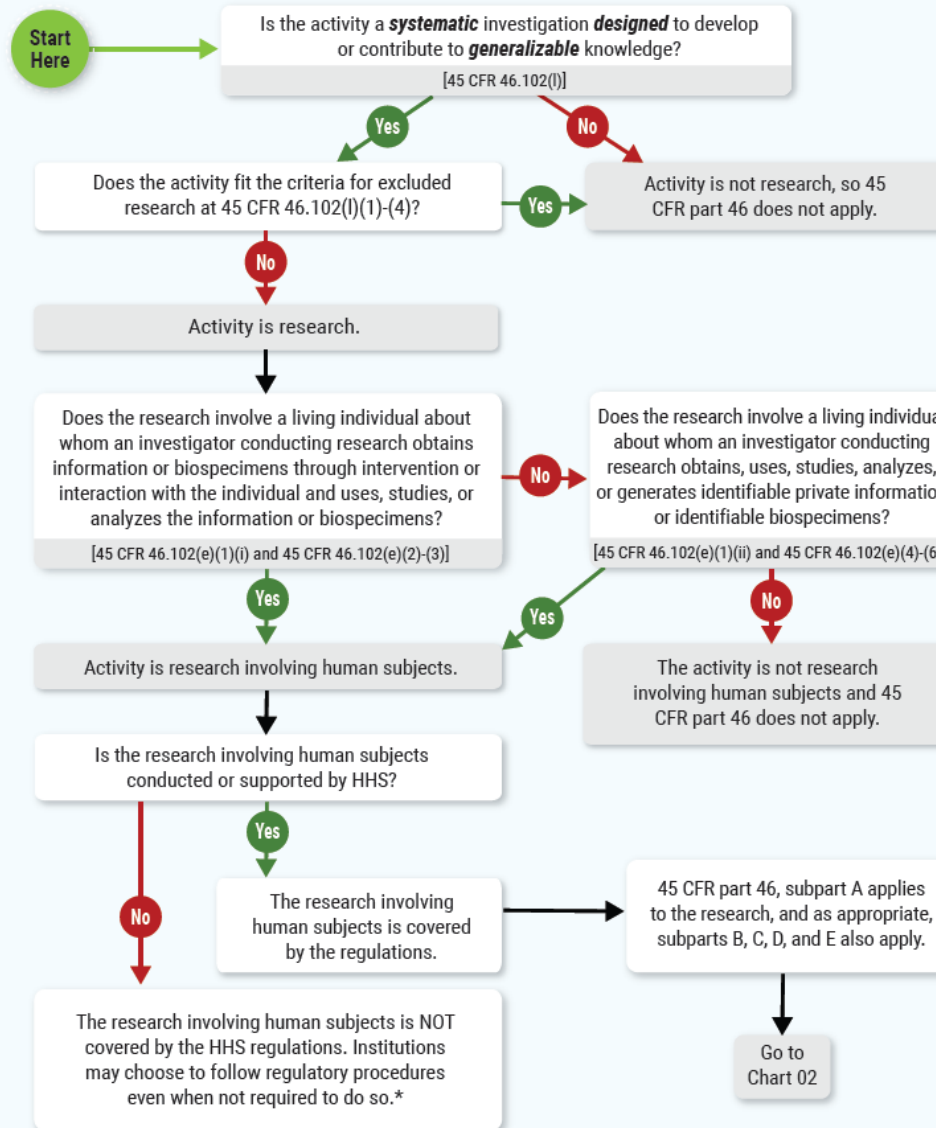
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<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html>

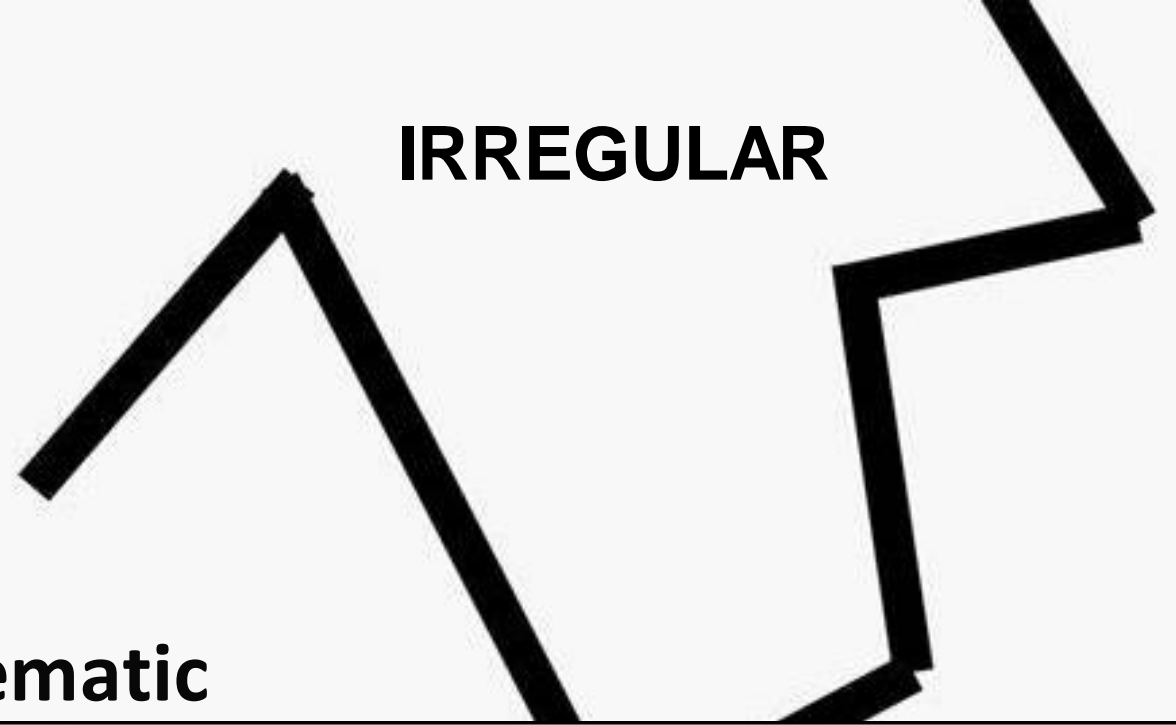


**What is Meant by a
Nonsystematic Activity?**

DISORGANIZED



IRREGULAR



**Nonsystematic
Adjectives**



UNPLANNED



HIT OR MISS

What Are Examples of Non-Generalizable Activities?

- Biographies, journalism, legal research, historical scholarship
- Oral histories that are designed solely to create a record of specific historical events
- Public health surveillance activities
- Service or course evaluations, unless they can be generalized to other individuals
- Criminal investigations (including collection and analysis of identifiable biospecimens)



Key Characteristics of Non-Research Activities: ORD Program Guide 1200.21: VHA Operations Activities That May Constitute Research

- **Issued by ORD on January 9, 2019 that includes criteria to assist in determining whether a VHA operations activity constitutes research.**
 - Replacement for VHA Handbook 1058.05 “VHA Operations Activities that May Constitute Research,” dated October 28, 2011.
 - Establishes procedures for verifying and documenting the non-research status of certain operations activities prior to publication of findings outside the Department of Veterans Affairs
- **Primary purpose of quality assessment and quality improvement for internal VA purposes.**
 - The activity is designed and implemented for internal VA operational purposes (i.e., its findings are intended to be used by VA or by entities responsible for overseeing VA).
- **Not designed for generalizability beyond VA.**
 - The activity is not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field).
 - However, this does not mean that a research activity done solely within VA is not research if it is only conducted within VA.



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Examples of Non-Research Operations Activities from ORD Program Guide 1200.21

Quality assessment and quality improvement activities designed for internal VA purposes, including routine data collection and analysis for operational monitoring, evaluation, and program improvement purposes.

- VHA system redesign activities, patient satisfaction surveys, case management and care coordination, policy and guideline development and related evaluation activities
- Competence or qualification reviews of VA employees and health care professionals, performance evaluations; peer review; training and education; accreditation

Examples:

- VA All Employee Survey (AES), Voice of VA Survey
- External Peer Review Program (EPRP), RAPID
- Home and Community Based Quality Care Initiative
- Inpatient Evaluation Center (IPEC)
- VA Surgical Quality Improvement Program (VASQIP)
- VHA Quality Improvement Initiative (VQuIP)



Activities that **are** Research and Require VA R&D Committee Approval and Any Applicable Committee or Subcommittee

- Any activity whose conceptualization, plan, or implementation is **supplemented or modified** in order to produce information expanding the knowledge base of a scientific discipline or scholarly field of study because it is a systematic investigation designed to develop or contribute to generalizable knowledge
- **Modifying or adding to** an existing non-research activity to produce information expanding the knowledge base of a scientific discipline or scholarly field of study as a systematic investigation designed to develop or contribute to generalizable knowledge
- Analyzing non-research data in a **different way** or combining datasets to produce information expanding the knowledge base of a scientific discipline or scholarly field of study when the activity is a systematic investigation designed to develop or contribute to generalizable knowledge



Identifying Research Activities

The following activities **ARE ALWAYS** Research:

- Activities funded or otherwise supported as research by the Office of Research & Development (ORD)
- Clinical investigations as defined under Food and Drug Administration (FDA) regulations

The following activities **ARE ALMOST ALWAYS** Research:

Activities using:

- Double blind interventions
- Placebo controls
- Prospective patient-level randomization to clinical interventions not tailored to individual patient benefit



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True or False:

Only an IRB can make determinations as to whether an activity is a research or non-research activity.



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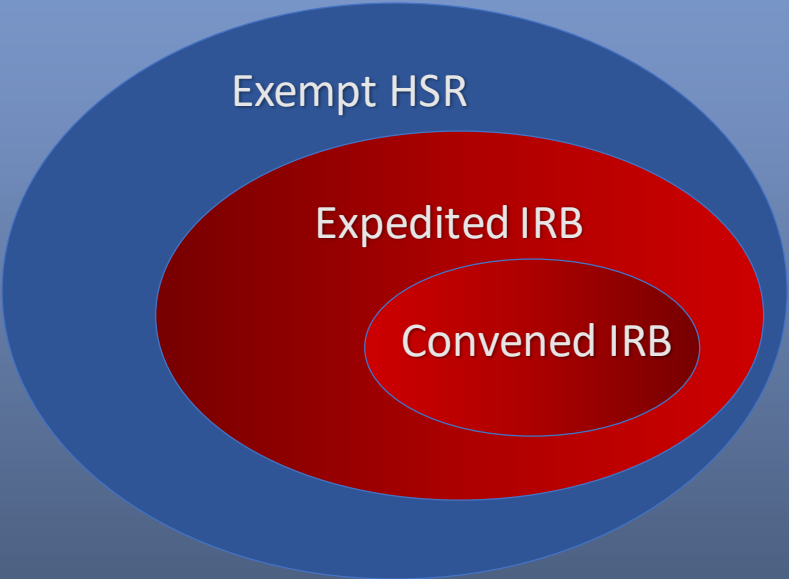


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Categories of Human Subjects Research

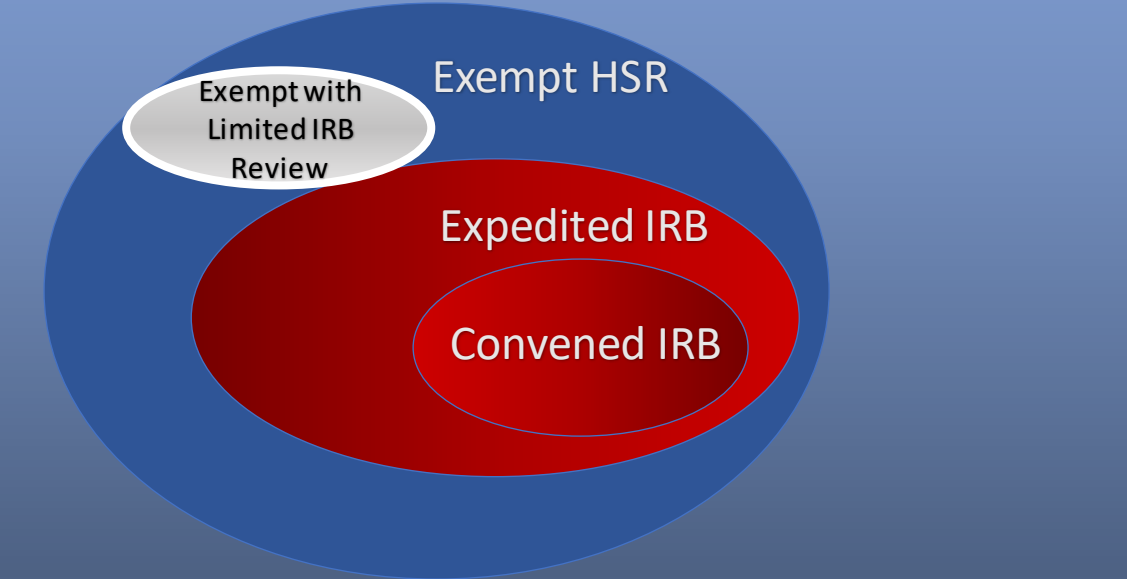
- Pre-2018

Not Human
Subjects Research



- 2018

Not Human
Subjects Research



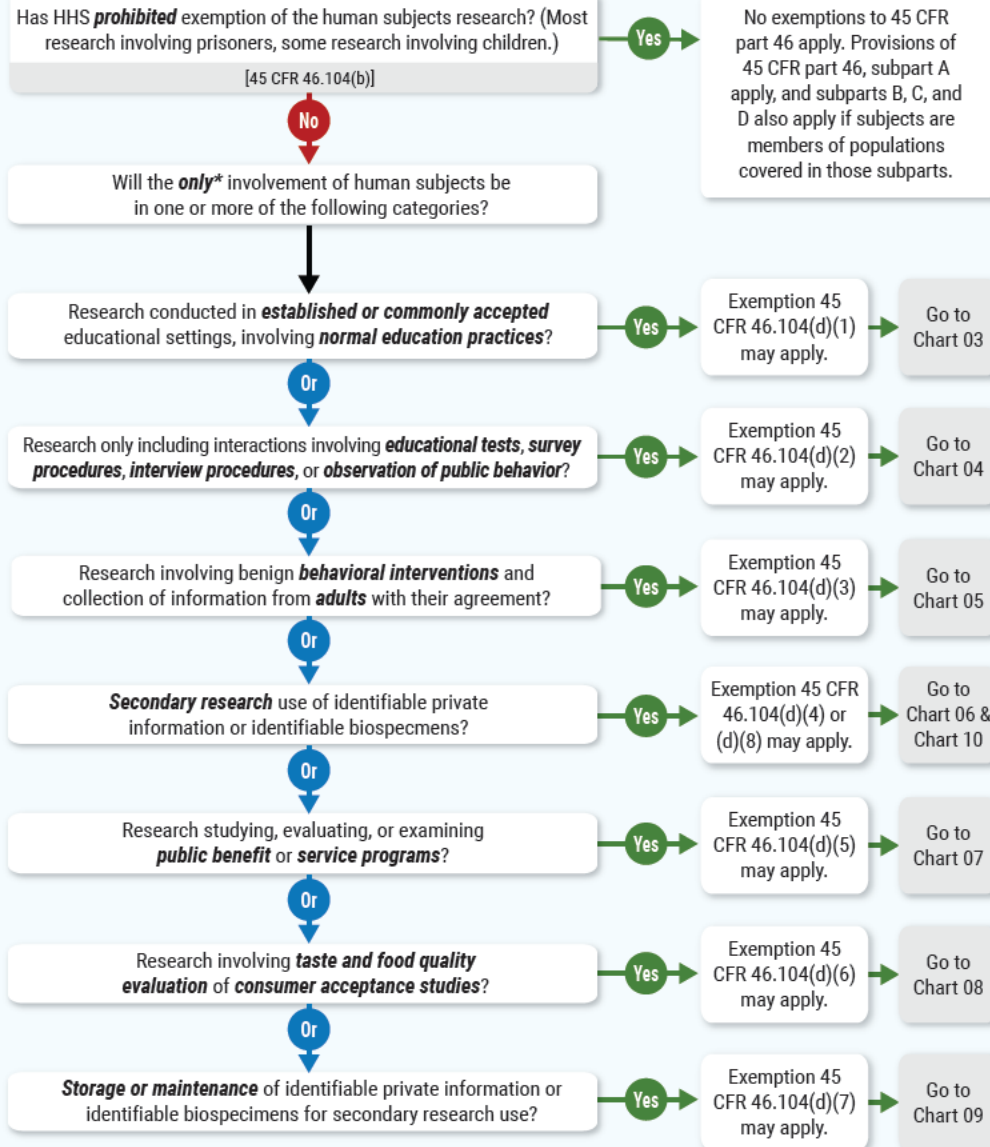
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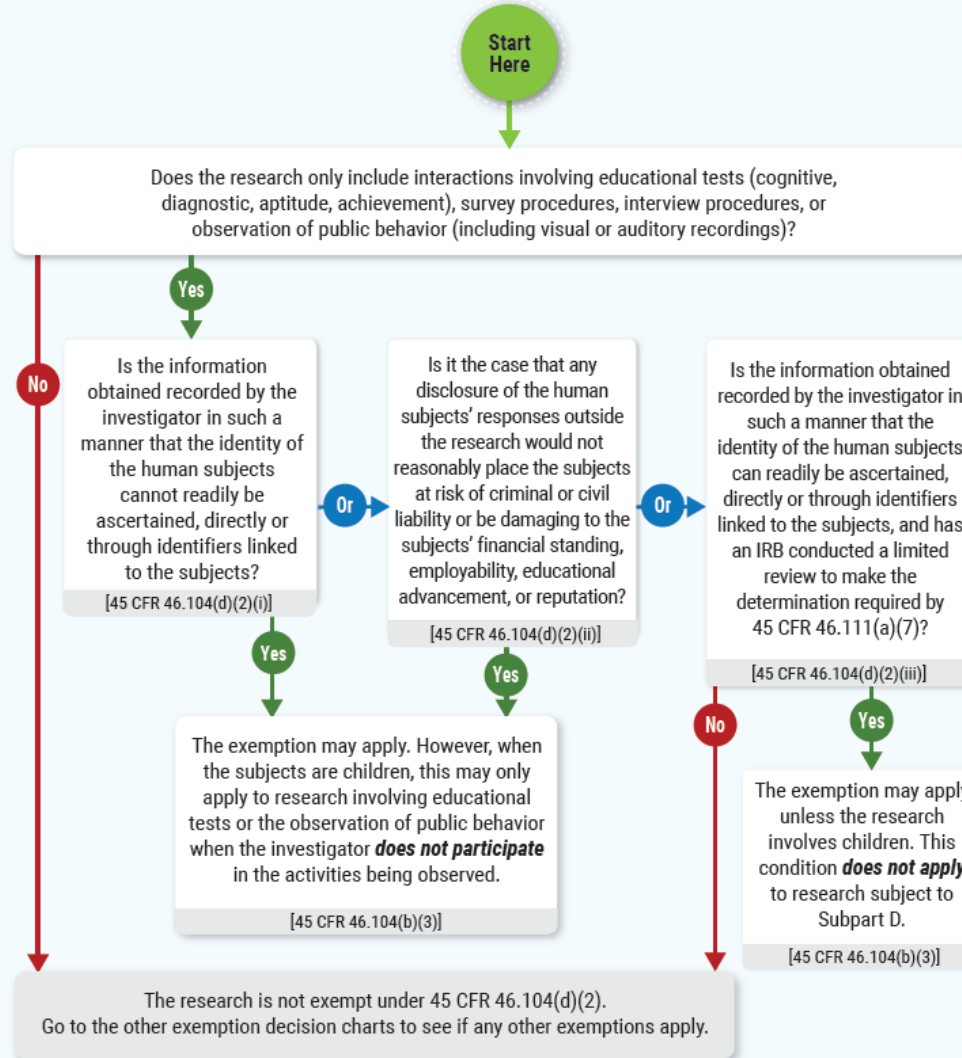
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<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html>



TO BE EXEMPT, NO NONEXEMPT ACTIVITIES CAN BE INVOLVED. RESEARCH THAT INCLUDES BOTH EXEMPT AND NONEXEMPT ACTIVITIES IS NOT EXEMPT. RESEARCH MAY INVOLVE ACTIVITIES EXEMPT UNDER MORE THAN ONE EXEMPTION CATEGORY.



<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html>

VA Electronic Determination Aid (VAEDA)

Acknowledgement: Adapted from a talk given by Dr. Molly Klote

The **VA Electronic Determination Aid (VAEDA)** is a decision support tool created to:

- **Reduce** variability in regulatory preliminary determinations for proposed research, quality improvement, program evaluation, and innovation projects.
- **Decrease** administrative burden on research offices and IRB members.

The VAEDA tool intends to harmonize and standardize project (research/not research) classifications for all VA facilities.

NOTE: Research studies that are known to need an IRB review (clinical trial) or involve animals (IACUC review) do not need to go through the VAEDA process.



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- Fully launched and available in all VAMCs as of September 2022, VAEDA is the validated enterprise solution for not-human-subjects-research determinations.
- VAEDA helps the project owner understand where a project should be routed for approval, since research offices and IRBs/RDCs have no authority to approve anything that is not research.
 - Project leaders can answer questions regarding their proposed project, and the VAEDA tool will, based on the logic questions answered, produce a preliminary determination
 - Preliminary determinations are intended to be provided to an approving authority (e.g., research into VAIRRS, not research to local process) to complete a final determination and move through the approval process.
- We need **Quality Management** to identify where **not research** determinations should be routed. Currently, >10,000 determination applications per year are routed to IRB chairs and >6,000 are determined to be not research



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How many total determinations – **797**

How many not research determinations – **428**

How many research determinations – **385**

How many exempt determinations – **138**

Estimated total time saved: > **2,000 person hours**

Estimated frustration saved: **PRICELESS!**

LIVE DEMONSTRATION



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VAEDA Screenshots

Demographics

Project Title * ✕

[+ Add me as PI/Project Lead](#)


PI/Project Lead First Name * ✕



PI/Project Lead Last Name * ✕


PI/Project Lead Salutation * ▼ ✕

VA Facility * ✕ ▼

Note: If your facility is not listed please contact VAEDAsupport@va.gov.

Project Duration *  The timeframe during which intervention will be administered and/or data will be collected. This may not match with your funding timeline. The start cannot be backdated.

 To 

% Effort *  The amount of time devoted to this specific project as a percentage of the project lead's total effort:

- one year (2080 hours) = 100% effort
- one month (173 hours) = 8.3% effort
- one week (40 hours) = 2% effort

✕

Users to Share [+ Select Users to Share](#)



VAEDA Screenshots

Definition of Human Subjects (s9.1)

10.1 Are **any** of your intended subjects **living** (this includes if the records or data you are using refer to living individuals)? (702)

- Yes (702.1)
- No (702.2)

The definition of human subject includes the phrase **a living individual about whom**. **About whom** refers to the fact that the information collected must be personal information **about an individual**.

For example:

- a. A survey that collects data about the activities of an organization, rather than its members, is not about the individuals.
- b. A project where fingerprints are collected to test methods of removal from surfaces and not to identify the individual would not be about the individuals.
- c. A researcher may contact non-governmental organizations to ask about sources of funding and that work would not be about any individuals.

Questions about your respondents' attitudes, opinions, preferences, behavior, experiences, or characteristics, are all considered **about whom** questions.

10.2 Is the information you intend to use **about** the living individuals? (703)

- Yes (703.1)
- No (703.2)

10.3 Does your project involve human fetal tissue (excluding NIH embryonic stem cell lines)? (704)

- Yes (704.1)
- No (704.2)



VAEDA Screenshots

Thank you for completing your preliminary determination.

Your Determination Results (*script_6*) (complete)

1. Thank you for completing the VAEDA tool. Based on your answers the project you describe meets the regulatory definition of research in accordance with 38 CFR 16.102(l) but does not meet the definition of human subjects research.
2. The information you are using is not private data.
3. All research projects are required to complete an Enterprise Data Security Plan (ERDSP) in the VA Innovation and Research Review System (VAIRRS).
4. This is a single institution project. (*301.2*)
5. A copy of this determination must be included with your project submission package to your research office with the following title: VAEDA Tool Determination: RESEARCH NOT INVOLVING HUMAN SUBJECTS.
6. If your intent, plans, or methods change you must amend this determination to ensure the regulatory category of your project has not changed. You are subject to audit by the RCO.
7. This is not an approval letter to begin your work. You may not begin work on your project until approved by a Research and Development Committee.
8. Best of luck with your research.

[« Go to My Determinations](#)

[Export](#)



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- Website Links
 - **VAEDA Tool:** [VINCI VAEDA - Home](#)
 - **VAEDA Site Admin Request Form:** <https://forms.office.com/g/FXT4g6tYVr>
 - **VAEDA Homepage:** <https://www.research.va.gov/programs/orppe/vaeda.cfm>
- VA Electronic Determination Aid (VAEDA) Cyberseminar Overview:
https://www.research.va.gov/programs/orppe/education/webinars/session_archive.cfm?RecordID=206910&Date09212022
- VAEDASupport@va.gov – for support



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Discussion

Understanding Quality Improvement vs Research

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QUESTIONS

- Discussant Q&A
- Audience Q&A