# PURPOSE

## This document describes the policies and procedures the Human Subjects Division (HSD) follows under the Post Approval Verification and Education (PAVE) program to confirm by observation that University of Washington (UW) human subjects research is conducted in compliance with relevant federal regulations, state laws, UW institutional polices and Institutional Review Board (IRB)-approved procedures.

# POLICY

## The PAVE program is established by delegated authority from the HSD Director, as described in the Vice Provost for Research Delegation Memo (December 30, 2010). The HSD Director is responsible for requesting the resources required to implement and support the PAVE program.

### Within HSD, the authority for management and oversight of the PAVE program is delegated to the Regulatory Affairs Manager (RAM).

## **Type of research reviewed** includes:

### UW IRB-approved research that was approved by either the expedited (“Minimal Risk”) process or by the full IRB;

### UW non-exempt research reviewed by a non-UW IRB on behalf of the UW IRB (e.g., WIRB; the Cancer Consortium IRB).

## **Areas of evaluation** are primarily focused on those that mitigate risk to subjects, ensure data integrity, and compliance with federal, state, and institutional requirements. These include (but are not limited to):

### Subject recruitment and screening, including subject populations and locations

### Subject eligibility

### Informed consent process and documentation (includes confirmation of any waivers, if applicable)

### Confirmation that key study procedures are conducted per IRB approval

### Data collection forms

### Data confidentiality and security (includes retention and storage of study records and specimens)

### Tracking of IRB approval dates and IRB requirements

### Study oversight by the lead researcher

### Research staff training and qualifications

### Data and safety monitoring plan

### Research collaborations with non-UW entities and/or individuals

### Drug and device dispensing and tracking documentation

### Compliance with federal, state and institution human subjects research reporting requirements (e.g., ClinicalTrials.gov, unanticipated problems)

### Compliance with any other relevant federal or state regulations or University policies and procedures as it pertains to human subjects research

## **Areas of evaluation that are not in scope** include:

### Financial information, procedures, practices (except subject payment, compliance with any plan for managing any significant financial interest, and recruitment incentives)

### Allegations of scientific misconduct

### Employee complaints about the lead researcher or research staff that are unrelated to the conduct of the research

### Comparison of study data with source documents (except in rare circumstances)

## **Routine vs. directed review.** Evaluation of a study may be performed for either routine purposes or in response to a request from the IRB that reviewed the study, HSD Leadership, or Office of Research leadership.

### The RAM determines whether a requested evaluation should be conducted based on whether the request meets one or more of the following criteria:

#### The necessary resources to conduct the evaluation are available

#### The purpose is to ensure that a corrective action plan has been implemented (i.e., in response to reported noncompliance or an unanticipated problem)

#### To identify or confirm alleged noncompliance (e.g., in response to a subject complaint, pattern of noncompliance on other studies)

#### Special circumstances as identified by the Director of the Human Subjects Division

### The RAM works with the requestor to identify the specific areas of concern, and the evaluation is generally limited to these areas only.

### The RAM works with the HSD Post-approval Monitor(s) (PAM) to identify studies for routine evaluation.

## **Routine visit prioritization.** Studies with several or all of the following characteristics are prioritized for routine evaluations:

### Meets the National Institutes of Health (NIH) definition of an applicable clinical trial

### Involves greater than minimal risk

### Is currently enrolling subjects

### Received its initial IRB approval within the past 6-18 months

### Has a history of noncompliance or unanticipated problems

### Enrolls a vulnerable population (e.g., children, pregnant women, fetuses, neonates, prisoners, decisionally impaired, terminally/seriously ill, Native Americans)

### Uses an investigational drug or device under an IND or IDE

### Is federally funded

### Is investigator initiated

### Is not being monitored by any other agent (e.g., independent medical monitor, data and safety monitoring board, Sponsor site monitors)

## **Report content.** A draft report is prepared after completing an evaluation. The report at minimum:

### Describes the nature of the evaluation (routine or requested)

### Identifies the areas evaluated

### Identifies any observations (e.g., deficiencies) that may need to be addressed

## **Researcher input.** The researcher is given an opportunity to respond to any observations. This may include providing any corrections, feedback, or proposal for corrective action.

## If the evaluation uncovers a situation that appears to pose an immediate risk to the safety, welfare and/or rights of research subjects or others, the PAM brings the matter to the attention of the RAM or a member of HSD Leadership (if the RAM is unavailable), who decides whether:

### IRB approval of the research should be administratively suspended;

### Other UW offices, other institutions, or regulatory agencies should be notified immediately;

### Other immediate action is warranted to protect subjects and/or others.

## **Compliance evaluation.** A final report incorporating the researcher feedback is submitted as a Report of New Information (RNI) and reviewed per the **SOP HSD Management of RNI**.

## **Program evaluation.** The RAM and HSD Director meet at least annually to:

### Evaluate the past year’s activities, findings, metrics, and feedback

### Plan or make any desired revisions to the program

### Establish the needs and priorities for any additional resources

### Plan and prioritize the program’s activities for the coming year

### Prepare an annual report for dissemination

# RESPONSIBILITIES

## **HSD Post Approval Monitor (PAM)** is responsible for:

### Scheduling and conducting evaluations

### Preparing the draft and final evaluation reports

### Performing quality assurance reviews of draft evaluation reports

### Recording program data

## **Researcher** is responsible for:

### Responding to requests to schedule an evaluation

### Responding to pre- and post-evaluation requests for information

### Being available during the evaluation

### Reviewing and responding to the final draft evaluation report

### Submitting the final report as a RNI

## **Regulatory Affairs Manager (RAM)** is responsible for:

### Determining which studies to evaluate

### Coordinating with the IRB to identify areas of review for requested evaluations

### Overall management and oversight of the program

### Preparing and disseminating the program annual report

# PROCEDURES

## **Initiate Contact.** The PAM contacts the researcher using the appropriate email template.

### A copy of the [PAVE FAQ](https://www.washington.edu/research/policies/pave-faq/) is included.

### Follow-up by email or phone is done as necessary until a response is received.

#### If the researcher is unresponsive, the PAM refers the matter to the RAM for follow-up.

### The PAM updates the **PAVE Visit Work Log**.

## **Verify that the criteria for evaluation are met.** The PAM verifies that the study is eligible for review.

### If the study is a candidate for evaluation (e.g., no subjects enrolled, study closed) the PAM updates the **PAVE Visit Work Log** and proceeds with scheduling another study.

#### For studies that may become evaluable in the future, the PAM solicits an estimated time frame from the researcher (e.g., subject enrollment will begin in 3 months) and notes this in the **PAVE Visit Work Log**.

#### The PAM continues to follow-up on a study until the evaluation is conducted or the study becomes ineligible for review (e.g., closed).

## **Confirm the date of evaluation.** The PAM confirms the evaluation date with the researcher and solicits additional pre-evaluation information using the appropriate email template.

### If there is an interview component to the evaluation, the PAM confirms the attendees, place, and time that this will occur.

## **Complete the pre-evaluation preparation.** The PAM performs the following activities prior to conducting the evaluation:

### **Create a study specific sub-folder** following the template format.

### **Compile study documents** relevant to the evaluation and save them to the study specific sub-folder.

#### Documents are saved in PDF format with Optical Character Recognition (OCR) applied.

#### Documents are organized and bookmarked according to the format outlined in the HSD shared drive.

### **Obtain from the researcher** and save to the study-specific subfolder:

#### A list of all enrolled subjects by subject ID number, including date of enrollment.

##### Subjects who were withdrawn or dropped from the study should also be included.

#### A copy of all of blank data collections forms associated with the study (e.g., Case Report Forms, Surveys/Questionnaires, etc.).

#### A copy of the delegation of authority log (if applicable)

#### Any applicable study data confidentiality and security materials for pre-review (e.g., written policies/procedures for accessing study data, training staff, etc.)

### **Select the subjects** whose records are to be reviewed.

#### The number of subjects reviewed is dependent on the number of subjects enrolled, complexity of the study (e.g., # of study visits, duration, # of data collection forms),

#### and nature of the PAVE visit (i.e., routine versus IRB requested). For most studies, the PAM aims to review about 10% of the subjects.

#### The sampling should represent all aspects of the research under evaluation (e.g., a subject from each study arm, from different time points [e.g., pre- and post-modification])

#### The sample should include at least one dropped or withdrawn subject (if applicable)

#### The researcher should be notified of the selected subjects a few days prior to the visit to allow sufficient time to pull the records for review.

### **Draft pre-visit report.** Pre-populate the draft PAVE Evaluation Report (see template) with all study summary data extracted from the IRB records.

### **Conduct pre-visit report QA**. Provide the draft PAVE Evaluation Report to another PAM or the RAM for a quality assurance review.

#### The PAM or RAM review the report for accuracy and completeness using the **WORKSHEET Pre-Visit PAVE Report QA**.

##### Edits or comments are noted as tracked changes and saved to the study-specific subfolder.

##### The PAM or RAM alerts the initial PAM when the review is complete.

#### The PAM who prepared the draft report incorporates any requested revisions and responds to any comments/questions.

#### The completed QA worksheet and final pre-visit report are saved in the study-specific subfolder.

## **Conduct the evaluation.** The PAM conducts the evaluation following the outline laid out in the prepared PAVE Evaluation Report.

### When possible the PAM seeks clarification or additional documentation during the evaluation in connection with any preliminary observations.

### Any observations that cannot be explained/resolved during the evaluation are noted in the PAVE Results Summary.

### The PAM may request copies of any supporting documentation for an observation.

#### Paper copies should be de-identified before being removed from the site.

#### Electronic copies should either be saved to a secure thumb drive or emailed to hsdpave@uw.edu.

### The PAM may, at their discretion, review additional areas or records not specifically outlined in the PAVE Evaluation Report if they observe additional issues that involve risk to subjects, impact data integrity, or indicate noncompliance with federal, state, and institutional requirements

### The PAM interviews the PI and research staff (where appropriate) to solicit additional information about the conduct of the research as outlined in the PAVE Evaluation Report, recording any observations in the PAVE Results Summary.

### If the researcher is interested and available, the PAM reviews any observations and provides any suggestions for best practices at the conclusion of the evaluation.

## **Complete post-evaluation activities.** Following the visit, the PAM completes the following activities:

### **Send a post-visit ‘thank you’** email using the template.

### **Finalize the draft PAVE Evaluation Report** and Results Summary outlining all observations made.

#### Editorial comments for the researcher with guidance on how to respond to particular observations may be included.

### **RAM review.** Send the draft report and summary with observations and comments to the RAM for review.

#### The RAM reviews the report and summary to ensure the observations are clear and consistent with the IRB approved study.

#### The PAM incorporates any requested revisions and responds to any comments/questions.

### **Researcher review.** Send the final draft report and summary to the researcher for review and comment, using the email template.

#### The researcher provides responses to all observations, which may include a description of any corrections to information in the report, feedback about the report, or the researcher’s proposal for corrective actions.

#### The researcher is asked to include the response within the results summary and to send it back to hsdpave@uw.edu within a specified timeframe.

### **Report & results summary finalization.** Incorporate agreed-upon changes made by the researcher, remove all editorial comments, remove the ‘draft’ watermark, and do a final review for spelling, grammar and formatting errors.

#### A copy of the final report and results summary are saved to the study-specific subfolder.

## **Submit the final evaluation report and results summary to HSD Compliance.** The PAM ensures that the final PAVE Evaluation Report and results summary is submitted to HSD Compliance as follows:

### 4.7.1 The PAM sends an email to the researcher (see template) with a copy of the finalized report and results summary attached, requesting they submit it following the [INSTRUCTIONS Submit RNI in Zipline](https://research-eval.ui.oris.washington.edu/research/hsd/training/zipline-online-help-library/reports-of-new-information/).

### 4.7.2 The PAM updates the **PAVE Visit Work Log**.

## **Send post-evaluation satisfaction survey.** The RAM sends a brief survey to the researcher after the report is submitted to HSD Compliance but before any regulatory determinations have been made, asking the researcher to evaluate the PAVE experience.

### Individual survey responses are evaluated by the RAM and where appropriate, followed up by the RAM for additional information or resolution of any concerns.

### Aggregate survey responses are evaluated at least annually by the RAM and HSD Director.

### The RAM updates the **PAVE Visit Work Log**.

# MATERIALS

## [INSTRUCTIONS Submit RNI in Zipline](https://research-eval.ui.oris.washington.edu/research/hsd/training/zipline-online-help-library/reports-of-new-information/)

## PAVE Evaluation Report Template

## [PAVE FAQ](https://www.washington.edu/research/policies/pave-faq/)

## PAVE Visit Work Log

## WORKSHEET Pre-Visit PAVE Report QA

## SOP HSD Management of RNI

# REFERENCES

## [National Institutes of Health (NIH), “Policy on the Dissemination of NIH-Funded Clinical Trial Information”, published September 21, 2016](https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information)

## Vice Provost for Research Delegation Memo

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| --- | --- | --- | --- |
| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 1.3 | 06.25.2024 | 06.25.2024 | Update link to Zipline RNI submission instructions |
| 1.2 | 09.27.2022 | 09.27.2022 | Replace Assistant Director of Regulatory Affairs (ADRA) with Regulatory Affairs Manager (RAM)  |
| 1.1 | 05.27.2021 | 05.27.2021 | Remove references to paper process; remove hyperlinks to HSD shared drives |
| 1.0 | 11.15.2019 | 11.15.2019 | Newly posted SOP |

## **Keywords:** PAVE