Development of P01

Deadlines: January 25, May 25, September 25
Check with relevant IC, if P series applications are accepted, and when

NIH Definition
For the support of a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective. Each research project is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.

Required Components
- 3 or more interdependent projects with unified goal
- Effective communication
- PPG Director = established leader; substantial commitment of time
- (At least) one research core
- One administrative core

➢ Contact IC staff at a minimum 12 weeks before submission

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Budget
not limited
up to 5 years; potential for one 5 year renewal

Overall Components:
- Specific Aims; program project as whole
- Research Strategy:
  - describe major theme
  - Need for PPG
  - Overall importance of research
  - overall strategy, how different projects/cores relate
  - coordination & communication

Specifically:
➢ history, purpose, objectives of program
PPG director duties
- advisory committees (internal: name members; include letters of agreement; describe expertise on external advisory committee; do NOT name)
- describe research program; relationship with cores
- describe preliminary results
- collaborative agreements

- **Letters of Support**: institutional support, internal advisory committee
- **Resource Sharing Plan**
- **SF424 Cover (Overall)**
- **R&R Project Information (Overall)**:
  - Facilities & Other Resources; parent institution only, proposed advisory committees, space assignment, organizational framework, provide organizational chart
- **Project Site Location (Overall)**: Primary site only
- **Key Personnel (Overall)**: only PI(s)
- **Budget (Overall)**: only include estimated project funding section of SF424 (R&R) cover

**Administrative Core**
- **Specific Aims for Administration Core**
- **Research Strategy**:
  - Objectives
  - Staffing
  - Resources
  - Services provided
  - Administration; management strategies; promote coordination & collaboration within the program
  - describe planning & coordination of research activities, integration of cross-disciplinary research, allocation of funds, management of resources & quality control, maintenance of communication, evaluation plans; who will be responsible for what
  - add tables/organizational charts
  - include past activities/accomplishments relevant to admin core

- **Letters of Support**: specific to Admin core
- **NO Data Sharing Plan for this component**
- **Planned Enrollment Report, Cumulative Inclusion Enrollment Report**
- **SF424 Cover (Administration Core)**
- **R&R Project Information (Administration Core)** (do not add project narrative for admin core)
- **Project Site Location (Administration Core)**
- **Key Personnel (Administration Core)**: use “other” “core lead”
- **Budget (Administration Core)**

**Research Core**
- **Specific Aims for Research Core**
- **Research Strategy (Research Core)**:
  - Objectives
  - Staffing
  - Resources
  - Services provided
  - Management: overall, decision making process, cost effectiveness, quality control
  - Utilization of core: past/projected usage of Core services

- **Letters of Support**: specific to Research core
- Data Sharing Plan for this component
- Planned Enrollment Report, Cumulative Inclusion Enrollment Report
- SF424 Cover (Research Core)
- R&R Project Information (Research Core) (do not add project narrative for research core)
- Project Site Location (Research Core)
- Key Personnel (Research Core): use “other” “core lead”
- Budget (Research Core)

### Research Projects (typically 3)
- Specific Aims for Research Project
- Research Strategy (Research Project):
  - focus on this particular project (synergy with others only to be discussed in overall component)
  - Significance, Innovation, Approach
  - Background with references
  - Project’s Objectives, relevance to overall theme
  - biomedical significance
  - preliminary data, prior experience
  - use of core services; need for such, cost effectiveness
  - justification for project’s location (if off site); plans for interaction/cooperation

- Letters of Support; specific to Research core
- Data Sharing Plan for this component
- Planned Enrollment Report, Cumulative Inclusion Enrollment Report
- SF424 Cover (Research Core)
- R&R Project Information (Research Core) (do not add project narrative for research projects)
- Project Site Location (Research Projects)
- Key Personnel (Research Projects): use “other” “project lead”
- Budget (Research Projects)