



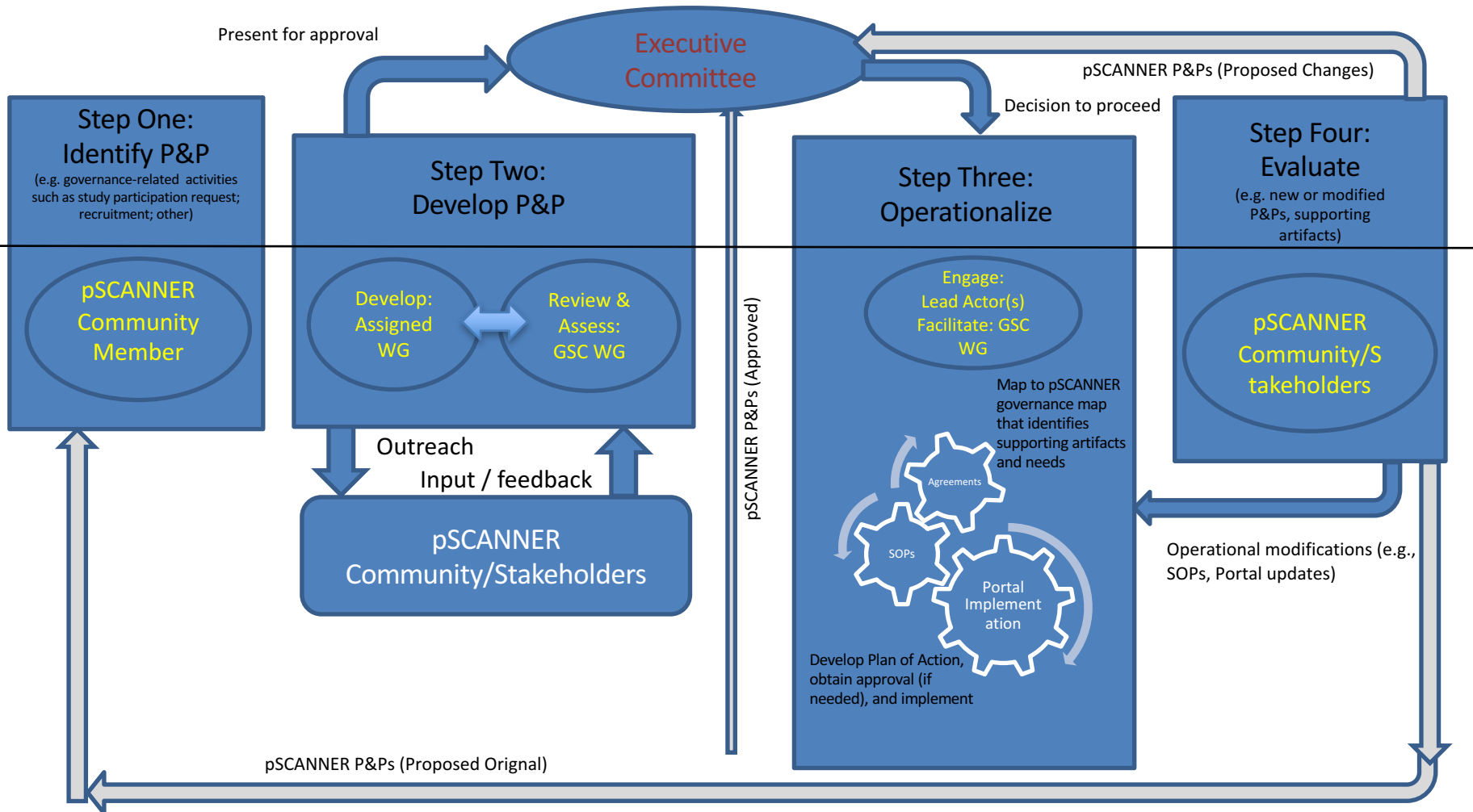
# Operationalizing Governance: The Path from Plan to Action

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# The Workflow



## Governance Plan Reference:

- Steps One and Two → Section 5.2
- Steps Three and Four → Section 5.3

- **Policy:**

- › Establish the principle or rule to guide decisions
  - » Enterprise (pSCANNER level)
  - » Issue
  - » System

- **Procedures:**

- › Describe actions that follow policy
  - » Set of instructions that performs a certain task
  - » Need at least one goal to accomplish
  - » Should have a metric that defines success

- **Plans:**

- › Coordination across P&Ps and related activities

- **Standard:**

- › Contains specific technical requirements
  - » Encryption
  - » Data elements for governance

- **Guideline(s):**

- › Recommends how to follow policy or procedure
  - » Change the must to should in a policy – you have a guideline!

- Define the activity
  - › Determine defining policies (and agreements)
  - › Define workflow/approval process and develop the list of SOPs
  - › Establish roles and responsibilities
  - › Define metrics and rubrics to evaluate the activity and its outcomes
  - › Define data elements and standards for Portal implementation (if appropriate)

- Develop the Plan of Action
  - › Decompose work effort into specific and granular actions
  - › Map to a detailed project plan with milestones
- Perform the work
- Document outcomes as part of pSCANNER roadmap development
  - › Supports strategic growth towards sustainability

- Activities: Request for Collaboration, Study/Research participation request
  - › Policies: DSAs, participation, and evaluation policies (PCORnet, pSCANNER, sites, IRB)
  - › Workflow: Evaluation and approval process for requests, study request completion instructions
  - › Roles & Responsibilities: Evaluation, approval
  - › Rubrics: Metrics to score study
  - › Data Elements: FHIR specification (for example) and study request form

- Plan of Action/Work Plan
  - › Complete study request form
  - › Determine related workflows, SOPs, IRB review
  - › Determine need for rubrics/metrics to evaluate requests (in support of eventual automation)
  - › Work with Portal team to implement activity
- Several GSC activities are coming together
  - › Review of data sharing agreements and policies
  - › IRB streamlining, impact on study request process