

VA Electronic Determination Aid (VAEDA)

Not Research Pilot Webinar

May 1, 2024

Dr. Molly Klote, Deputy CRADO, ePROS

Dr. Jeff Ferraro, Associate Director, VINCI



CONTENTS

1. What is VAEDA?
2. How VAEDA Works
3. The VAEDA Process Explained
4. Not Research Module
5. References

What is VAEDA?

The VA Electronic Determination Aid (VAEDA) is a decision support tool that provides a *preliminary* determination. It was created to:

- **Improve standardization** in regulatory preliminary determinations for proposed research, quality improvement, program evaluation, and innovation projects
- **Reduce** administrative burden on research offices and IRB members
- **Decrease** regulatory risk to the Agency

The VAEDA tool harmonizes and standardizes project classifications (research/not research) 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.



U.S. Department
of Veterans Affairs

Benefits of the VAEDA tool

- **Increases accuracy** in the research preliminary determination process by standardizing the questions asked and the information provided to project owners which decreases regulatory risk for the VHA.
- **Reduces** time to preliminary determination result.
- **Saves** resources (time, funds, etc.) that can then be applied elsewhere within the VAMC.
- **Grows VA's capability** by having all determinations consolidated in one platform, allowing VA to see all preliminary determinations.
- **Increases efficiency** of research offices and IRBs.
- **Promotes access** to preliminary determinations for facilities without research offices.
- **Democratizes** education regarding determinations to all project owners.

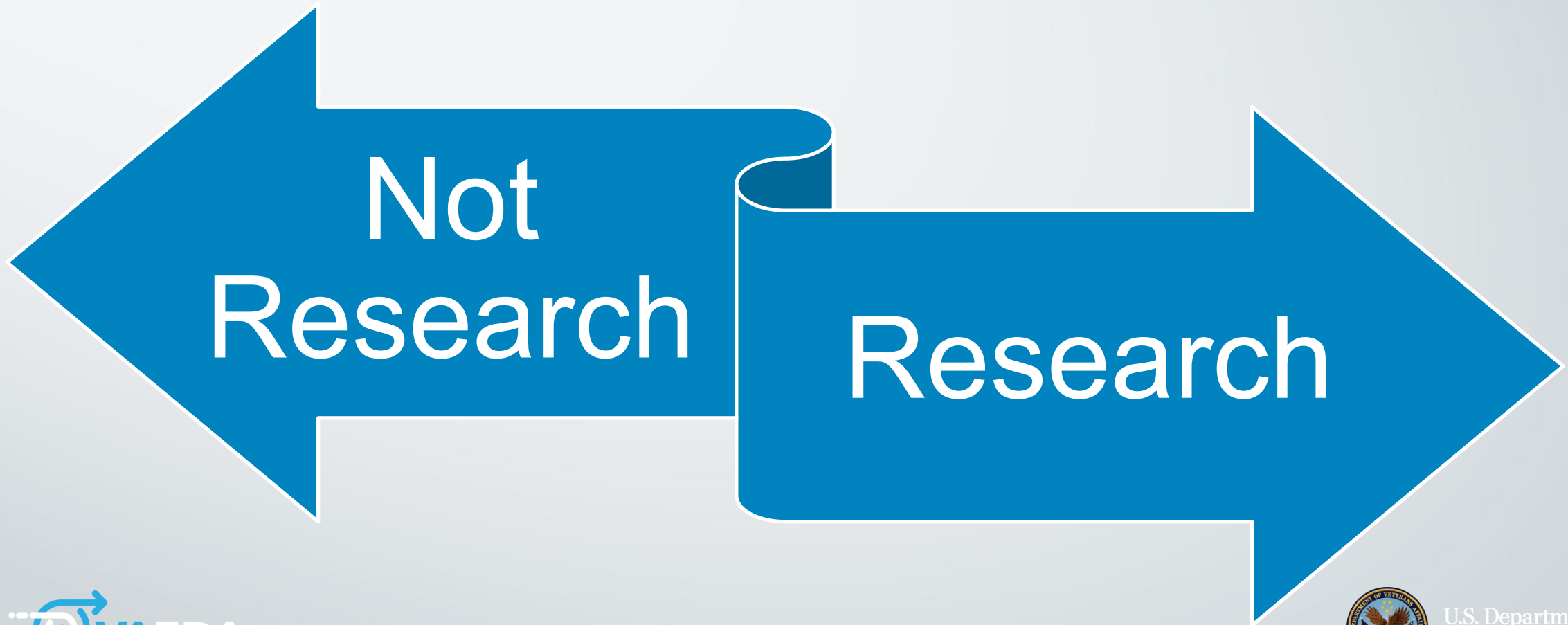
How does VAEDA work?

VAEDA helps to tell the project owner where a project should be routed for approval, since research offices and IRBs/RDCs have **no authority to approve anything that is not research.**

Preliminary **Research** determinations may be shared with your local Determination official or downloaded for submission to the regulatory oversight committee.

Preliminary **Not Research** determinations may be submitted to the local supervisor, Determinations Official, or Quality Management contact for concurrence and approval.

The VAEDA process explained



The VAEDA process explained

Research



?



?

Not Research



?



?

The VAEDA process explained

Research



Determination
Official



?

Not Research



?



?

The VAEDA process explained

Research



Determination
Official



Regulatory Approval

Not Research



?



?

The VAEDA process explained

Research



Determination
Official



Regulatory Approval

Not Research



?



?

The VAEDA process explained

Research



Determination
Official



Regulatory Approval

Not Research



Determination
Official



?

The VAEDA process explained

Research



Determination
Official



Regulatory Approval

Not Research



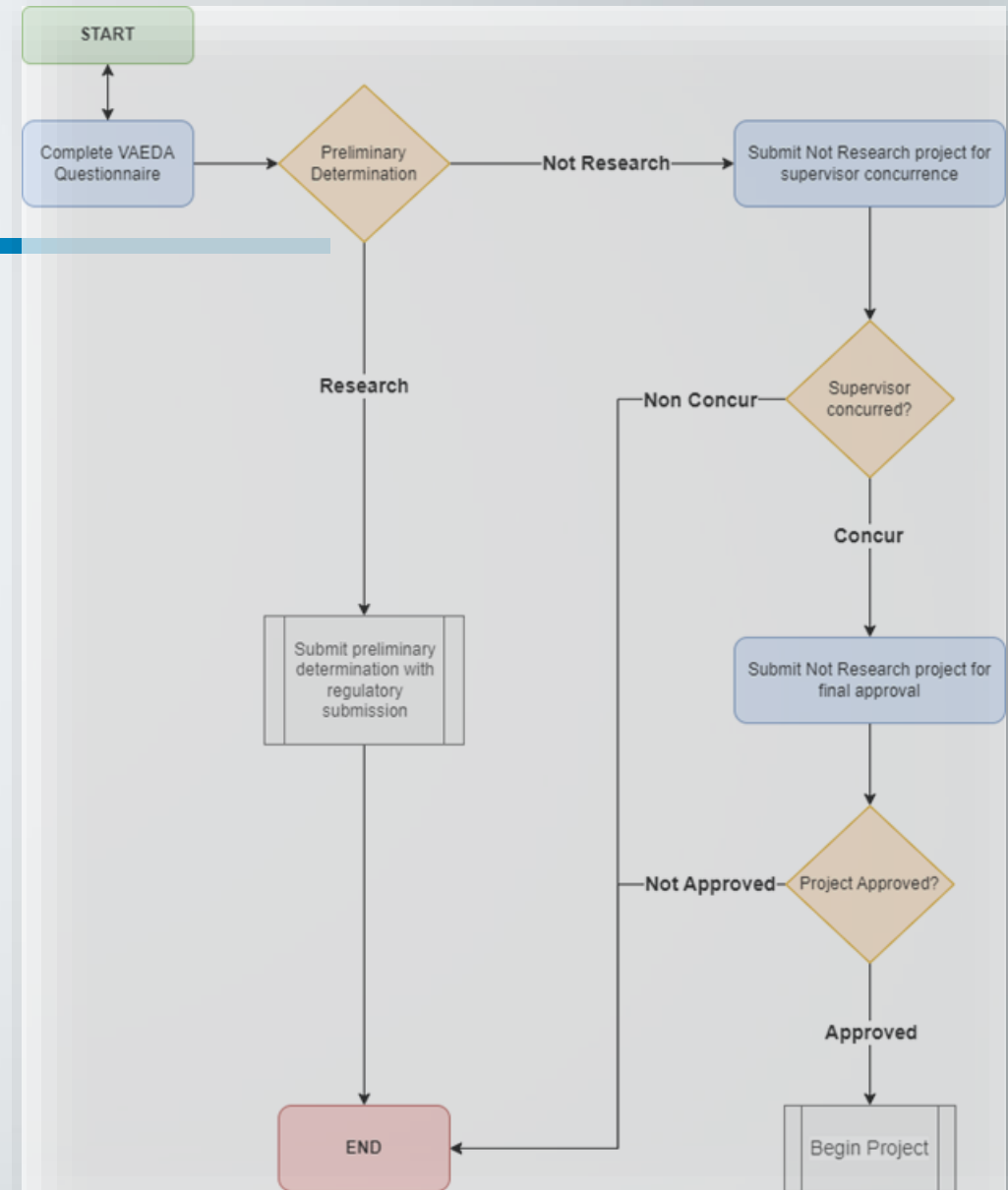
Determination
Official



Project Approval

VAEDA Not Research Module

- Project leaders (or designees) interact with a decision support tool and answer questions about their proposed project.
- The VAEDA tool produces a preliminary determination based on responses to a series of logic-based questions.
- Project leader submits Not Research project for Supervisor concurrence.
- Upon Supervisor concurrence, project is routed to approver for final review.



VAEDA Not Research Module Pilot

- Pilot will run from **May 2024** until **August 2024**
- Participating sites will need to identify a **Site Administrator, Project Reviewers** and **Quality Controllers**
 - No limit to number of reviewers and quality controllers
- **Notification emails** are automatically sent to Supervisors and Project Reviewers
- Project leaders can **monitor progress** from submission to final project approval
- Send all role requests and feedback to VAEDASupport@va.gov

VAEDA Not Research Module

DEMONSTRATION

REFERENCES

VAEDA Tool: <https://vhacdwdwhvda01.vha.med.va.gov/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



U.S. Department
of Veterans Affairs