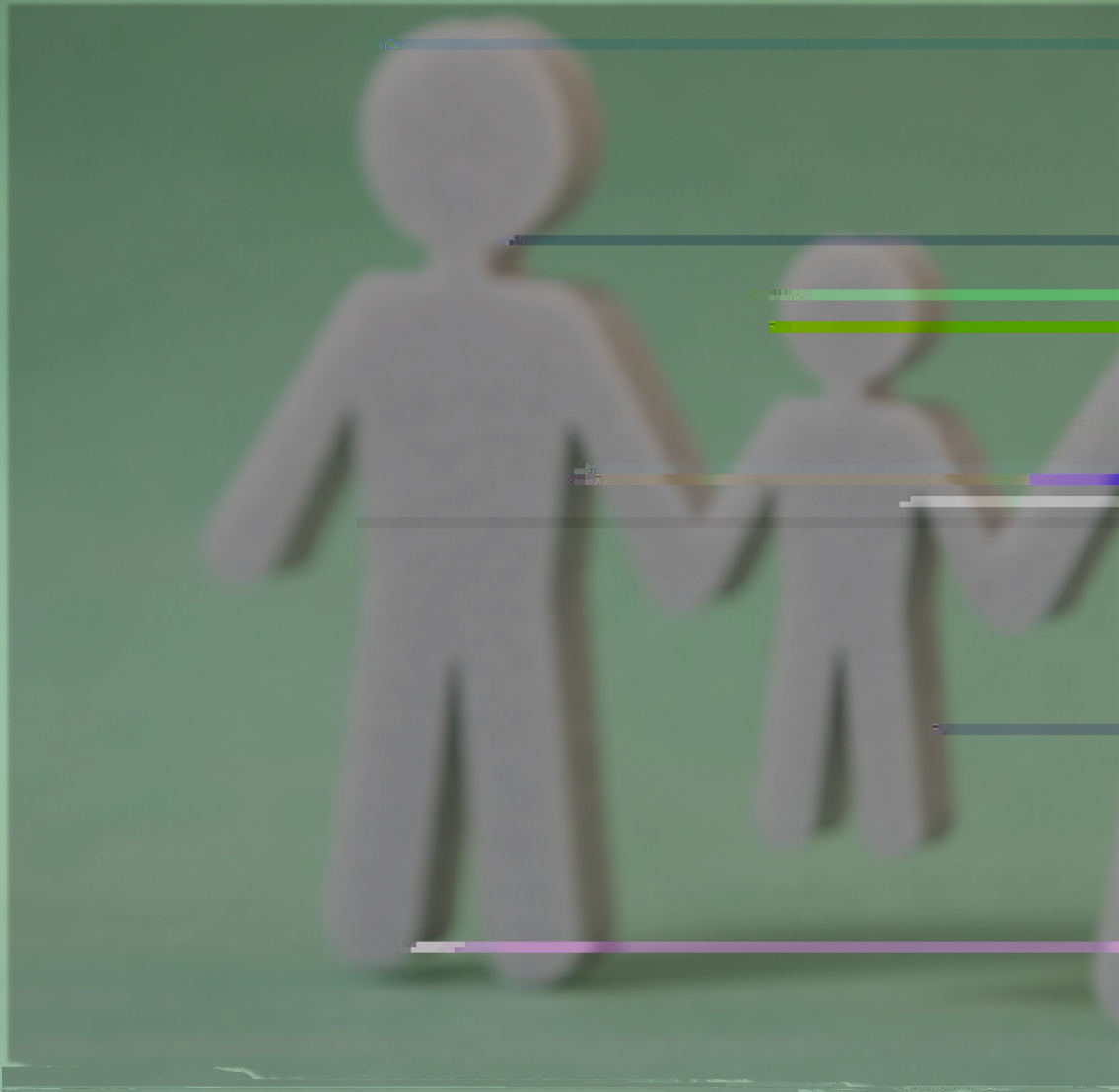


VILLANOVA
UNIVERSITY
COMPLIANCE
ASSISTANCE
PROGRAM
(CoAP)

Institutional Review Board
Office of Research
Protections



GOALS OF CoAP

Assist

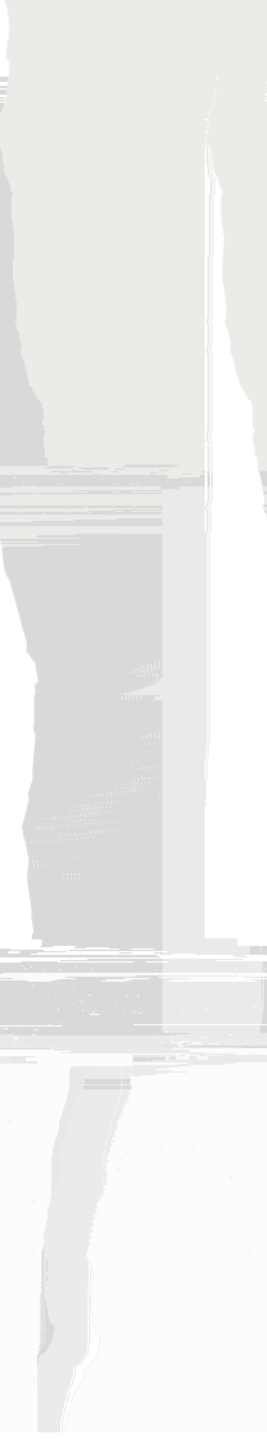
- Assist researchers in maintaining



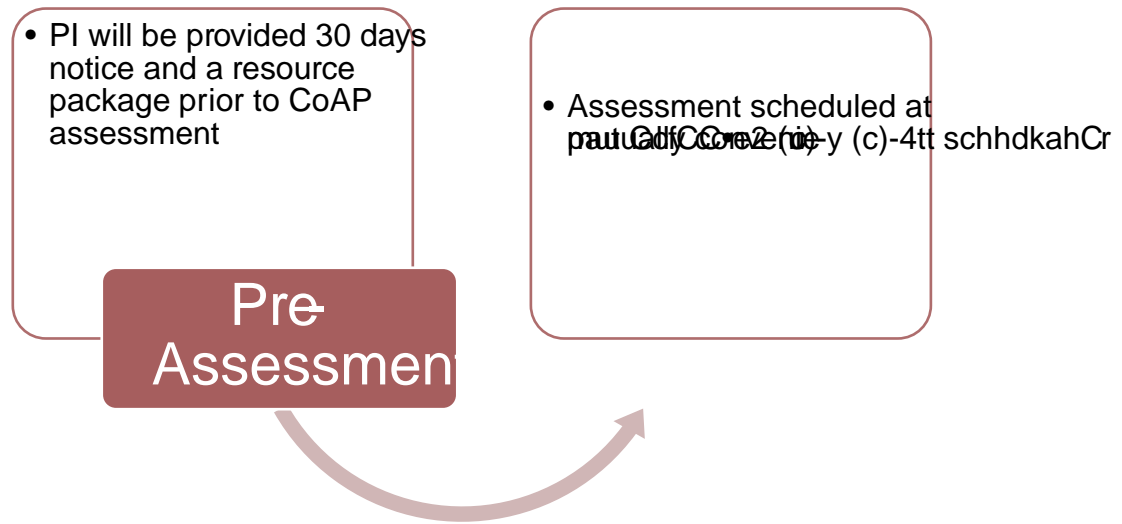


Pre Assessment

- IRB/ORP selects PI candidate, notifies him or her of CoAP opportunity
- PI performs self
 -



CoAP TIMELINE



CONTENT OF ASSESSMENT

CRITERIA FOR SELECTION

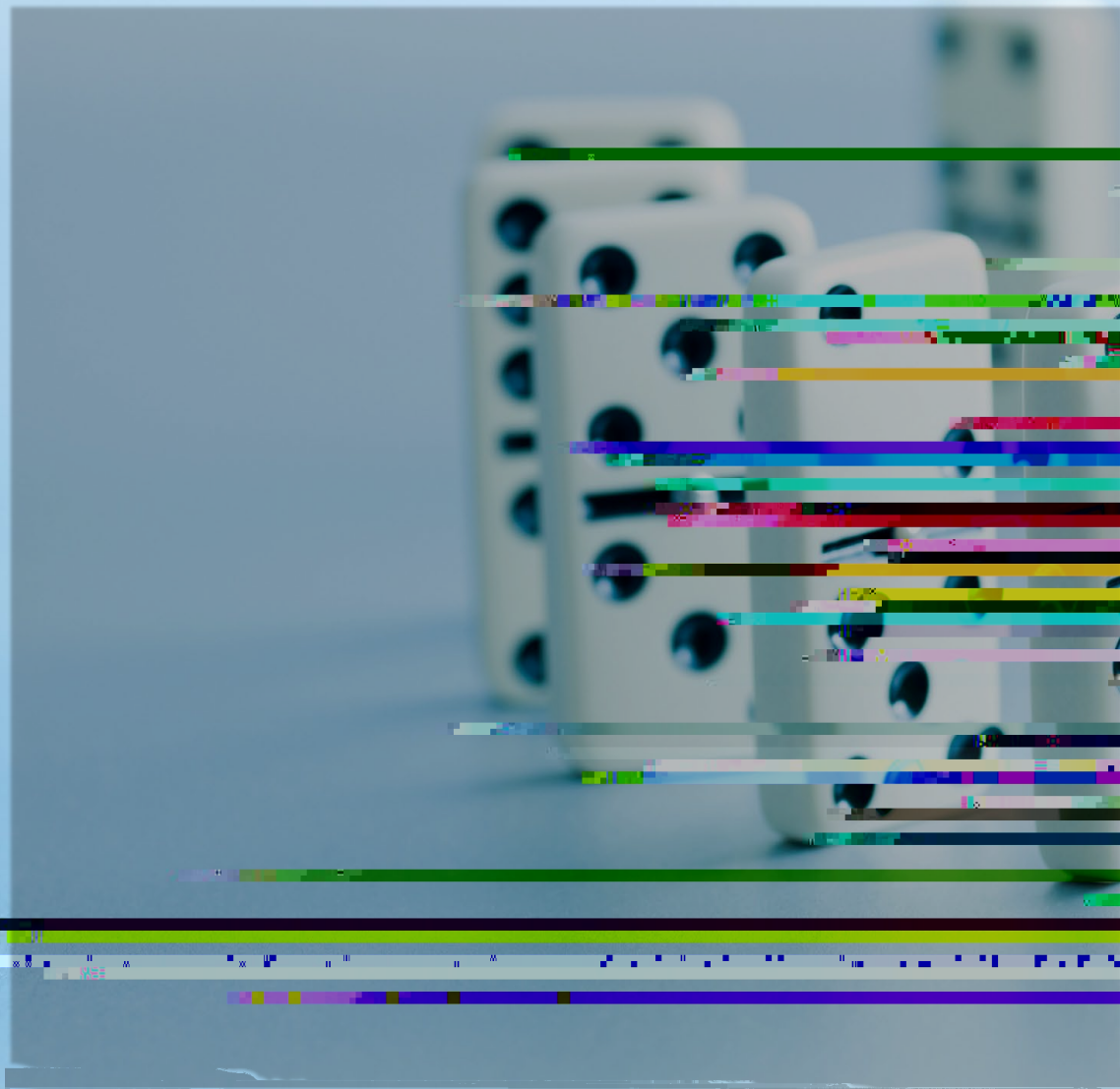
Voluntary election by the PI

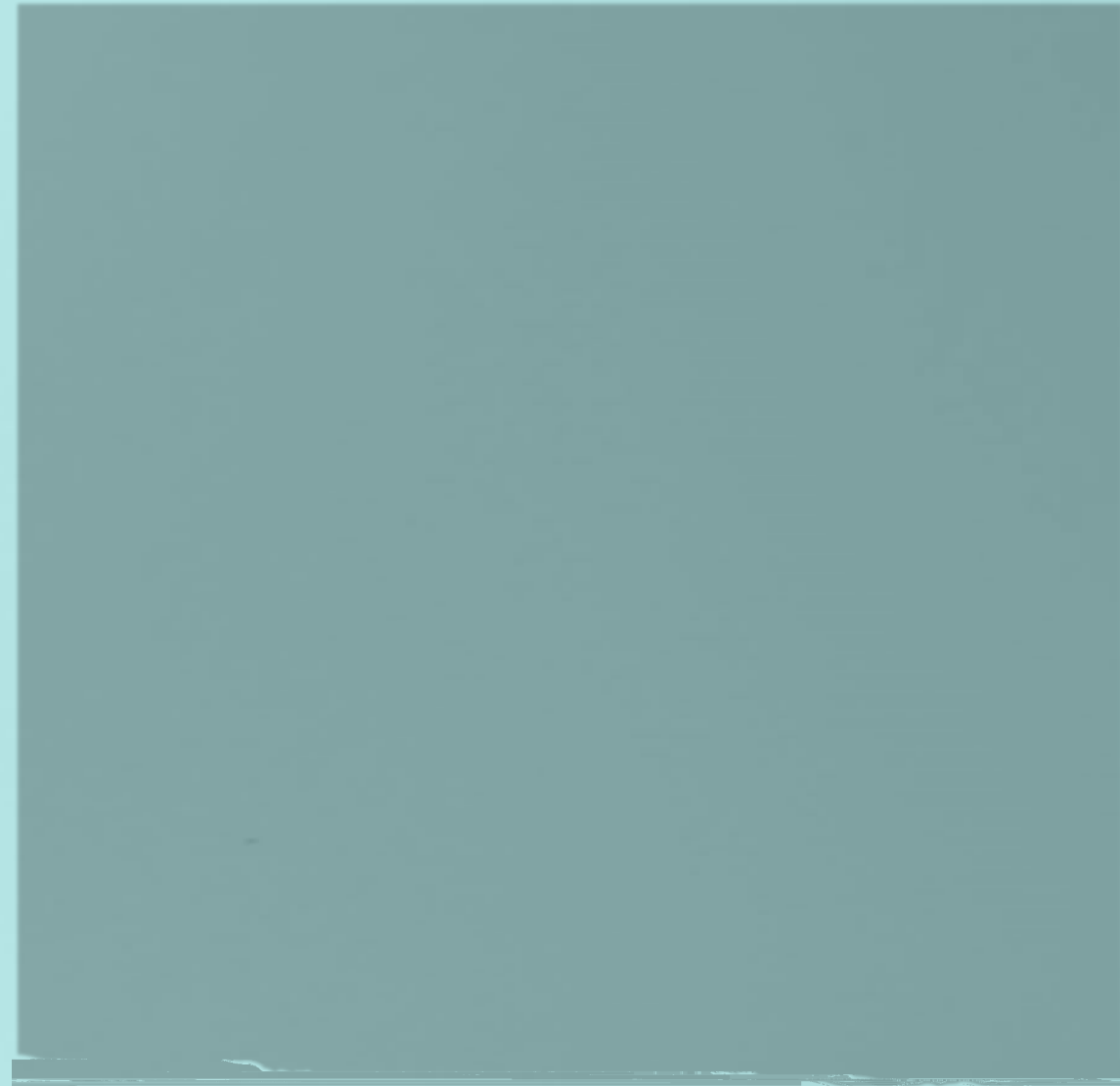
Higher risk study or vulnerable population study

Request by a grant sponsor

Request by the IRB

Rare: participant complaint reveals unforeseen risks





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 any 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!

