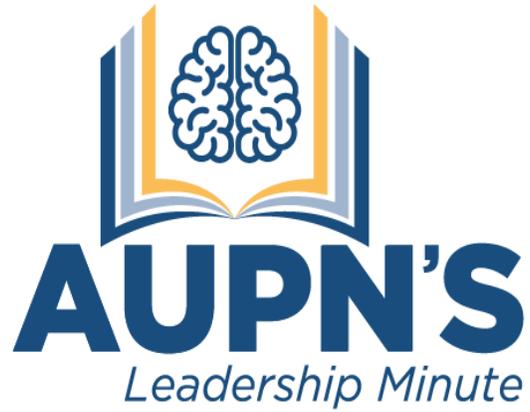




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***Building Clinical Research
(while actually making money)***



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Description

Clinical research has been integral to medical progress since the time of Hippocrates; without it, laboratory discoveries would never translate into human therapies. However, in contrast to basic science research (which has a clear career path undergirded by prestigious federal support), the keys to building a successful clinical research enterprise often seem shrouded in mystery to many department chairs and their senior leaders. In this summary, we outline the hidden strategies for building successful and fiscally sound clinical research

Getting Started: CLINICAL RESEARCH FACULTY

- **WHY CLINICAL RESEARCH?**
 - Critical to the translational research mission
 - Education of residents & fellows
 - Recruitment/Retention of academic clinical
 - Clinical research revenues can offset salaries
- **FACULTY**
 - Clinical Research Experience
 - Established network in Clinical Research
 - Other Investigators & Clinical Trial Centers
 - Pharma & Device Companies



Workflows & Critical Waypoints

- **Pre-Award**

- **Feasibility Assessment Key #1**
 - Facilities & Personnel
 - Sufficient number and type of patients
 - Screening/Enrollment Ratio (Inclusion/Exclusion)
- **Contract Negotiations Key #2**
 - Start-Up Costs
 - Other Costs: Salaries, labs, imaging, etc.
- IRB and other Institutional Approvals
- Account Setup



- **Post-Award**

- **Enrollment Monitoring Key #3**
 - Pay per visit and/or milestone payments
- **Fiscal Management: Submission and Tracking of Billing and Payment**
- **Indirect Cost Sharing Key #4**

- **Competent, properly paid employees are required for these functions!**

Startup Funding & Revenues

- **Startup Funding Sources**

- Chair's Startup funds
- Philanthropic Funds
- State or Federal (State rate, VA, etc.)
- Other funds

- **Revenues**

- **Direct**

- Personnel conducting the research: Support Staff & MDs + labs, imaging, etc.

- **Indirect**

- Contracting, Fiscal Management, Compliance, etc.

- **Residuals**

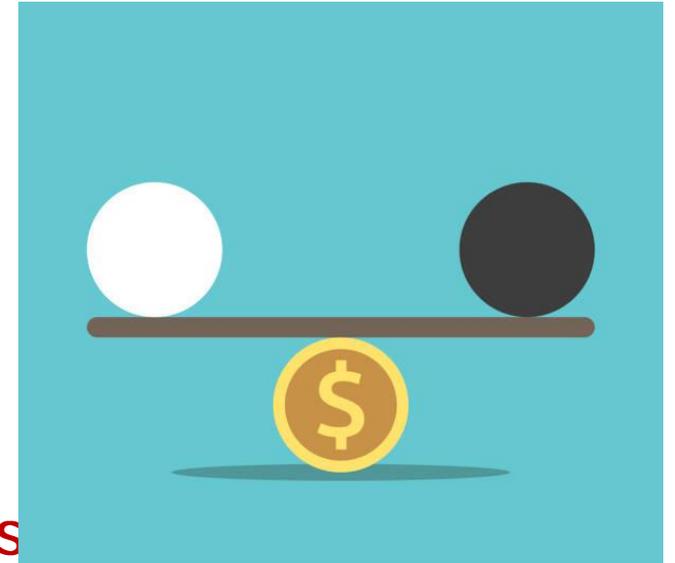
- Funds remaining after all expenses (does not go back to the company!)

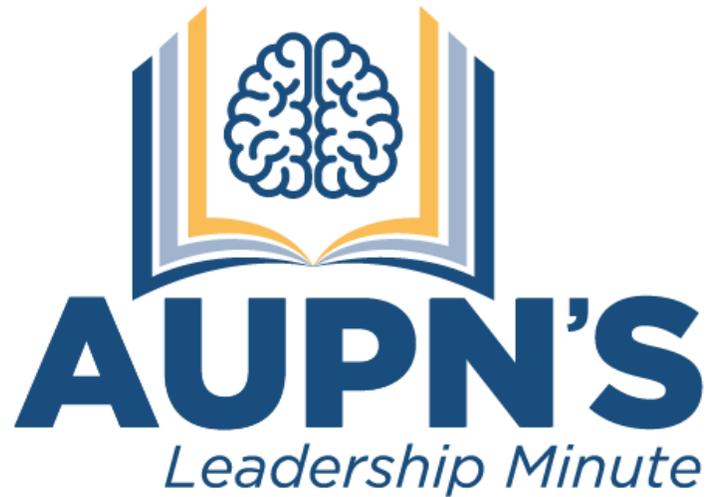


Can Clinical Research Support Itself?

Yes, IF:

- You properly manage the Critical Waypoints
 - Feasibility Assessment
 - Contract
 - Enrollment (you must deliver!)
- You “right-size” the team
 - Enough personnel to do the work (no more, no less)
- You ensure fair sharing of revenues within your institution
 - Indirect Costs
 - Residuals





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