

Chapter 6 Center Administration

As soon as you are notified of an AP4 center grant award, you need to finalize your center's organizational structure. Although you have already selected a center director, for example, because this is required to receive an AP4 center grant, the roles and responsibilities of this individual and other center personnel should be spelled out. You must also finalize all formal arrangements with partners to begin center research projects. This chapter provides an overview of the roles of center players, relationships between the center and its host institution and partners, and how to document these relationships.

Center Personnel

Figure 6-1: Center director's responsibilities*

- Manages center operations, including:
 - Organizing semiannual meetings.
 - Overseeing the maintenance of center databases, records, and publications.
 - Overseeing the budget.
 - Preparing the center's annual report.
 - Completing surveys and reports required by the NCI and the university or nonprofit's administration.
- Manages center's research program, including:
 - Preparing and implementing the center's strategic and action plans.
 - Monitoring and overseeing research projects.
- Manages center's external operations, including:
 - Coordinating recruitment of partners.
 - Facilitating technology transfer to partners.
 - Preparing and/or approving public relations materials.
- Oversees communication and coordination among all center operations.
- Responds to steering committee recommendations.

*Adapted from: "Sample Job Description—Center Director," in Gray and Walters, p. 67.

Center Director

The center director is responsible for managing all center operations, including the research program and recruitment of partners. Ideally, the center director is a full-time position because managing a center is very time consuming. If the budget does not permit a full-time center director, the center should consider hiring a professional-level administrative assistant. Alternatively, the director may delegate some responsibilities to other investigators.

Administrative Assistant

The administrative assistant is key to helping

the center director manage the workload and, ultimately, to the center's success. The responsibilities of this individual depend on the salary and grade level permitted by the budget.

Depending on the budget and on center needs, the administrative assistant may be responsible for basic secretarial and clerical tasks, managing the center budget, and/or overseeing many day-to-day operations. The administrative assistant may also help recruit partners.

Evaluator

All AP4 centers must have an evaluator who collects information on center activities through observation and surveys of steering committee members and investigators (see Chapter 9 for details on the role of the center evaluator). The evaluator provides objective feedback on center activities and results to help improve operations and prevent problems. This individual may be a faculty member of the center's host university or nonprofit, but is typically in a different department than the center director.

Because the evaluator is a skilled, objective observer, he or she may also serve as a liaison between the center and the steering committee. In addition, the evaluator may help resolve center problems.

Figure 6-2: Responsibilities of the center evaluator

- Submitting reports to the center director and steering committee describing the center's progress.
- Administering and analyzing the results of the annual center survey to steering committee members and investigators.
- Conducting exit interviews when partners leave the center.
- Attending the center's semiannual research review meetings and other important internal meetings.

Research Personnel

The successful AP4 center offers partners a strong group of multidisciplinary projects that are relevant to the interests and needs of each partner, benefit from cross-fertilization, and show synergy. To accomplish this, center research may be organized within research areas and by research project.

Research Area Coordinators

One investigator should serve as coordinator for each center research area. This individual is responsible for encouraging communication and collaboration between projects, facilitating the development of new projects in the research area, and discussing the area's current and proposed research with the steering committee and prospective partners. The coordinator may also share some of the center director's responsibilities.

Figure 6-3: Responsibilities of the PI

- Making technical decisions consistent with the research plan.
- Supervising or carrying out research.
- Managing the project budget.
- Preparing reports.
- Communicating and cooperating with partners at every stage, from proposal development to project completion and planning for clinical trials.
- Communicating and coordinating with other investigators in the program area and the center.
- Assisting the director with administrative duties, such as recruitment and retention.

Teams

AP4 research projects are typically conducted by small teams of researchers, including a principal investigator (PI). PIs are usually tenure-track faculty members or postdoctoral research associates who oversee the research. Day-to-day research tasks are typically

conducted by graduate students, and often form the basis of the student's thesis or dissertation.

Although AP4 center projects may be staffed in the same way as other grant-funded research projects at the institution, they are developed using a very different process:

1. As discussed in Chapter 7, ideas for research projects are developed after several interactions among investigators, partners, and other investigators, rather than by a single investigator.
2. Teams that conduct AP4 research projects are multidisciplinary because this is a requirement of the AP4 center program.
3. Each project undergoes review by the partners and other investigators on a semiannual or even an ongoing basis, and refinements are made as necessary.

The process used to develop and oversee AP4 center projects differs from the way in which other research projects are developed and managed, because the goal of each AP4 center project is the discovery and development of a new cancer intervention.

Steering Committee

The AP4 center must conduct research that is relevant to its biotechnology and pharmaceutical company, academic institution, nonprofit organization, and non-NCI government agency partners. The challenge to accomplishing this is that the center is a consortium with several partners, not just one, and is sponsored by one or more government agencies. Balancing the needs and interests of each stakeholder is challenging. Therefore, the steering committee may be the most critical and challenging element of a center’s administrative structure.

The steering committee consists of one voting representative from each partner organization plus the nonvoting NCI representative. The steering committee meets twice a year and makes decisions regarding policy and research.

Figure 6-4: Steering committee member responsibilities

- Representing the interests of their organizations within the AP4 center.
- Reviewing and evaluating proposed and existing research projects.
- Terminating research projects when appropriate.
- Voting on issues concerning center policies and its research program.

Because each partner organization must periodically review the value of continuing to serve as a center partner, the representative who serves on the steering committee

should support the organization’s partnership with the center.

Steering committee members should select a chairperson, usually the AP4 center director, to run the executive sessions of semiannual meetings and represent steering committee interests between meetings. The chair can also help recruit new partners. Chairs can be elected or periodically rotate.

It can be difficult for each steering committee member to keep up with all AP4 center research projects. To help with this responsibility, the center may allow each partner to assign bench-level scientists or other members of their organizations to attend steering committee meetings as monitors. Monitors can track certain projects and report on them to the steering committee member. They may also be assigned to particular projects as project mentors, helping guide projects and assisting with technology transfer upon project completion. A monitor’s familiarity with the center and its research can make him or her an effective replacement for a departing

steering committee member. Non-NCI government agencies that join the center as partners have the same rights as all other partners.

Governance, Policies, and Procedures

Having a formal governance structure with explicit policies and procedures helps make an AP4 center predictable and reliable. However, such a structure can also make the center overly rigid and inflexible. Balancing the need for reliability with the importance of flexibility requires different levels of formalization for center tasks. For example, the center's relationship with its home institution is likely to be formal. Relationships with partners regarding certain issues, such as intellectual property, should also be formal. But the center director's administrative relationships with investigators and with partners concerning the center's research may benefit from less formality.

Relationship Between the AP4 Center and the University or Nonprofit

Universities and large nonprofit organizations are often structured in a very formal way, although the degree and form of this structure varies by institution. For example, state and land-grant universities typically have more formal structures than private universities and may have rules on extension activities that private universities do not typically address. The degree of formality at each AP4 center should be in line with that of its host institution.

The AP4 center is unlikely to have control over policies and procedures of its host institution concerning personnel appointments, budget, equipment and facilities ownership, or intellectual property. As employees of the host institution, individual investigators who conduct AP4 center research must also abide by the rules governing their appointments. However, investigators and students conducting AP4 center research may have requirements for their activities that cannot be met under current institutional policies. In such cases, the AP4 center may need to negotiate with institutional officials to change certain regulations, such as those concerning publication delays or cost sharing.

The center is more likely to successfully negotiate changes to institutional policy if it reports to someone at a high level in the institution's hierarchy. NCI and other government agency guidelines can be used to support arguments for policy changes.

Figure 6-5: Issues to address in the membership agreement*

Parties: Which legal entities will sign the agreement?

Purpose: Statement of the center's purpose (vision and mission statements).

Center participants: Include the NCI and anyone else involved in the center.

Requirements for partners: Criteria that must be met by an organization to become a center partner.

Partner fees: How much each partner must contribute to the center, manner of payment, and payment schedule.

Length and terms of commitment: How long the agreement will be in force and conditions for terminating the agreement.

Organization and operation: The agreement may refer to the policies and procedures manual for this information.

Steering committee role: Role, responsibilities, and rights of steering committee members (details should be covered in the policies and procedures manual).

Publication policy: Procedures for reviewing publications and regulations concerning when and under what circumstances publication delays are permissible.

Intellectual property policy: Ownership and rights to intellectual property discovered through AP4 center research.

Indemnification: Each party holds the other party harmless.

Official signatures: From designated representatives of the AP4 center and the partner.

*Adapted from: "Elements of Typical Center Membership Agreement," in Gray and Walters, p. 75.

***Relationship
Between the Center
and the Steering
Committee***

Because the relationship between an AP4 center and its partners involves such legally binding transactions as exchanging money, completing research projects, hiring staff, committing resources to projects, and creating and protecting intellectual property, these aspects of this relationship need to be addressed in a formal, legally binding way. A list of issues that may be covered in a contract between an AP4 center and its partners is provided in Appendix 6-1. These issues are typically addressed in the membership

agreement and the center's policies and procedures manual.

Centers must be careful to avoid arbitrarily limiting or restricting membership, even though antitrust concerns related to center membership were minimized by the passage of the National Cooperative Research Act of 1985. Centers may limit membership under certain circumstances. For example, they can require that any pharmaceutical or biotechnology company that becomes a partner have significant research and development or manufacturing operations in the United States.

Membership agreement: The membership agreement (see Appendix 3-2 for a sample agreement) is a formal legal contract between the AP4 center's home institution and one of its partners. The center director must develop a membership agreement that covers all necessary issues and is acceptable to all partners. This can be very time consuming.

Each AP4 center may determine the duration of its membership agreements, but these are typically for 3 years. Membership agreements usually include a cancellation provision requiring 90 days notice. This allows companies or organizations operating under fiscal uncertainty to make a commitment to the center that they intend to keep for several years, but permits termination of that commitment if the circumstances of the companies or organizations change. The requirement that partners give notice when they plan to terminate their agreements gives the center some warning if its budget is about to change and offers an opportunity to attract a new partner to fill the disciplinary and budget gap.

Membership fees: To be a partner in an AP4 center, a biotechnology or pharmaceutical company, nonprofit organization, academic institution, or non-NCI government agency must pay a fixed annual membership fee. However, AP4 centers may offer different privileges in exchange for different fee levels. Centers may also permit partners to provide certain services, such as offering compounds for testing in lieu of some or all of the membership fees (although these services cannot be counted as part of the required membership fee total). According to NCI requirements for AP4 center grant recipients, membership fees must total at least \$300,000 a year (see Chapter 1 for details on NCI funding requirements). Centers must set initial membership fees carefully because raising them after contracts are signed can be difficult. Centers may choose to incorporate periodic fee increases into membership agreements to avoid this difficulty.

Publication delays: Negotiations over publication delays may require a great deal of time and effort. An AP4 center might allow partners to request a publication delay of 3–12 months to allow it to file patent applications. If the delayed publication affects a student's thesis or dissertation, the student is allowed to complete the degree but the thesis or dissertation is withheld from the library for a limited period.

Policies and procedures manual: Internal operations of AP4 centers may be less formal than other aspects of center administration because centers tend to be relatively small and have highly professional personnel. But to ensure that the AP4 center is consistent and predictable in all its commitments and transactions, some functions and activities should be laid out formally. The challenge is laying out—typically in a policies and procedures manual—which aspects of the center's internal administration need to be formalized and which do not.

Policies are general guidelines; procedures are sequential steps that must be taken to accomplish a task. Both are important for standardizing organizational behavior. They are most appropriate for activities that can and should be routine and as predictable as possible, and activities for which a way that is known to be effective (a best practice) exists. Although many institutions believe that their policies and procedures are understood, the best way to ensure this is to document them. AP4 center members should consider describing key policies and procedures in a manual that is distributed to all center personnel, including the director, evaluator, administrative assistant, PIs, other investigators, and partners.

Figure 6-6: Issues to address in the center’s policies and procedures manual*

Organizational issues:

- The office within its home institution to which the center reports.
- Who has the authority for what types of decisions?
- Descriptions of:
 - Committees.
 - Roles of personnel.
 - Research areas.

Routine institutional procedures (covered by the host institution’s regulations):

- Travel.
- Changes in budgets.
- Acquiring equipment.
- Approval of release time.

Categories of membership:

- Rights and privileges of different membership levels.

Operating procedures:

- Schedule.
- Reports and record keeping.
- Meetings (semiannual, strategic planning).
- Types of research projects and proposal submission formats.
- Mechanisms for technology transfer and publications.
- Financial guidelines, fees, and rights related to equipment use.

Appendices:

- Organizational chart.
- Description of center research areas.
- Calendar of regular events.

*Adapted from: “Elements of Typical Center Bylaws,” in Gray and Walters, p. 77.

AP4 centers may choose to describe all organizational chart functions in their policies and procedures manual, as well as details of such issues as:

- Membership rights and privileges.
- Types of support that partners can provide for center research.
- Schedule of steering committee meetings.
- How amendments may be made to policies and to the membership agreement.

Roles and

responsibilities of center personnel should be described formally, because active participation in center tasks by investigators and partners is critical to the center’s success. Because these individuals are so busy and spend much of their time on noncenter business, it is easy for them to forget their responsibilities to the center. Written role descriptions, such as those provided in Figures 6-1, 6-2, 6-3, and 6-4 in this chapter, can help reinforce responsibilities when center personnel neglect them.

The manual should be written clearly and succinctly, and its organization should make it easy to follow. Every issue discussed in the manual should be critical to center efficiency and effectiveness, and the contents should avoid bureaucracy as much as possible. The policies and procedures manual may be published in a notebook. Alternatively or in addition, the manual may be available on a website that can be easily updated.

Conclusion

One of the most important rules for organizational design is that the structure be tailored to the organization’s circumstances. Although AP4 centers are required to have a director and a

steering committee composed of representatives of the NCI and partner organizations that pay an annual membership fee, centers do have a great deal of operational discretion.

Decisions about roles and responsibilities of center personnel, relationships between the center and the institutions and people it works with, and internal policies and procedures should be based on the center environment and the needs and goals outlined in its strategic plan. Some aspects of center structure should be formally documented in some detail; others may be informally organized. Ultimately, designing a center's structure may require some trial and error, but careful planning and identifying in advance issues that are likely to arise and will minimize the need for mid-stream corrections.

Reference

Gray D.O., Walters S.G. *Managing the Industry/University Cooperative Research Center: A Guide for Directors and Other Stakeholders*. Columbus, OH: Battelle Press, 1998.

**Appendix 6-1: Issues to address in agreements
between the AP4 center host institution and its partners.***

1. Number of research projects.
2. Administrative structure of research projects.
3. Time period of membership agreement.
4. Provision for continuing membership agreement.
5. Methods for selecting and approving projects.
6. Provisions for researcher interaction.
7. Formula for adjusting partner funding for inflation or deflation.
8. Publication restrictions on center researchers.
9. Ownership of patents and technical developments.
10. Protecting the host institution's proprietary information.
11. Protecting a partner's proprietary information.
12. Partner monitoring of research for patentable and novel inventions.
13. Prompt partner reporting of and filing for patentability.
14. Prompt partner reporting of possible results.
15. Who files for U.S. patents?
16. Who files for foreign patents?
17. Who pays the cost of patent filings and prosecution?
18. Is prosecution beyond patent office rejection required?
19. May the host institution use independent patent counsel?
20. Royalty to host institution adjusted, based on contribution of partner.
21. Host institution to provide records for patent application.
22. Host institution to assure title to all technical developments.
23. Host institution waiver of patent claim against partner.
24. Individual inventor waiver of patent claim against partner.
25. Indemnification clause for claims arising from patent.
26. Host institution agreement to grant licenses to partner.
27. Exclusive license on patentable inventions to partner.
28. Licensing of nonpatentable technical developments to partner.
29. Licensing of nonprogram patents by host institution to partner.
30. Licensing requirements specified in membership agreement.
31. Reasonable attempt to be made by partner to market research results.
32. Nonexclusive sublicense in lieu of reasonable attempt by partner to market results.
33. Partner requirement to submit marketability schedule during exclusive license period.
34. Partner's right to sublicense.
35. Partner's royalty payments to host institution.
36. Arbitration in lieu of royalty agreement.
37. Law to be applied to agreement.
38. Action to be taken in the event of infringement.
39. Who may sue the infringer?
40. Infringement suit cost recovery.
41. Host institution right of approval prior to partner bringing suit.
42. Host institution assignment of title to partner bringing suit.

43. Right of host institution to license elsewhere if partner does not elect to license.
44. Terminating agreement for breach or default.
45. Terminating for insolvency of a party.
46. Survival of patent and license rights upon agreement termination.
47. Host institution warrant of sufficient insurance and workers' compensation for employees.
48. Partner to hold host institution harmless for partner's employees injured at the host institution.
49. Assignment of rights and obligations by either party.
50. Use of host institution or partner name in publicity.
51. Research participant nondisclosure agreement.
52. Distributing the research center product by host institution for research only.
53. Providing for dispute resolution.

*Adapted from: "Issues Addressed in Typical Industry-University Legal Agreement," in Gray and Walters, pp. 81-82.