P41 Outline (with notes and details)

Text in quotes is guidance from either the P41 FOA (PAR-14-021) or from the SF424 guide.

The proposal will contain the following components:

- Overall (1)
- TR&Ds (min. 3)
- DBPs (1)
- Collaboration & Service (1)
- Training (1)
- Dissemination (1)
- Administration & Management (1)

Comparison of 2011 and 2016 P41 proposal formats

<table>
<thead>
<tr>
<th>Section</th>
<th>2011 instructions</th>
<th>2016 instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>12 pages</td>
<td>12 pages + 1 page S.A.</td>
</tr>
<tr>
<td>TR&amp;Ds</td>
<td>30 pages per TR&amp;D</td>
<td>12 pages + 1 page S.A. per TR&amp;D</td>
</tr>
<tr>
<td>DBPs</td>
<td>6 pages per DBP</td>
<td>12 pages + 1 page S.A. for all DBPs tog.</td>
</tr>
<tr>
<td>Collaboration &amp; Service</td>
<td>30 pages</td>
<td>12 pages + 1 page S.A.</td>
</tr>
<tr>
<td>Training</td>
<td>6 pages</td>
<td>6 pages + 1 page S.A.</td>
</tr>
<tr>
<td>Dissemination</td>
<td>6 pages</td>
<td>6 pages + 1 page S.A.</td>
</tr>
<tr>
<td>Administration</td>
<td>6 pages</td>
<td>6 pages + 1 page S.A.</td>
</tr>
</tbody>
</table>

Overall Component

- Cover Letter
- Project Summary / Abstract (max 30 lines of text)
- Project Narrative (2-3 sentences)
- Biographical Sketch for PI
- Specific Aims (1 page) (specific aims are separate from the 12 pages for the research strategy)
  - "Describe the overall aims of the proposed Resource."
- Research Strategy (12 pages)
  - "The narrative portion of the application should begin with an overview of the proposed BTRR. This section need not adhere to a specific outline but should address the following topics: the rationale for the Resource, discussion of the technological theme(s) at its heart, and its anticipated impact on biomedical research; an overview of the Resource’s components, including the Technology Research and Development (TR&D) projects, the Driving Biomedical Projects (DBPs), Collaboration and Service (C&S), Training, and Dissemination; and their integration to form a coherent whole."
  - "The Overall section should describe the complementary nature of the TR&D projects. It should also describe the overall themes of the DBPs, the motivation for selection of the projects included in the application, and the expected interplay among the TR&D projects and DBPs. This section should describe the general approach to C&S in the proposed BTRR, and the relationship of the C&S activities to the technology development mission of the Resource. Similarly, this section should
also describe the general approach to the Training and Dissemination components of the BTRR, and their relationship to the Resource as a whole.

- **Progress Report** (this is included in the 12 pages of the Research Strategy)
  - "Include a progress report describing the major advances and national impact achieved in the previous performance period."
  - "Progress in each of the component areas (TR&D, DBPs, C&S, Training and Dissemination) should be included in those components when appropriate."

- **Annotated Timeline** (this is included in the 12 pages of the Research Strategy)
  - "Include an annotated timeline that describes how the various projects relate to one another and the target dates for availability of technologies"
  - "This is intended only to describe the research plan and should not be interpreted by applicants or reviewers as a series of milestones."

- **Bibliography** (no page limit)
- **Facilities and Other Resources** (no page limit)
- **Equipment** (no page limit)
- **Progress Report Publication List** (no page limit)
  - "For renewal applications, the title and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the BTRR since it was last reviewed competitively must be included in the publication list included as part of the progress report."
  - "Publications that explicitly acknowledge support from this BTRR award should be distinguished from those that do not."

- **Letters of Support** (no limit)
  - "Include letters of support from investigators specifically collaborating with Resource investigators on any TR&D, DBP, C&S, or other projects."
  - "The purpose of letters of support is to describe the nature of the collaborative relationship, including its scope, and any special circumstances (e.g. materials or technology transfer, or intellectual property agreements)."

- **Resource Sharing Plan** (no page limit)
- **Budget**
  - "The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover."
  - "A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission."

- **Appendices (if applicable)**

**TR&D 1** (minimum of 3 TR&Ds required - each TR&D gets a separate core)

- **Project Summary / Abstract** (max 30 lines of text)
- (no Project Narrative as specified in FOA)
- **Biographical Sketches for Key Personnel relevant to this TR&D component**
- **Specific Aims** (1 page) (specific aims are separate from the 12 pages for the research strategy)
  - "Describe the specific aims of this specific Technology Research and Development Project."
- **Research Strategy** (12 pages)
  - "Each TR&D project Research Strategy section should address the background and rationale for the project, its significance, specific aims, and methods."
  - "All related DBP(s) should be listed for each TR&D project."
"TR&D projects should be responsive to the emerging needs of the biomedical research community."

"To encourage synergistic interaction, Driving Biomedical Projects (DBPs) serving as test beds for TR&D projects must be included. The relationship between TR&D projects and DBPs must be described explicitly for each TR&D project."

"It is expected that the TR&D projects will be related to each other and that the description of these projects will show synergy among them. The application should describe the relationship and complementarity among these projects, and their support of the overall goals of the BTRR."

"Elements of high risk (and potentially high payoff) are appropriate in the TR&D projects."

"Present alternative approaches to solving technological problems in the event that their main conceptual thrust should prove unfeasible."

"For renewal applications, new activities should be specifically identified."

"The continued development of innovative technology and the steady infusion of new areas of technological R&D are important considerations in reviewing renewal applications."

"Long-term support of a Resource depends strongly on demonstrated commitment to the introduction and application of new technologies and to serving biomedical investigators on a national basis."

- **Bibliography** (no page limit)
- **Budget**
- **Budget Justification** (no page limit)
- **Appendices (if applicable)**

**TR&D 2** (same structure as above)

**TR&D 3** (same structure as above)

**Driving Biomedical Projects** (there is only **ONE** DBP core for **ALL** the DBPs)

- **Project Summary / Abstract** (max 30 lines of text)
- (no Project Narrative as specified in FOA)
- **Biosketches for relevant Key Personnel**
- **Specific Aims (1 page)** (specific aims are separate from the 12 pages for the research strategy)
  - "Describe the aims addressed by inclusion of the Driving Biomedical Projects and their rationale."
- **Research Strategy:** (12 pages)
  - **Overview**
  - **(up to 10 DPBs described in detail)**
    - "A Driving Biomedical Project (DBP) should either: (a) present an opportunity to clearly demonstrate the significant impact of technologies under development in the Resource, or (b) represent a research problem hindered by a significant technical challenge that motivates the Resource's technology development, driving it forward."
  - "There is no upper limit to the number of DBPs that can be proposed."
  - "A representative selection of no more than ten proposed DBPs may be presented in detail."
  - "In the case of a renewal, these may include ongoing projects carried over from the previous competing segment."
  - "This component of a BTRR is a set of biomedical research projects that will be pursued by the Resource in collaboration with outside investigators. The overarching purpose of a collection of DBPs is to provide a context for the demonstration, integration, and refinement of Resource technologies."
"DBPs should be selected on the basis of both their potential for significant biomedical impact and their appropriateness as test beds for new technology."

"The selected biomedical research projects should present substantial technical challenges providing the opportunity for an iterative push-pull relationship to develop between Technology R&D and the DBPs, advancing both. Such efforts are expected to lead to joint publications."

"The DBPs served by the new technology should be broad in scope and involve a variety of biomedical research areas."

"Because BTRRs must demonstrate a national scope and impact, applicants are encouraged to seek out a significant number of DBPs outside their home institutions. ... In exceptional cases where a majority of DBPs are local, the applicant should provide justification and rationalize this with respect to the overall mission to achieve a national impact."

"Project descriptions should focus on their role as a test bed and/or driver for technology development, and the relationship of the DBP to the corresponding TR&D project(s)."

"The biomedical aspects of the project should be described only in sufficient detail to allow the reader to understand the significance of the project and how it will benefit from access to the technologies being developed in the Resource."

"Because this program does not provide direct support for the collaborating biomedical investigator, the description in the BTRR application should not focus on the approach or feasibility of that aspect of the proposed DBP."

"The description of each DBP should follow the following outline:

- Collaborating investigator’s name
- Institution of the collaborating investigator
- Funding status of the project
- Explanation of the driving relationship between the DBP and specific TR&D project(s).
- Innovation: Describe the technological innovations that will result from the DBP interaction with Resource TR&D and their implications beyond this project.
- Methods: Describe methods and procedures to be used, emphasizing the relationship between the personnel and technologies of the DBP and those of the BTRR; provide rationale for the proposed approach to the problem and impact of the expertise of the BTRR investigators and technology on the project."

- Bibliography (no page limit)
- Budget
- Budget Justification (no page limit)
- Appendices (if applicable)
- Other Attachments: DPB core has one additional required attachment
  - Table of DBPs
    - "The DBP section of the application must, as an attachment, include a table of every DBP being pursued."
    - "For renewal applications, DBPs from the previous funding period that are not continued in the renewal application should also be included."
    - "Each entry in the table should include:
      - The name of the primary collaborating investigator for the DBP
      - The institution of the PD/PI
      - The title of the project
      - The name(s) of BTRR personnel involved with the project
      - The TR&D project(s) with which the DBP interacts
      - A concise statement of how the DBP acts as a driver or test bed for the BTRR’s TR&D program
      - Start and end (if applicable) dates for the DBP
      - The external funding status of the project
      - For renewal applications only: publications that have resulted from the DBP"
Collaboration and Service

- **Project Summary / Abstract (max 30 lines of text)**
- **(no Project Narrative as specified in FOA)**
- **Biosketches of relevant Key Personnel**
- **Specific Aims (1 page)** (specific aims are separate from the 12 pages for the research strategy)
  - "Describe the aims of the Collaboration and Service component of the proposed center."
- **Research Strategy: (12 pages)**
  - "This component of the application should begin with a description of the overall goals of the C&S functions of the Resource."
  - "The Resource’s approach to, and plans for, Collaboration and Service activities should be described, as well as the manner in which service will be provided."
  - "That [approach and plans for C&S] should be the focus of this section of the application, rather than concentrating solely on the scientific aspects of the C&S projects that are included."
  - "This section should make clear the impact of the C&S functions of the Resource on the research community."
  - "The BTRR should strive to conduct the majority of its C&S projects with researchers who are outside the applicant institution, broadening the scope of the Resource’s impact as technologies mature."
  - "The primary purpose of this component of a BTRR is to provide access to the advanced technologies created in the Resource."
  - "A BTRR is expected to actively engage the research community to collaborate and provide broad access to Resource capabilities."
  - "[C&S] projects may make extensive use of Resource technologies and expertise, but are distinguished from DBPs in that they do not serve as primary drivers or as test beds for the new technologies in the early stages of development. C&S projects generally exploit the more mature capabilities of the Resource."
- **Bibliography** (no page limit)
- **Budget**
- **Budget Justification** (no page limit)
- **Appendices (if applicable)**
- **Other Attachments: C&S core has two additional required attachments**
  - **Table of Collaboration and Service Projects**
    - "There is no limit to the number of C&S projects that may be proposed. A table of all Collaboration and Service projects should be provided."
    - "For renewal applications, C&S projects from the previous funding period should be included in the table following the listing of current and proposed activities."
    - "Each entry in the table should include:
      - The collaborating investigator for the Collaboration/Service project
      - The institution of the PD/PI
      - The title of the project
      - The name(s) of Resource personnel involved with the project
      - Start and finish dates for the project
      - The external funding status of the project
      - Publications that have resulted from the project"
  - **Representative Sample of Collaboration and Service Projects (10 pages max)**
"A representative sample of no more than 10 C&S projects should be presented in greater detail."
"Each project should be described in sufficient detail to allow the evaluation of the need for the BTRR technologies in the proposed project."
"The description of each C&S project should be limited to no more than one page, and include the following:
- Collaborating investigator’s name
- Institution of the collaborating investigator
- Funding status of the project including
  - Grant number
- Project period dates
- Source of funds
- The principal investigator s name if it is different from the collaborating investigator.
- Description of the biomedical research problem that will form the basis of the C&S project.
- Description of the methods and procedures to be used, emphasizing the relationship between the personnel and technologies of the collaborator and those of the BTRR. Provide the rationale for the proposed approach to the problem and impact of the expertise of the BTRR investigators and technology on the project."

Training
- Project Summary / Abstract (max 30 lines of text)
- (no Project Narrative as specified in FOA)
- Biosketches of relevant Key Personnel
- Specific Aims (1 page) (specific aims are separate from the 6 pages for the research strategy)
  - "Describe the aims of the Training component of the proposed Resource."
- Research Strategy: (6 pages)
  - "The overall goal of the Training component of a BTRR is expected to be twofold: to improve the general understanding of the Resource’s technologies in the appropriate research communities and to create a cadre of biomedical researchers trained in the technology so that they can effectively apply it in their own research."
  - "Well-defined plans for training should be presented in the application."
  - "A BTRR must allocate sufficient resources for training both specialists and non-specialists to make the best possible use of the new tools."
  - "Training should simply be well thought out, accessible, and effective."
  - "The Resource’s Training component should aim to build technical competence in the broader community of researchers."
  - "For renewal applications, a progress report on Training activities from the previous project period should be included in this section."
- Bibliography (no page limit)
- Budget
- Budget Justification (no page limit)
- Appendices (if applicable)

Dissemination
- Project Summary / Abstract (max 30 lines of text)
• (no Project Narrative as specified in FOA)
• Biosketches of relevant Key Personnel
• Specific Aims (1 page) (specific aims are separate from the 6 pages for the research strategy)
  o "Describe the aims of the Dissemination component of the proposed center."
• Research Strategy: (6 pages)
  o "Dissemination activities should have two overall objectives: informing the scientific community about the technical capabilities and accomplishments of a BTRR, as well as promoting and enabling the broader use of technologies."
  o "A robust web presence is required for every BTRR."
  o "In Resources that are developing software, emphasis should be placed on producing portable, well-documented, user-friendly software, making it readily available to the user community and providing user support."
  o "Plans for tracking the demand for and utilization of Resource resources should be described."
  o "A progress report of Dissemination activities from the previous project period should be included in this section for renewal applications."
• Bibliography (no page limit)
• Budget
• Budget Justification (no page limit)
• Appendices (if applicable)

Administration and Management
• Project Summary / Abstract (max 30 lines of text)
• (no Project Narrative as specified in FOA)
• Biosketches of relevant Key Personnel
• Specific Aims (1 page) (specific aims are separate from the 6 pages for the research strategy)
  o "Describe the aims of the Administration and Management functions of the proposed center."
• Research Strategy: (6 pages)
  o "This section should be broken down into: organizational structure and staff responsibilities, Resource operating procedures, and the External Advisory Committee (EAC)."
  o Organizational Structure and Staff Responsibilities
    ▪ "Describe the organizational structure of the BTRR."
    ▪ "Indicate the relationship of the Resource to the administrative structure of the grantee institution."
    ▪ "Describe how the PD/PI and the proposed Resource staff will be organized with respect to the Resource components: each of the TR&D projects, DBPs, C&S, Training, Dissemination, and general Resource Administration."
    ▪ "Describe the scientific and technical expertise of the staff that will operate, maintain, and develop the Resource capabilities specifying their distribution of effort across their areas of responsibility."
    ▪ "Include a table specifying distribution of personnel effort across these domains."
    ▪ "The organizational structure of the Resource, particularly the TR&D projects, should be carefully justified."
  o Resource Operating Procedure:
    ▪ "Describe operating procedures and policies planned for the Resource."
    ▪ "Include criteria and mechanisms to review requests for the use of the equipment and facilities in the Resource and to schedule that use once it has been approved."
"Describe criteria and process for prioritizing and selecting DBPs as well as Collaboration and Service projects."
"Include instructions on how users are to acknowledge support provided by the Resource in any resulting publications."

- **External Advisory Committee:**
  - "In this section of the application, the role of the EAC should be described."
  - "The committee's role in advising on instrument purchases, reviewing collaborative and service projects for merit and appropriateness, allocating instrument time, and on the research plans for the BTRR should be presented."
  - "In renewal applications, names of current committee members and a brief description of their qualifications should be included."
  - "A local executive committee or other local committee appointed to deal with specialized topics may be proposed as an adjunct to the EAC."
  - "The function and meeting schedule for these committees should be described in this section."

- **Bibliography** (no page limit)
- **Budget**
- **Budget Justification** (no page limit)
- **Appendix:** the Admin core asks for the following in an appendix:
  - **Sample forms for collaborators and/or users**
  - "Include samples of any forms to be filled out by collaborators and users."