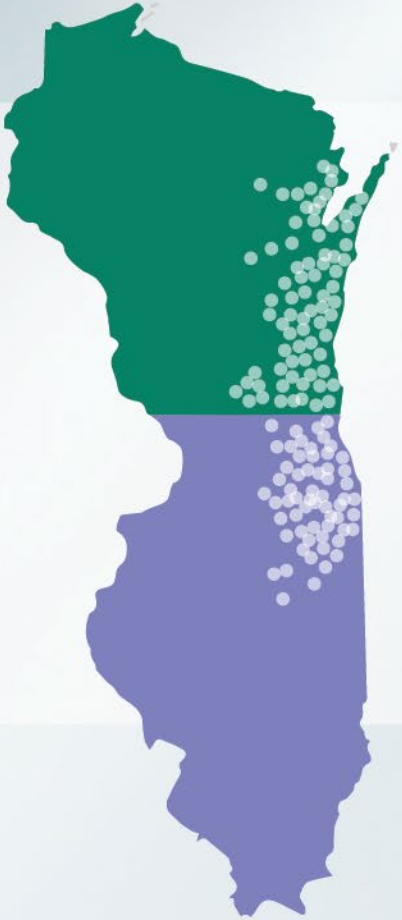


# Reinforcing meritorious, efficient research using a system-wide study authorization process

## SRAI Midwest/Northeast Section Meeting

April 29, 2019 | Mindy Waite, PhD and Nina Garlie, PhD

Aurora Health Care®

We are AdvocateAuroraHealth™

# Contact Us

Mindy Waite, PhD

Manager, Research Grants and Projects

mindy.waite@aurora.org

Nina Garlie, PhD

Director, Neurosciences and Specialty Research

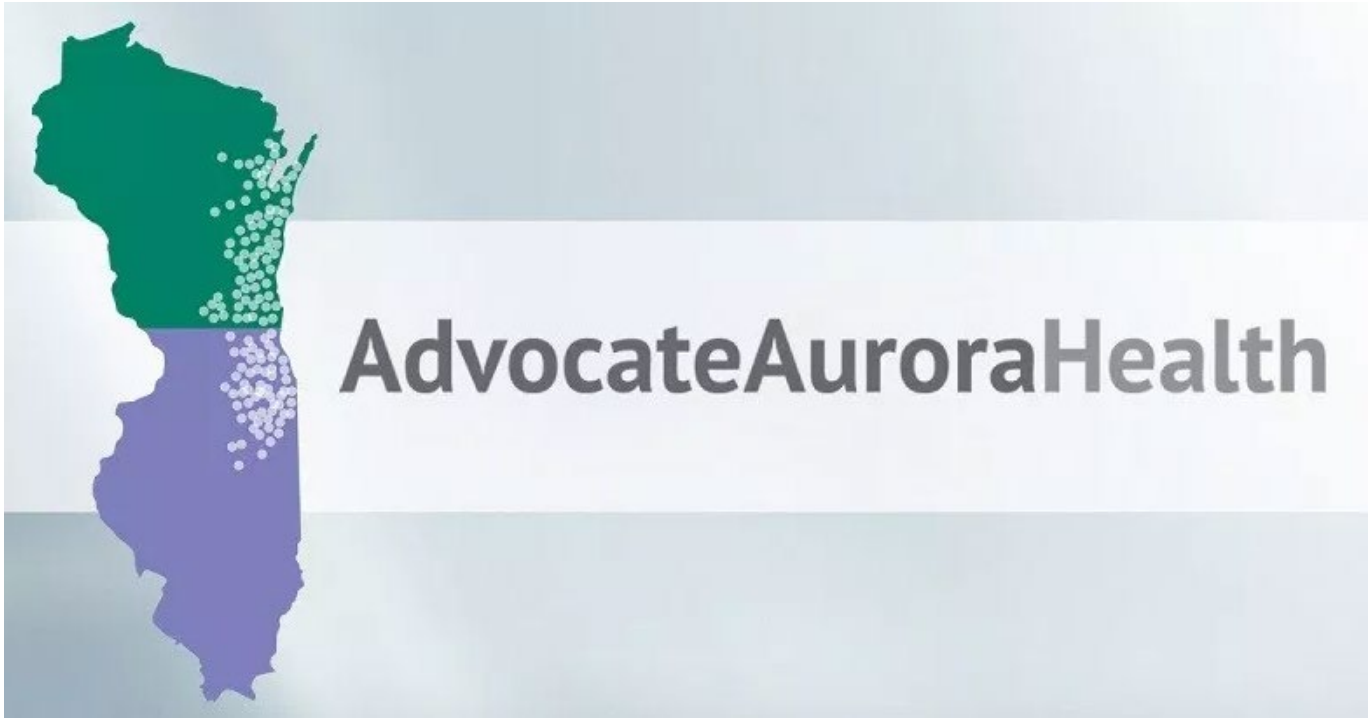
nina.garlie@aurora.org

***No conflicts of interest***

# Objectives

- Discuss the need for research administrative preauthorization (RAP) process.
- Illustrate RAP process steps.
- Share preauthorization tools.
- Discuss basic requirements and issues.
- Translate generalizability of RAP.

# Advocate Aurora Merger



# Aurora Health Care

- Serves 60% of WI population.
- 30,000+ employees.
- 3,600+ physicians.
- $25M+ in research expenditures.

# Aurora Research Institute

Purpose: Help people live well *through innovative research.*

- Performs research (12 PhD researchers).
- Supports system-wide research.

- 180 employees
- 300+ sponsored clinical trials
- 250+ investigator-initiated research projects

# Aurora Research Institute

Main research areas:

- Neuroscience
- Cardiovascular
- Oncology
- GI
- Maternal/fetal health

# Research Resources

- Research scientists
- Research associates
- Data analytics
- Research contracting
- Biorepository
- Research coordinators
- Regulatory specialists
- Sponsored Programs Office
- Publishing office
- Internal funding
- 5,000 sq. ft. wet laboratory

# Before RAP

**Originally: *Wild wild West.***

IRB oversight only.

Research team connected directly with resources teams.

# Before RAP

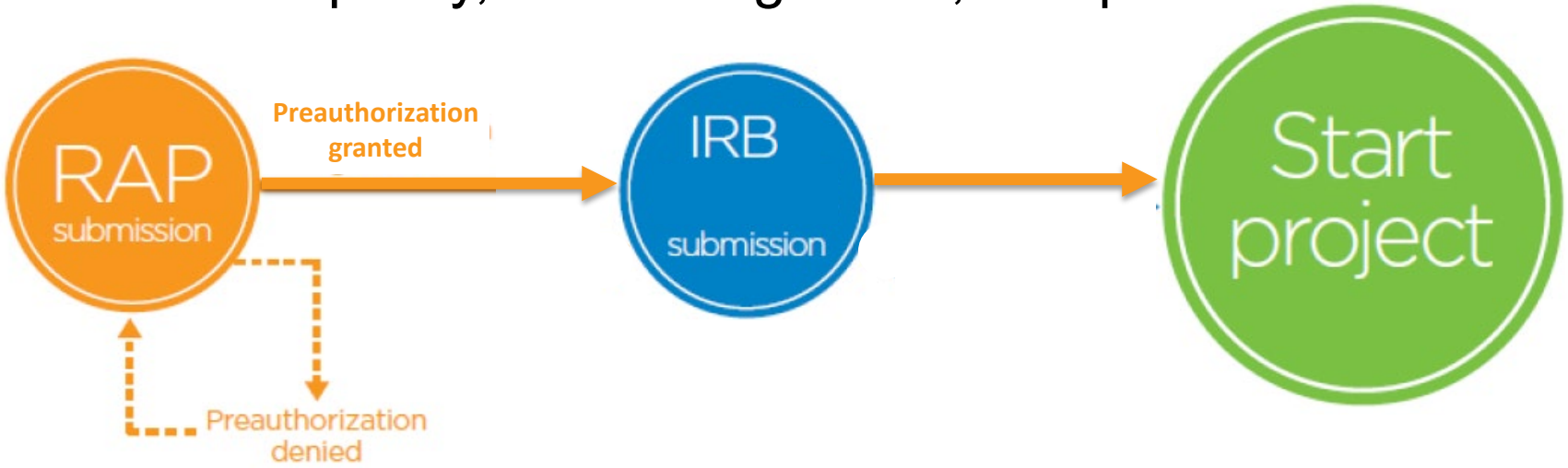
- Resource teams overwhelmed; difficult to sync around projects.
- Research teams upset at speed of resource teams.
- Inequality for research support.
- Lack of awareness of projects, so struggle to manage:
  - Quality
  - Ethics
  - Compliance
  - Resource efficiency
- Need to centralize the research administration and resources.

# RAP v1.0 (2014)

**0.1 FTE**

## RAP launched in 2014

**Purpose:** To provide pre-review early in research process to maximize quality, ethical alignment, and priorities.



# RAP v2.0 (2017)

**0.6 FTE**

## + Delegates + research expert + all research

# RAP v2.0 (2017)

**Pros:**

- Faster decisions.
- Delegates understand area's priorities and teams.
- Delegates acquire better understanding of all research in their area.
- Feedback to investigator, not just judgement.
- Better understanding of all research.

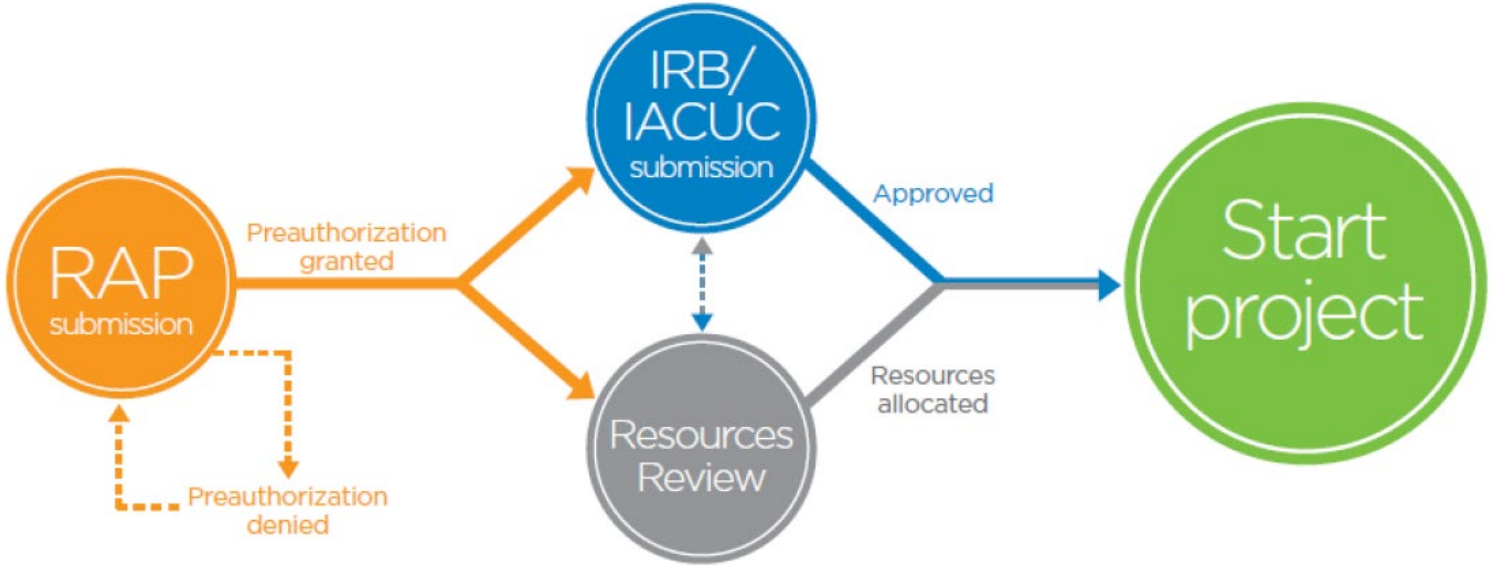
**Cons:**

- Resources teams still overwhelmed.
- Still no coordination by resources teams.

# RAP v3.0 (2017)

1.1 FTE

**+ Delegates + research expert + all research + resources review + admin**



# RAP v3.0 (2017)

**Pros:**

- Quantifies the resources needed.
- Proposals only reviewed by resources committee if preauthorized.

**Cons**:

- Resources quantified after the decision was made.
- Allows some feedback by scientific reviewer, but not really feedback from resources teams.

# RAP v3.0 (2017)

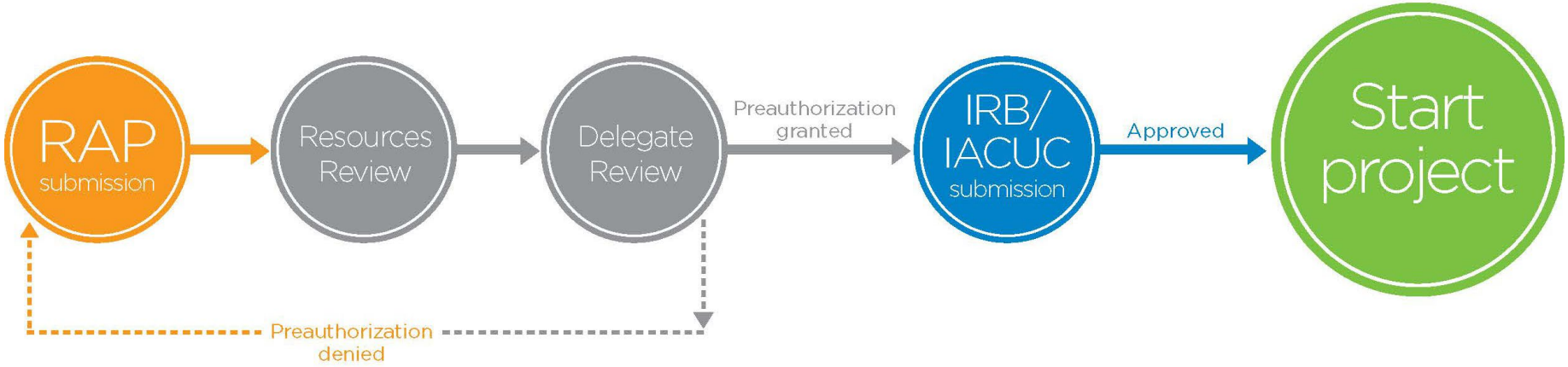

- RAP Manager
- RAP Scientist
- Data Analytics

- Contracting
- Biorepository
- Regulatory
- Coordinators
- Biostatistics

# RAP v4.0 (2018)

1.1 FTE

**+ Delegates + research expert + all research**
**+ resources review + admin + policy**



# All research requires RAP

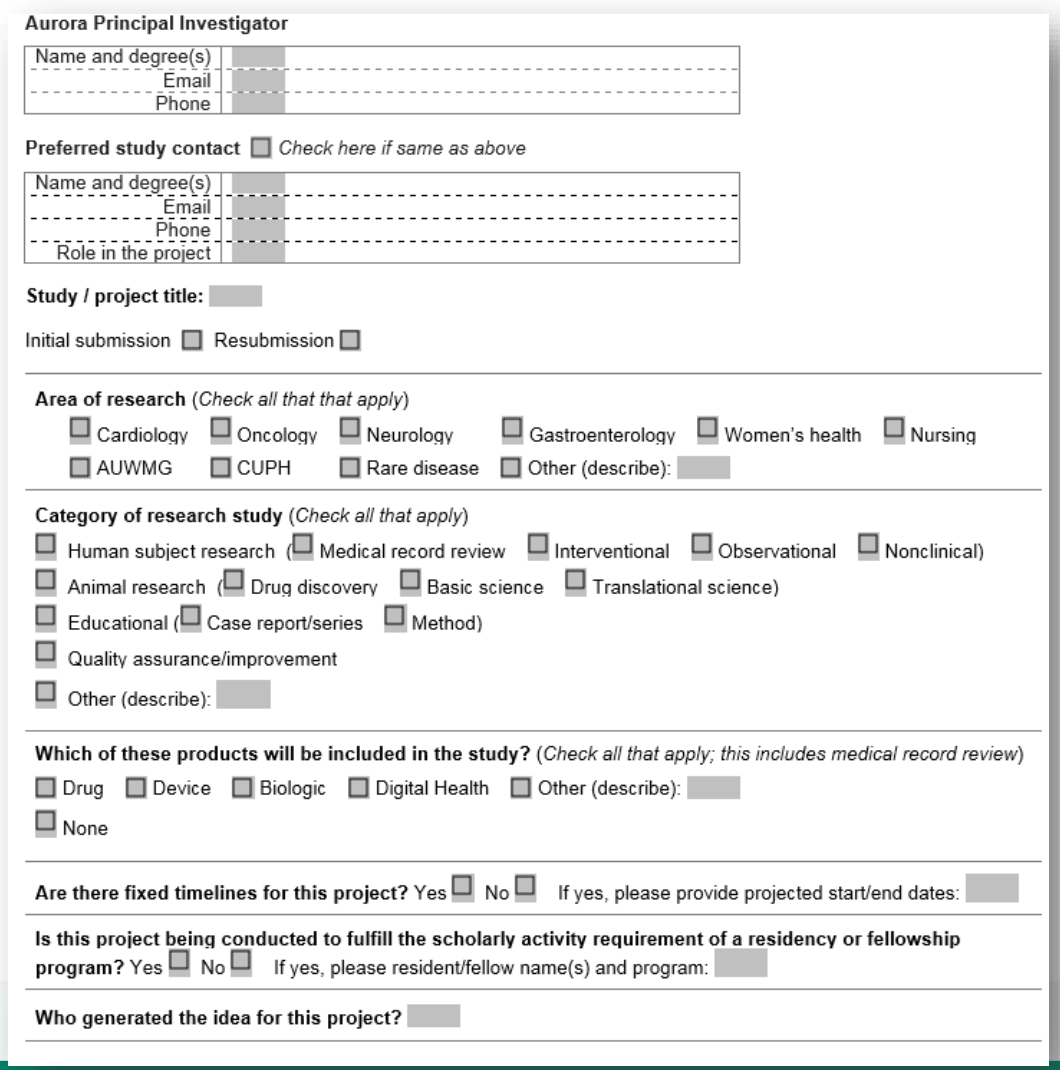
- **Sponsored studies (e.g., clinical trials, grants):** Review process and authorization by protocol selection committee, manager, or President.
- **All other studies (investigator-initiated):**
  - RAP form.
  - Resource & scientific scoring committee.
  - Delegate review and authorization.

# Tracking of projects

- Confirmation of preauthorization email.
- RAP administrator maintains project list:
  - Clinical trials
  - All other studies

# RAP Form

- PI/team
- Rationale
- Objective/Hypothesis
- Endpoints
- Design
- References
- Resources



**Aurora Principal Investigator**

| | |
|---|---|
| Name and degree(s) | |
| Email | |
| Phone | |

**Preferred study contact** ☐ *Check here if same as above*

| | |
|---|---|
| Name and degree(s) | |
| Email | |
| Phone | |
| Role in the project | |

**Study / project title:**

Initial submission ☐ Resubmission ☐

**Area of research** (*Check all that that apply*)

☐ Cardiology ☐ Oncology ☐ Neurology ☐ Gastroenterology ☐ Women's health ☐ Nursing
☐ AUWMG ☐ CUPH ☐ Rare disease ☐ Other (describe):

**Category of research study** (*Check all that apply*)

☐ Human subject research (☐ Medical record review ☐ Interventional ☐ Observational ☐ Nonclinical)
☐ Animal research (☐ Drug discovery ☐ Basic science ☐ Translational science)
☐ Educational (☐ Case report/series ☐ Method)
☐ Quality assurance/improvement
☐ Other (describe):

**Which of these products will be included in the study?** (*Check all that apply; this includes medical record review*)

☐ Drug ☐ Device ☐ Biologic ☐ Digital Health ☐ Other (describe):
☐ None

**Are there fixed timelines for this project?** Yes ☐ No ☐ If yes, please provide projected start/end dates:

**Is this project being conducted to fulfill the scholarly activity requirement of a residency or fellowship program?** Yes ☐ No ☐ If yes, please resident/fellow name(s) and program:

**Who generated the idea for this project?**

# RAP Form

*How can we help support your study?*

**Biological samples / Biospecimens**

*If none, check here:* ☐

A. Will biological samples be collected from Aurora patients as part of the study? Yes ☐ No ☐
B. Will biological samples be sent to / received from an external organization? Yes ☐ No ☐
C. What types of biological samples are needed (e.g. fresh tissue, blood/plasma/serum, urine, slides, etc.)?
D. Approximately, how many biological samples will be needed in total?
E. Will biological samples be collected and stored for future unspecified research (banking or sub-study)? Yes ☐ No ☐

**Data**

*If none, check here:* ☐

A. Briefly describe data collection methods.
B. Who will be collecting these data (e.g. your study team, Res
C. Who will de-identify the data and how?
D. Do you plan to use an Aurora Research Institute biostatistici

**Regulatory and research coordinator support**

*If none, check here:* ☐

A. Who will be submitting the regulatory filings for the study?
B. Will this study require a research coordinator? Yes ☐ No

**Innovation**

*If none, check here:* ☐

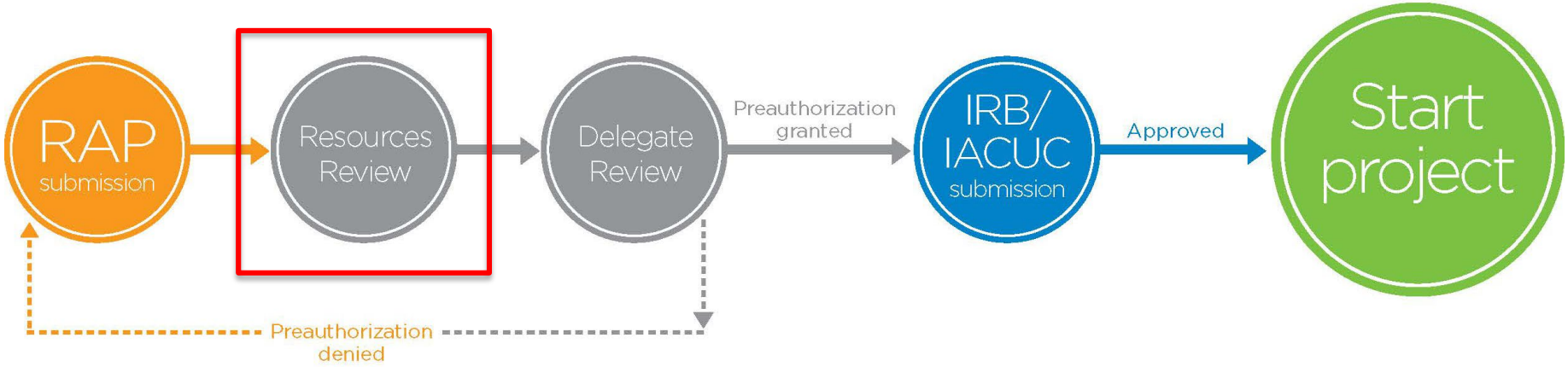
A. Could the results of your study apply to, or study design include, therapies directed to rare disease, patients with inadequate therapeutic options, or patients without a FDA-approved therapeutic option? Yes ☐ No ☐
B. Have you conducted a Medtrack review? Yes ☐ No ☐
C. Is the approach, method or test article (drug, device, digital health, other) novel? Yes ☐ No ☐
D. Has any aspect been publically disclosed? Yes ☐ No ☐

**Animal research**

*If none, check here:* ☐

A. What animal type is being used?
B. Do you have an existing IACUC approval for this study? Yes ☐ No ☐

# RAP v4.0 (2018)


RAP
submission
Resources
Review
Delegate
Review
Preauthorization
granted
IRB/
IACUC
submission
Approved
Start
project
Preauthorization
denied

# Resources & Scientific Scoring

- Resource Needs
- Patient Impact
- Therapeutic Potential and Priority
- Institutional Priority
- Funding

| Score Summary | |
|---|---|
| Resource (-) | 100 |
| Scientific (+) | 295 |
| Funding (+) | 0 |
| **Total** | **195** |

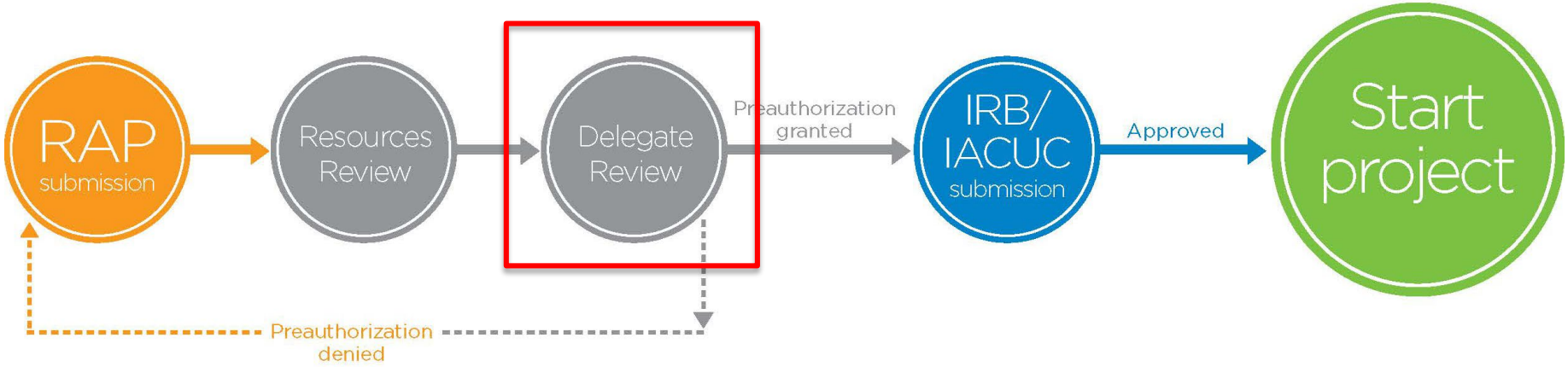
| Score | Weighted Score |
|---|---|
| **Total Score** | **195** |

# Resources & Scientific Scoring

| | Scored 0 (no resources) to 4 (heavy resource needs) | Score | Weighted Score | |
|---|---|---|---|---|
| Resource Needs | Biorepository and Specimen Resource Center (BSRC)<br>(Consent, collecting, storage, distribution) | 0 | 0 | None |
| | Research Analytics<br>(Data collection, biostatistics) | 3 | 75 | Data collection, de-identify data and biostadistician. NDVI calculations. 40 hours data pull, but M components 150-200 hours. Biostatistician lightly engaged on this. Data Analytics would have to figure out how to do the NDVI and document the process for reproducability. |
| | Regulatory and Coordinator<br>(IRB or FDA filing, consent patients) | 1 | 25 | Expedited review for retrospective chart review. Consent waiver. Gary already assigned to it for the application. |
| | Research Business Services (RBS)<br>(Medicare coverage analysis, budgets, agreements) | 0 | 0 | None |
| | | **Resource Score** | **100** | |

| | Scored 0 (lowest) to 4 (highest) | Score | Weighted Score | |
|---|---|---|---|---|
| Patient Impact | Scope of problem<br>(e.g., # of individuals affected, rare disease, patient cost, prevalence) | 4 | 40 | X is a sizeable patient population problem. |
| | Degree of patient health impact<br>(e.g., unmet medical need, severity, quality of life, communicability) | 2 | 10 | The association between x and Y has been already determined. Residing in urban regions with more x may lead to a reduced risk of y (Author1, 2012; Author2, 2017; Seo, 2019). Moreover, residential proximity to x is associated with higher survival rates after y (Author3, 2008). However, the authors will investigate other socioeconomic factors associated with the incidence of x using Tool Y. |
| | Potential to impact related conditions | 4 | 20 | Yes, there is potential to identify an association between x and z and y. |
| | Immediate impact to improve patient care/outcomes<br>(within 3 years) | 0 | 0 | No immediate impact to improve patient care/outcomes. |
| | Long-term potential to improve patient care/outcomes<br>(within 10 years) | 1 | 10 | Uncertain potential to improve patient care long-term. The authors claim that data from this study may support a cost benefit analysis of x intervention on health care costs and health outcomes. However, there is no pathway to practice described in RAP form. |
| | Study includes a credible plan to change patient care/outcomes<br>(completion within timeline, likelihood of success, Pathway to Practice) | 0 | 0 | This is a retrospective matched case-control study and thus,there is a risk for selection and observation bias that will limit the findings. Pathway to practice was not described. |

# RAP v4.0 (2018)


RAP
submission
Resources
Review
Delegate
Review
Preauthorization
granted
IRB/
IACUC
submission
Approved
Start
project
Preauthorization
denied

# Who provides authorization

Protocol Selection Committee (Clinical Trials)

- Members include:
  - Research leader
  - Clinical service line leaders
  - PI (presents proposal)

# Who provides authorization

Protocol Selection Committee (Clinical Trials)

- Review criteria include:
  - Financial feasibility
  - Patient availability
  - Sponsor history
  - PI history
  - Other

# Who provides authorization

Non-clinical Trials: RAP delegate

- Research leader
- Aligned with clinical service line(s)
- Administrative responsibility for project
- May be involved in an appeal for a re-review


# Delegate review of proposal

- Conduct own review.
- Consider:
  - PI/study team research history (likelihood of success).
  - Strategic alignment with program goals.
  - Financial feasibility.
- Then, consider resource review committee score and recommendation.

# Decisions. Decisions.


Delegate communicates with other research leaders when:

- Project crosses clinical disciplines.
- Resources from multiple areas needed for project.
- Assistance is needed to make decision.
- Support is needed when decision is not favorable.

# Example: New investigator

New to research.

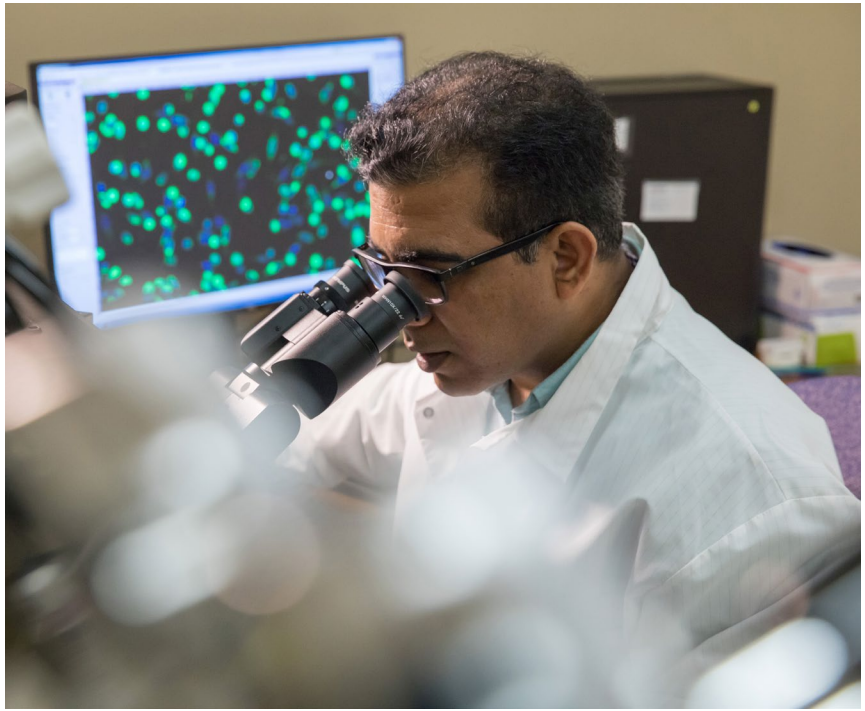
Has scientific question.

Needs resources.

No funding.

→ **Contact RAP!**

# Example: Seasoned investigator

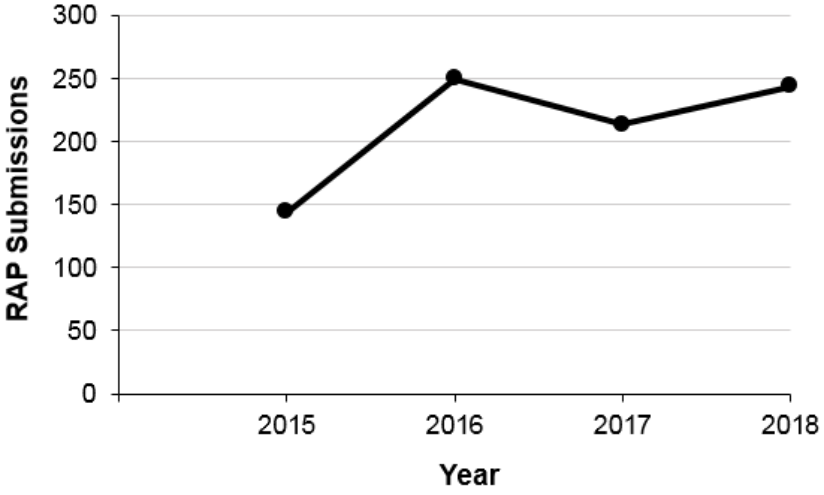


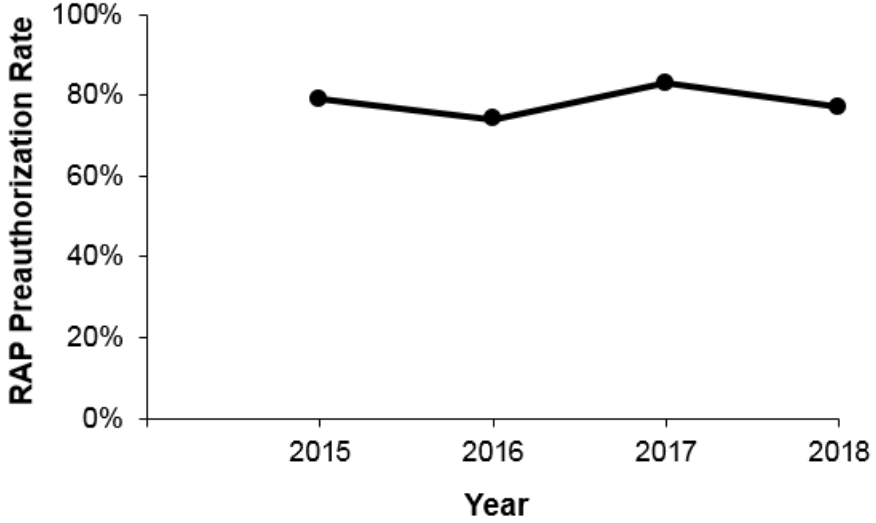
Submits RAP proposal

**or**

Authorized via grant

# RAP measurements



# Lessons learned

- No contingent approvals.
- Say “try again” instead of “no.”
- Reinforce projects with funding.
- Ensure consistent communication (one mailbox).
- Keep delegates anonymous.
- Keep it short and sweet.

# Ingredients

- ✓System authorization for research oversight.
- ✓Policy or SOP.
- ✓A carrot (resources?).
- ✓RAP form.
- ✓Scientific and resource assessment.
- ✓Engaged leader or delegates.
- ✓Expedient, communicative process.

# Environment

- ✓Health Care System.
- ✓Centralized research support services and administration.
- ✓Institutional funding for research support services.
- ✓Clinical service lines are similar to departments in academic setting.
- ✓Communication essential between service lines and research.

# To-do list for AAHRI

- Gauge total research resources and set system limits.
- Set a timeline for resource utilization by teams.
- Develop process for following up on project outcomes.
- Increase communication around delegate/resource team disagreements.
- People still upset when their proposals are declined – can we improve?

# Contact Us


Mindy Waite, PhD

Manager, Research Grants and Projects

mindy.waite@aurora.org

Nina Garlie, PhD

Director, Neurosciences and Specialty Research

nina.garlie@aurora.org