Villanova University Compliance Assistance Program (CoAP)

Institutional Review Board

Office of Research Protections

Compliance Assistance Program (CoAP)

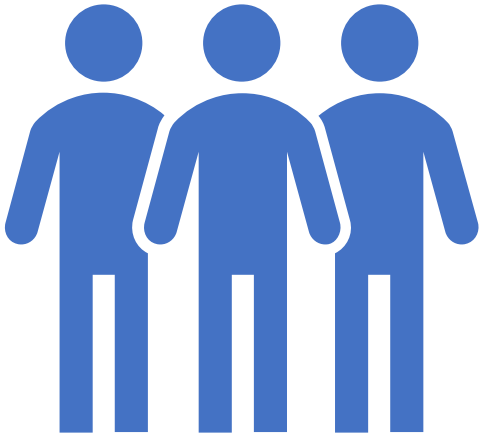
- The Office of Research Protections offers resources to researchers to help all through the research ethics process.
- CoAP is a new program that aims to expand support for researchers to the period following receipt of IRB approval.
- An overarching goal is to help maintain a high standard of research activity at Villanova,

Compliance Assistance Program (CoAP)

- CoAP is a program that aims to support researchers in the conduct of research that is in accordance with IRB reviewed and approved procedures.
- CoAP reviews allow the IRB and ORP to identify areas of deficiency in education for PIs about their roles and responsibilities in human subjects research and improve established processes.

Compliance Assistance Program (CoAP)

- CoAP-PI check-ins are performed by the VU CoAP committee who will meet with study teams, observe participant activities, and compare observations with the approved protocol.
- The CoAP committee will also review IRB actions to ensure they reflect best practices.
- Any identified opportunities for improvement will be communicated to the IRB and the study team.
- *Only the IRB has final authority to suspend research activity in the rare cases it would be necessary.*



Goals of CoAP

Assist	Assist researchers in maintaining consistency with approved IRB protocols to **protect human subjects**
Ongoing Review	
Prepare	

What CoAP IS

- The program goal is to provide **constructive** and **instructive** feedback on running a research project
- **Prevent** non-compliance and serious or reportable problems
- Ensure that all approved processes and procedures **protect** human subjects

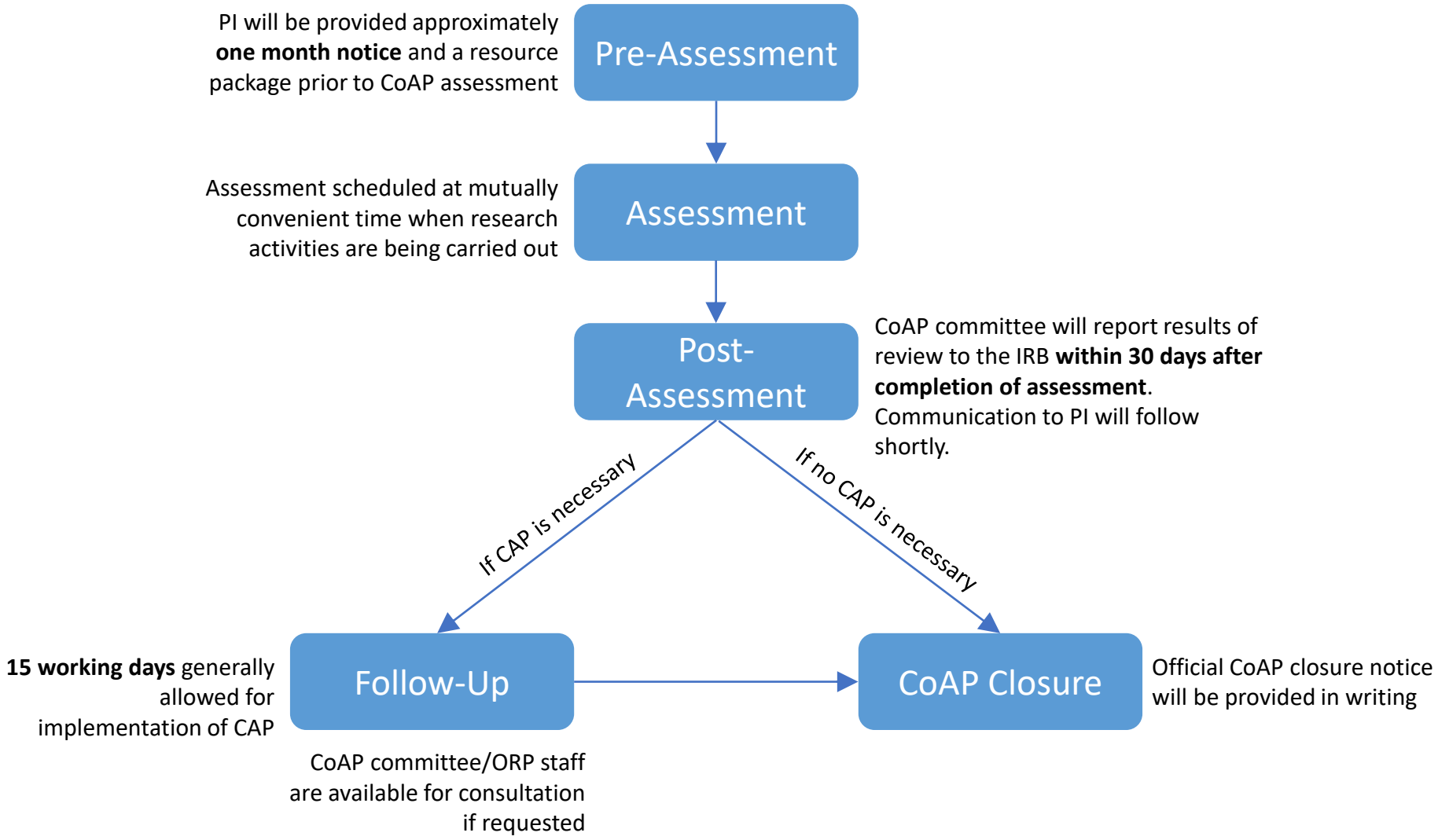
What CoAP is NOT

- Not designed to interrupt research activity
- Not designed to “police” researchers or to be a “trap” to catch non-compliance
- Not an investigation, grant review, or audit
- The intention of the assessment is to be collegial and un-obtrusive

Villanova University Compliance Assistance Program (CoAP)

Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Pre-Assessment	Assessment	Post-Assessment	Follow-Up	CoAP Closure
• PI candidate is selected and notified of CoAP opportunity • PI performs self-assessment using provided materials • CoAP committee reviews approved protocol	• CoAP committee meets with study team and observes research activities to ensure they are occurring in accordance with IRB approved protocol • CoAP committee reviews IRB activities	• Committee reports opportunities for improvement to the IRB and the PI • The IRB determines if any Corrective Action Plan (CAP) is necessary	• ORP provides resources for implementing CAP (if necessary) • PI implements new procedures based on CAP • CoAP committee verifies improvements if CAP directs	• IRB/ORP issues CoAP completion record

Villanova University CoAP (Timeline)



Content of Assessment

- **Does approved protocol protect the rights and welfare of human subjects?**
- Alignment between approved protocol and study procedures
- Recruitment
- Study population
- Enrollment procedures and participant numbers
- Consent forms and consent process
- Compensation management
- Records (completion, storage)
- Study site congruence

- Unexpected or adverse events/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

- Many situations might lead to the start of the CoAP process:
  - Voluntary election by PI
  - Especially complex or high risk studies
  - Request by sponsor
  - Request by IRB
  - Rare cases: participant complaint reveals unforeseen risks or other concerns
- Generally only studies reviewed as expedited or full board will be assessed.

Typical findings from CoAP visits:

Consent forms are not dated by participants	Informed consent documents on file are not complete (e.g. only signature page is stored)	Study records are not stored as indicated in approved protocol	Tracking of consent and participation for multi-session studies is disorganized such that the PI cannot ensure procedures are followed appropriately.

Should any areas of concern be identified, the IRB, ORP, and the CoAP committee will work with researchers to troubleshoot problems and resolve any remaining issues.

Resources for PIs

- CoAP materials (such as checklist and preparation tip sheets) will be available to researchers involved in the CoAP so they may prepare for an assessment.
- These materials are also available upon request for self-assessment by researchers not formally involved in the program.
- CAP letters are formally disseminated in writing with clear expectations of activities and timeline for the PI.

For further information

Contact IRBadmin@Villanova.edu