VILLANOVA UNIVERSITY COMPLIANCE ASSISTANCE PROGRAM (CoAP)

Institutional Review Board
Office of Research
Protections

OFFICE OF RESEARCH PROTECTIONS

- The Office of Research Protections offers resources to researchers to help you through the research ethics process.

- For example:

  IRB orientation and project consultation

  (new!) CoAP

  Modification and closure consultation
  Fact Sheets for quick education

- CoAP is a new process that will help maintain a high standard of research integrity at Villanova

COMPLIANCE ASSISTANCE PROGRAM

The Compliance Assistance Program (CoAP) is a program that aims to support researchers in the conduct of research that is in accordance with IRB reviewed and approved procedures.

A program such as CoAP is an expectation of federal funding sources such as the NIH and NSF.

Participation in CoAP allows IRB/ORP to identify areas of deficiencies in education for PIs about their roles and responsibilities in human subjects research and improve established processes.

The Villanova IRB will start the CoAP as a pilot program, beginning with several practice assessments in 2022.

CoAP check ins are performed by the VU CoAP sub-committee who will observe research activity and compare with the approved protocol.

Only the IRB has final authority to suspend research activity if necessary.

GOALS OF CoAP

Assist

- Assist researchers in maintaining consistency with approved IRB protocols to protect human subjects

Ongoing review

- Provide ongoing overview of research at the university to ensure compliance with federal regulations to reduce liability

GOALS OF CoAP
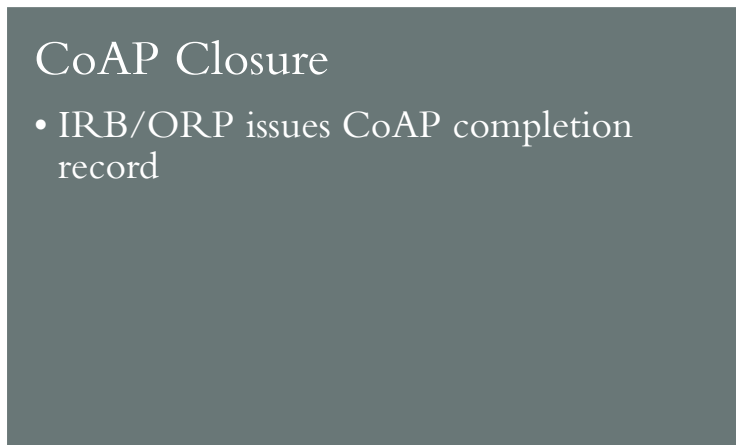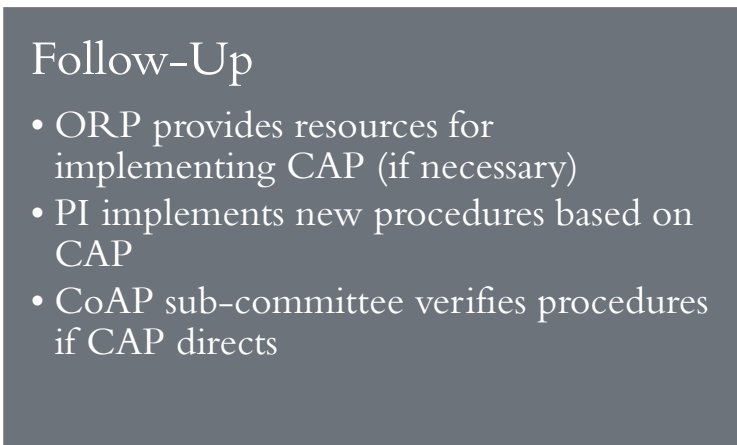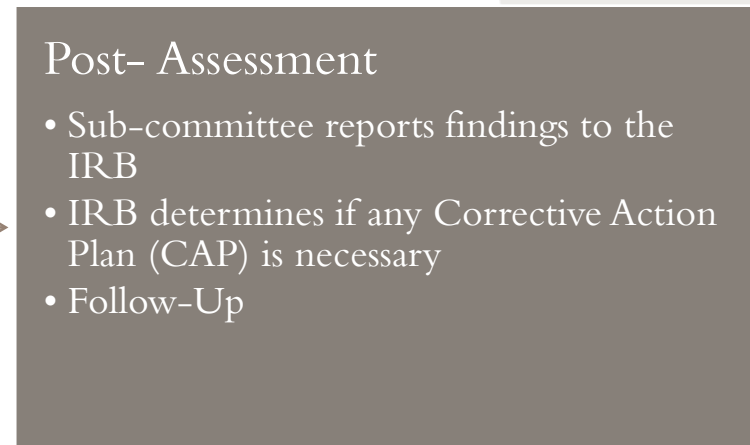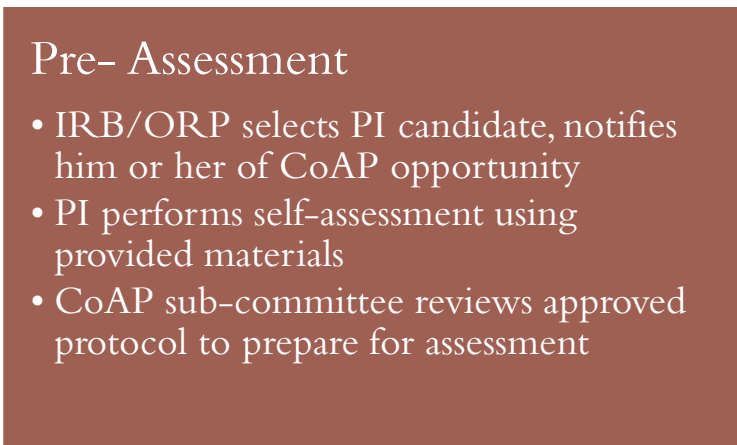
Prepare

- Prepare researchers for external audits (e.g. from sponsors)

Prevent

- Give researchers the resources and time to submit modifications if needed before the assessment to prevent incident reports or corrective action plans

Pre- Assessment

- IRB/ORP selects PI candidate, notifies him or her of CoAP opportunity
- PI performs self-assessment using provided materials
- CoAP sub-committee reviews approved protocol to prepare for assessment

Assessment

- CoAP sub-committee observes research activities to determine if they are occurring in accordance with IRB approved protocol

Post- Assessment

- Sub-committee reports findings to the IRB
- IRB determines if any Corrective Action Plan (CAP) is necessary
- Follow-Up

Follow-Up

- ORP provides resources for implementing CAP (if necessary)
- PI implements new procedures based on CAP
- CoAP sub-committee verifies procedures if CAP directs

CoAP Closure

- IRB/ORP issues CoAP completion record

CoAP Process

CoAP TIMELINE

Pre-Assessment
- PI will be provided 30 days notice and a resource package prior to CoAP assessment

Assessment
- Assessment scheduled at mutually convenient time when research activities are being carried out

Post-Assessment
- CoAP sub-committee will report findings to the IRB within 30 days after completion of assessment. Notice to PI will follow shortly thereafter.

Follow-Up
- If a CAP is necessary, 15 working days will be allowed for implementation.

CoAP Closure
- Official CoAP closure notice will be provided in writing.

CONTENT OF ASSESSMENT

- Alignment between approved protocol and study procedures

- Recruitment

- Study population

- Enrollment procedures and participant numbers

- Consent forms and process

- Compensation management

- Records (completion, storage)

- Study sites

- Unexpected or adverse event incidents

- Compliance with continuing review requirements

- Review of participant privacy/confidentiality issues and data management

- Personnel management (training, identification of all study staff on protocol)

CRITERIA FOR SELECTION

Voluntary election by the PI

Higher risk study or vulnerable population study

Request by a grant sponsor

Request by the IRB

Rare: participant complaint reveals unforeseen risks

TYPICAL FINDINGS FROM CoAP VISITS

- Consent forms are not dated by participants

- Informed consent documents on file are not complete (e.g. only the signature page is stored)

- Study records are not stored as indicated in the approved protocol

- Tracking of consent and participation for multi-session studies is disorganized such that the PI cannot ensure procedures are followed appropriately.

RESOURCES FOR PIs

- CoAP Materials (such as checklist and preparation tip sheets) will be publicly available to researchers involved in the CoAP so they may prepare for an assessment.

- CAP letters are formally disseminated in writing with clear expectations of activities and timelines for the PI.

- The IRB posts information and resources online such as Fact Sheets and Frequently Asked Questions for any researcher on campus that has questions regarding what the IRB evaluates in reviews and in CoAP.

ARE YOU SURE THIS ISN'T AN AUDIT?

AUDIT

Surprise visits

Authoritarian environment

Unknown search parameters

Policing noncompliance

COAP

Observation sessions are scheduled one month in advance

Collegial environment

Self-assessment tool is available before observation sessions

Preventing noncompliance

FREQUENTLY ASKED QUESTIONS

- Are you going to shut down my research?

  The CoAP subcommittee would only recommend suspending research if a very serious issue arose during the observation. We believe these are unlikely and we go into our observations without the expectation we will find <u>any</u> issues.

- Why am I being singled out?

  Every expedited and full board study are up for CoAP review. Most protocols selected are chosen without cause.

- If I am assigned to CoAP does that mean I'm in trouble?

  Not at all! There are some cases where the IRB will assign a CoAP observation after an incident report, however many CoAP observations will occur because of risk level, the involvement of a vulnerable population, or by request of a funding source.

FOR FURTHER INFORMATION

Email: IRB@villanova.edu

Email: caitlin.stamour@villanova.edu

Call: 610-519-4250