

## **QUESTIONS TO CONSIDER FOR COLLABORATIVE RESEARCH**

### **Scientific Goals:**

- What is the goal of the collaboration?
  - What scientific issues will your collaboration address?
  - What is the relevance of your goals to local, national, and international health issues?
  - What are the anticipated outcomes or products of your research collaboration?
- What are the expected contributions of each participant?

### **Financial Obligations:**

- Will the collaborators transfer funds to support the project such that a Cooperative Research and Development Agreement (CRADA) is appropriate?
- How will you determine what equipment is and supplies will to purchase and who will purchase them?
- Have you fully disclosed to other collaborators your sources of financial support?

### **Research Agenda/Decision-Making:**

- How will the Principal Investigators decide the initial scope and direction of the research project?
- How will you decide who will write the initial research implementation plan?
- How will you redirect the research agenda as new discoveries are made?
- Who will be responsible for writing interim and final reports which set forth technical progress made, identify problems encountered, and establish goals and objectives requiring further effort?
  - How will you approach modifying the research plan (e.g., by mutual written consent of the Principle Investigators)?
- How will you negotiate the development of new collaborations?

### **Project Duration:**

- What is the estimated duration of the collaboration?
  - What are the contemplated time periods for various phases of the project?
- How will you decide when to terminate the collaboration?
- If the collaboration is mutually or unilaterally terminated prior to its expiration, how will the collaborators handle issues such as staffing commitments, equipment access, and data access?

### **Communications:**

- How will you approach establishing effective communication with clear assumptions, including access to data, regularly scheduled meetings, and an identified flow of information?

- Who will convene regularly scheduled project team meetings?
  - How often will meetings occur?
  - How will you ensure full representation and participation in meetings?
- How often will the Principal Investigators meet to brainstorm potential risks, develop action plans, assign individual responsibilities, determine critical dates, and review the status of disputed issues?
- What needs to be in place to regularly evaluate the effectiveness of the partnership?
- When will the team reconvene to sustain the collaboration, especially when major shifts have occurred in the scientific direction or in staffing?

**Dispute Resolution:**

- What is the level of commitment to engage in collaborative problem solving, before resorting to formal processes in resolving disputes?
- What are the agreed upon processes for dispute resolution?
- What built-in informal conflict resolution mechanisms, such as alternative dispute resolution (ADR), are available?
- How will the collaborators ensure continued performance of obligations during the resolution of a dispute?

**Authorship and Acknowledgement:**

- What is your process and criteria for assigning authorship and credit for the research?
  - Are the policies on co-authorships on publications clear to all participants?
  - Do these criteria follow established guidelines (e.g., NIH Guidelines for the Conduct of Research)?
  - How will collaborators negotiate differences in evaluating different kinds of contributions?
- If collaborating across sectors, what are the restrictions on publication and requirements flowing from legal obligations of the participants?
- How and when should significant accomplishments be recognized?

**Intellectual Property and Patent Applications:**

- What are the legal responsibilities of each individual with respect to the products of the joint research? Have you discussed your individual responsibilities?
  - Is each collaborator prepared to meet the requirements of his or her own institution?
  - How are invention disclosures and patent applications processed at each institution?
  - What is your institution's policy on commercial licensing?

**Legal Obligations:**

- What special obligations of confidentiality and release of information apply to each collaborator?

- How will you articulate to each participant the legal obligations regarding intellectual property, confidentiality, establishing new collaborations, and regulatory compliance?

#### **Accountability:**

- How will responsibilities be allocated among collaborators?
- To whom are you accountable?
- What additional participants figure into the collaboration (e.g., lawyers, patent officers, marketing officers, sponsored research officials, etc.)?
- What is your responsibility to:
  - The public?
  - National Institutes of Health?
  - Other Investigators?
  - Trainees?
  - Regulatory agencies?
  - Other research institutions?
  - Private industry?
  - The larger scientific community?

#### **Data Management**

- What are the standard operating procedures for data management in each researcher's environment?
- What are the policies on data recording, retention, access, and ownership?
  - What are the data?
  - Who owns the data?
  - Who controls access to the data?
  - Who is responsible maintenance and storage of the data?
  - What becomes of the data when a PI moves to another institution or leaves the project?
  - How long should laboratory records be stored?
  - What principles apply to preservation of original data?
  - What general guidelines apply to manipulation of original data (Meyer, Lab Management Conference, Tucson, AZ, 1998)
  - What general guidelines apply to dissemination of data (e.g., for regulatory filing)?
- How will you handle sharing data that is generated or published prior to the collaboration?
- How will you reconcile differences in traditional experimental methods and procedures across specialties and subspecialties?

#### **Sharing Material and Resources:**

- How will the collaborators ensure equal access to research materials?
- Under what conditions will a Material Transfer Agreement (MTA) be needed?
- Who will be responsible for maintenance of shared equipment and costs of transportation for equipment and materials?

**Quality Assurance:**

- How will the collaborators develop and maintain an awareness of safety—daily and throughout the project?
- How will you deal with allegations of scientific misconduct?
- What are the implications for or effects on all members of the joint effort if one team member fails to comply with applicable regulations?
- *Experiments, analysis and reporting*

**Staffing:**

- How will the collaborators decide the staffing needs of the project?
- What will be the working arrangements between and among scientists, trainees, and support staff?
- Who will be responsible for recruiting, hiring, terminating, etc.?
- How will the Principal Investigators plan for team expansion (educating and involving new members)?

**Training and Mentoring:**

- How have you defined trainee's topic of research in context of the larger collaboration?
- Are all trainees and fellows informed about the issues of research ethics and proper procedures for data management?
- How will the collaboration provide practical experience for the trainee?
- What are your expectations about how the collaboration will facilitate scientific ideas, exchange of reagents, development of new collaborations, and exchange of information about job opportunities? What are the trainee's expectations?
- Are you and your project team prepared to deal with diversity issues, including ethnicity, culture, sex, and disability?

**Professional Development:**

- How will your collaboration provide opportunities for career advancement of principle investigators, staff scientists, technicians, fellows, and students?

**Publicity:**

- Are you prepared to discuss the timing of the release of results and its impact on the collaboration?
- What are the outlets for presentation of work?
- How will public presentations be made? By whom?
- What are the agreed upon policies and practices for attributing credit to collaborator's institutions for public presentations and written articles?

(Developed by Howard Gadlin, Office of the Ombudsman, National Institutes of Health.)