

## **Guidance for Reviewers of NCRR Biomedical Technology Research Centers Extracted from PAR-10-225**

### **I. The Purpose of the Biomedical Technology Research Centers Program**

The National Center for Research Resources (NCRR) uses the P41 mechanism to support Biomedical Technology Research Centers (BTRCs) in a variety of areas of biomedical science. BTRCs create critical, often unique, technologies and methods at the forefront of their respective fields, and apply them to a broad range of basic, translational, and clinical research. They also promote the broadest possible use of those technologies through training and dissemination activities.

BTRCs may be developed in a specific, narrow technological area, or they may integrate multiple technologies and methods in order to create transformative approaches to a broad class of research problems. (BTRC and Center are used as synonyms throughout this text.) In either case, a BTRC contains a critical mass of both technological and intellectual resources assembled with the intent of exploiting advances in instrumentation and methodology for biomedical research. These Centers create critical technology and methods at the forefront of their respective fields that are applicable to a wide variety of problems in the biomedical sciences. This is accomplished through a synergistic interaction of technical and biomedical expertise, both within the Centers and through intensive collaborations with other leading laboratories. Ideally, these Centers identify opportunities for transformative technological advances that open new lines of biomedical inquiry. They also should be uniquely positioned to appreciate which biomedical research problems the Resource can solve by the creation of new tools. This intense synergy between technology development and biomedical problem-solving defines the Centers as fundamentally different in character from laboratories engaged in investigator-initiated research or other center-related projects that may have more narrowly defined goals.

A BTRC also has three other critical components that set it apart from other NIH research centers. A BTRC must provide service and training to outside investigators and must disseminate the technology and methods it has developed. These efforts require the commitment of far greater financial and personnel resources to activities outside of their primary focus than is expected for other types of research efforts. Providing other investigators with ready access to Center tools and expertise has a substantial impact on administration and daily operation of the laboratory. Efforts to train the broader scientific community and disseminate technology require a fundamentally outward-looking philosophy that may, on the surface, appear at odds with the competitive nature of modern science. The goal of these efforts is, so far as is possible, to export the technology and expertise of the Center into the community, achieving a broader impact on biomedical research than would be possible through the projects in which the Center can participate directly. Industrial partnerships are not required, but they are welcome when appropriate. Ultimately, this process should aim for the widespread and routine application of the technologies being actively disseminated.

## II. The Components of a BTRC

### Technology Research and Development (TR&D)

The central focus of a Biomedical Technology Research Center should be its Technology Research and Development (TR&D) projects. TR&D projects serve as the foundation for all other Center activities. A BTRC may focus on advancement of a single technology area (e.g., accelerator mass spectrometry, flow cytometry) or the development of an integrated approach to a general class of problems (e.g., proteomics, data visualization). The BTRC technology must be dynamically evolving and an important area for research and development in its own right. The proposed TR&D projects should be at the cutting edge of the technological field, with a goal of increasing its utility in biomedical research.

Regardless of the scope of the TR&D activities undertaken, a BTRC is an inherently multidisciplinary enterprise, requiring a range of specialized expertise to integrate multiple approaches to complex technical and biomedical challenges. For example, these projects may involve development of new or significant modification of existing instruments and associated control and data analysis systems, development of new computer algorithms and related software, new physical or chemical methods to prepare samples for analysis, or development of innovative applications through the integration of existing technologies.

TR&D projects are most effective when they respond to the emerging needs of the biomedical research community. To encourage synergistic interaction, Driving Biomedical Projects (DBPs) serving as test-beds for TR&D must be included in the application (see below). The relationship between TR&D projects and DBPs must be delineated explicitly for each project.

A TR&D project should not focus on data collection. However, in some cases, modest sub-projects designed to generate data for use in technology development or testing may be included as a part of a TR&D project. Such projects should be included only when data to test tools, devices, or software are not available elsewhere. These small data collection components cannot substitute for DBPs.

The TR&D projects must be presented in detail. A separate Research Strategy section should be prepared for each TR&D project and should address the background and rationale for the project, its significance, specific aims, and methods. The facilities available to conduct the project should also be described. The investigator(s) who primarily will be responsible for each project should be listed and their roles described. All related DBP(s) should be listed for each TR&D project. A BTRC is expected to have at least three TR&D projects. The application should describe the relationship between these projects, and their support of the overall goals of the BTRC. 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. An element of high risk (and potentially high payoff) may be present in one or more of the TR&D projects and is appropriate. Investigators should, however, 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 Center depends strongly on commitment to the introduction and application of new technology and to serving biomedical investigators on a national basis.

## **Infrastructure**

In some circumstances, TR&D activities may require substantial investment in the design and development or implementation of technological infrastructure that does not constitute a research challenge in its own right (e.g., a test platform for new instrument components or a laboratory information management system). If necessary, such activities may be included in the application under the Infrastructure heading. In many applications, an Infrastructure section will not be necessary. This section of the application will be reviewed but will not receive a separate score.

Infrastructure projects typically require expertise and intellectual effort from Center investigators, but are not innovative. To be appropriate for the Infrastructure section of the application, a project should be clearly separate from other TR&D projects. Activities such as software development or instrument design and fabrication that are inherent in a TR&D project should be included within that project.

## **Driving Biomedical Projects (DBP)**

This section of the application must describe a set of biomedical research projects not funded through the Center that will benefit from and drive the Center's TR&D projects. Development of new biomedical research tools is most effective when pursued in the context of challenging problems that drive the technology forward. A Driving Biomedical Project (DBP) should be collaborative in nature, with Center personnel working jointly with investigators outside the Center who have expertise in a particular biomedical discipline. 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 that make them difficult to solve with current approaches. Projects should present the opportunity for an iterative push-pull relationship to develop between Technology R&D and the DBPs, advancing both the technology and the biomedical projects. Such efforts are expected to lead to joint publications, and in some cases, patents.

The DBPs served by the new technology should be broad in scope and involve a variety of biomedical research areas. The Resource is expected to be highly responsive to a national user community whose members are primarily grantees and contractors of other NIH programs. It is the applicant's responsibility to identify user communities that both need and will use the research capabilities to be provided by the Center. The scope of a BTRC's portfolio of DBPs should be reflective of the breadth of the technology's potential impact.

Because BTRCs must demonstrate a national scope and impact, applicants are encouraged to seek out a significant number of DBPs outside their home institution. However, it is understood that in many instances there are significant technical and logistical obstacles associated with distant collaborations (e.g., access to patient populations, the need for repeated ready access to biological materials). If 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. DBPs stemming from biomedical research projects that have already been peer-reviewed will be evaluated solely on the basis of how they advance and stimulate BTRC technological development. DBPs that have not been peer-reviewed should include more detail and will be evaluated for scientific merit of the research proposed in addition to their impact on a TR&D project. It is expected that most of the DBPs will have been peer reviewed.

Purely technical collaborations focused on advancing some aspect of TR&D should be included within the relevant TR&D project. Collaborations with biomedical researchers that make use of the technology and expertise of the BTRC but are not intended to serve as a primary driver for technology development should be included in the Collaboration and Service section (see below).

### **Collaboration and Service**

The primary purpose of this component of a BTRC is to provide access to the advanced technologies created in the Center. The concentration of instrumentation, software, methods, and expertise developed in a BTRC represents an important resource for biomedical and clinical researchers. A BTRC is expected to actively engage the research community to collaborate and provide broad access to Center capabilities.

Collaboration and Service (C&S) projects are distinct from DBPs. DBPs are selected because they present challenges that require development of new technological solutions, but C&S projects directly apply more established technologies to biomedical research problems. Nonetheless, Collaboration and Service may involve long-term projects and may require significant creativity and intellectual involvement on the part of both Center staff and the collaborating biomedical or clinical researchers, resulting in joint publications. These projects may make extensive use of Center technologies and expertise, but are distinguished from Driving Biomedical Projects in that they do not serve as primary drivers for the newest technologies still in the early stages of development. C&S projects generally exploit the more mature capabilities of the Center.

Collaboration and Service may also include access to expertise in the Center for consultation and data interpretation, access to software and associated technical support, and access to instrumentation for routine work by outside users. It also includes assistance provided to other laboratories or institutions as they work to build their own independent capabilities.

Collaboration and Service are key elements of a BTRC, but this program is not intended for support of a Center that is predominately focused on routine service. The BTRC should strive to conduct the major portion of its Collaboration and Service projects with researchers who are outside the applicant institution, broadening the scope of the Center's impact as technologies mature.

### **Training**

The technologies, methods, and software developed in BTRCs likely are sophisticated and conceptually novel. Training generally is necessary to facilitate use by scientists outside the BTRC. This training of the research community should be planned for and provided by the BTRC. A BTRC must allocate sufficient

resources for training both specialists and non-specialists to make the best possible use of the new tools.

The Center's Training component should aim to build technical competence in the broader community of researchers who may or may not be formally affiliated with the Center. The overall goal of the training component of a BTRC is expected to be twofold: to improve the general understanding of the Center's technologies in the appropriate population and to create a cadre of biomedical researchers trained in the technology so that they can effectively apply it in their own research. Training courses that constitute a requirement for receipt of an academic degree should not be considered a component of the Center's Training mission.

Formal pedagogy and direct responsibility for training of students and post-doctoral fellows are important components of the academic research enterprise, and it is expected that students and post-doctoral fellows within the BTRC will play major roles in the Technology R&D component of the Center. However, those educational activities are not the focus of the Training component of a BTRC.

Plans for training should be presented in the application, but no specific methods or activities are prescribed. The choice of approaches should be informed by the special constraints and opportunities presented by the circumstances of the BTRC in question. A defining feature of Training activities is the direct interaction between Center personnel and the trainee. Note that activities such as web-based self-service tutorials would fall under Dissemination since there is no direct interaction between Center personnel and the researcher.

Examples of successful approaches may include hands-on laboratory experience such as residencies in the BTRC laboratories for researchers from other laboratories or reciprocal visits by BTRC personnel; seminars and lectures; courses offered for academic credit; short courses or symposia offered independently or in conjunction with society meetings attended by the user community; workshops on appropriate topics that bring together researchers in multidisciplinary areas from academic institutions, hospitals and industry for discussions on the use of the BTRCs technology in biomedical research. Because of the increasing importance of translational and clinical research, plans for training researchers involved in those efforts are strongly encouraged.

The boundary between Training and Dissemination activities may not be well defined. Approaches that incorporate elements of both components should be presented only within one section of the application, whichever is deemed more appropriate by the applicant.

## **Dissemination**

A fundamental motivation for the BTRC program is to bring cutting edge technology to bear on biomedical research problems. A critical step to meeting this objective is to share new technologies and methods as broadly as possible in order to bring them into routine use. The DBPs, Collaboration and Service, and Training components of a BTRC all build toward this overall goal of broad dissemination.

Dissemination activities should have two overall objectives: informing the scientific community about the technical capabilities and accomplishments of a BTRC, as well as promoting and enabling the broader use of technologies. A variety of approaches can be proposed to meet these goals. These approaches can include, but are not limited to: publishing articles, books, patents, newsletters, annual reports, or special issues of technical journals; issuing press releases; presenting research results at meetings; conducting workshops and conferences; distributing software products; transferring technologies to other laboratories directly; licensing technologies to industry; and web-based training modules and tutorials. A robust web presence is required for every BTRC.

In Centers 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. NCCR encourages sharing of source code, consistent with the NIH data-sharing policy. Although software is not required to be open source, if a restrictive license will be used to distribute the software, written justification is required in the application.

## **Administration**

Following the research plan, the administrative structure of the BTRC should be described. This section should be broken down into: organizational structure and staff responsibilities, Center operating procedures, and the external advisory committee.

### **Organizational Structure and Staff Responsibilities**

Describe the organizational structure of the BTRC. Indicate the relationship of the Center to the administrative structure of the grantee institution. Describe how the principal investigator and the proposed Center staff will be organized with respect to the Center components: Technology R&D, Driving Biomedical Projects, Collaboration and Service, Training, Dissemination, and general Center administration. Describe the scientific and technical expertise of the staff that will operate, maintain, and develop the Center capabilities specifying their distribution of effort across their areas of responsibility.

### **Resource Operating Procedure**

Describe operating procedures and policies planned for the Center. Include criteria and mechanisms to review requests for the use of the equipment and facilities in the Center and to schedule that use once it has been approved. Describe criteria and methods for prioritizing and selecting DBPs as well as Collaboration and Service projects. Include samples of the forms to be filled out by collaborators and users. Include instructions on how users are to acknowledge support provided by the Center in any resulting publications.

### **External Advisory Committee**

The External Advisory Committee (EAC) is appointed by the principal investigator (PI) and advises the PI on future directions for the Center, particularly in planning additional grant applications and in setting

priorities for allocation of Center facilities. Each BTRC must have an EAC. The committee chair should be knowledgeable about the Center's technology and the science it serves, but should not be a member of the Center staff or a major user of the Center. Other committee membership should be balanced among scientists knowledgeable about the Center's technology, experts in its application to biomedical research problems and users of the technology.

EAC members and the chair should be from outside the host institution. NCRR encourages the inclusion of scientists who are not affiliated with the Center; however, inclusion of collaborators on the EAC is not prohibited. Membership should be rotated periodically. The EAC should meet at least annually and prepare a written report of its recommendations, addressed to the PI. This report must be supplied as part of the BTRCs Annual Progress Report.

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 BTRC should be presented. In renewal applications, names of current committee members and a brief description of their qualifications should be included. Potential EAC members should not be contacted or appointed prior to submission and should not be named in the application; however, the scientific disciplines of anticipated committee members should be described.

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.

### **III. Application Review Information**

Only the review criteria described below will be considered in the review process.

#### **Review Process**

Applications that are complete will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Center for Scientific Review and in accordance with NIH peer review procedures (<http://grants1.nih.gov/grants/peer/>), using the review criteria stated below. As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned an impact/priority score.
- Receive a written critique.
- Receive a second level of review by the National Advisory Research Resources Council.

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative

agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

## **Overall Impact**

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria (as applicable for the project proposed).

## **Scored Review Criteria**

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

**Significance.** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Investigator(s).** Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

**Innovation.** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

**Approach** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

**Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition to the above review criteria, the following criteria will be applied to applications in the determination of scientific merit and the impact/priority score.

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### **Component scoring:**

Each TR&D project receives a separate score. Components that are scored as a whole regardless of the number of activities subsumed within the component:

- -Driving Biomedical Projects
- -Collaboration and Service
- -Training
- -Dissemination

The Infrastructure and Administrative and Management sections do not receive separate scores, but are factored into the determination of the overall, impact/priority score.

### **Priority Score (the final score, which is recorded by all reviewers who are present for the discussion of the BTRC and who are not in conflict):**

A single, overall impact/priority score for the BTRC grant application will be assigned at the end of the discussion of the components. The overall score for the Center should not be the average of the individual scores, but rather should take into account the synergy of the individual components. The impact/priority score may be more or less than the average of the component scores. In determining this final score, the goals of the Center and the stage of development of the Center technology and community engagement should be taken into account.

### **A) Technological Research and Development Review Criteria**

Is the Center technology dynamically evolving, state-of-the-art, an important area for research and development in its own right, and likely to advance the frontiers of biomedical research? Are alternative approaches to solving technological problems presented? What is the potential impact of the BTRC's technological goals? Is there synergy between a TR&D project and the DBP(s) in advancing the focal technology? How is this Center unique and useful to the community in the technological goals it is pursuing as well as in the cluster of driving biomedical projects to which the advanced technology is being applied? Is the Center technology already broadly available? Are the TR&D projects synergistic?

In renewal applications, is evidence provided of new meritorious efforts and significant progress during the past grant period?

### **B) Infrastructure**

Is the technological infrastructure requested in this section necessary for the BTRC? Has the applicant chosen the most cost effective and appropriate infrastructure?

### **C) Driving Biomedical Projects**

Is the Center staff continuously developing new, significant applications of the Center technology in the biomedical sciences through high quality Driving Biomedical Projects?

For DBPs that have already been peer-reviewed, does the DBP advance and motivate further technological research and development in the Center? Is the technology appropriate and will it have high impact on the science being explored in the DBP? In addition, for DBPs that have not been peer-reviewed, what is the level of scientific merit of the research proposed?

For renewal applications, does the BTRC have an appropriate balance between time and effort spent on DBPs and on Collaboration and Service projects? Are DBPs driving TR&D research and are Collaboration and Service projects making good use of the new technological advances? For this Center, is the balance right between continuing DBPs, DBPs that have finished, and DBPs that have turned into Collaboration and Service projects? Are new DBPs in important biomedical fields being actively sought to invigorate the Center?

### **D) Collaboration and Service**

Is the BTRC available to outside users? Are the equipment and technology utilized for Collaboration and Service state-of-the-art? Do the equipment and technology meet significant biomedical research needs? Do the Collaboration and Service projects have a national geographical distribution? For Centers that do a substantial amount of service, are the plans for sharing costs by the users, including fee for service systems, appropriate?

### **E) Training**

Are plans for providing opportunities for training appropriate?

In renewal applications, have there been reasonable results accruing from these efforts to date?

### **F) Dissemination**

Are the proposed dissemination plans adequate and appropriate? In Centers that are developing software, is the software portable when appropriate, well-documented, user-friendly, and readily available to the user community? Have there been efforts to make both non-expert and expert communities aware of the new technology?

In renewal applications, is the web site easy to find? Does the material on the web site provide useful information to the biomedical research community? Has there been reasonable and timely progress in this area?

### **G) Administrative and Management**

Are the administrative and managerial aspects presented in the written proposal appropriate and adequate? In addition, if a site visit takes place, is the discrete space set aside for the Center and the laboratory facilities, including those available to visiting scientists, appropriate and adequate? In the case of a renewal application, is the usage of the instruments developed and supported by the Center appropriate and adequate? Are instruments in place and operational, and are staff members currently on site?

Is the institution's commitment to the Center appropriate and adequate? For example, are the allocated space, costs associated with alterations and renovations and purchase of instrumentation and computers, and salary support for some Center staff adequate?

Are the scientific and managerial credentials of the Principal Investigator and the credentials of other key professional and technical staff appropriate?

In renewals, is the role of the external advisory committee or in new applications plans for the committee and types of committee members appropriate? Do the members of this committee have sufficient breadth and ability to take an effective role in the review and guidance of the Resource operations? In renewal applications, is there evidence that the EAC is active? Are there plans for rotation of the members of this committee?

If other committees such as a local executive committee are proposed, are the composition and organizational plans for these committees adequately described?

How they will benefit the Center?

### **Additional Review Criteria**

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items:

***Protections for Human Subjects.*** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

***Inclusion of Women, Minorities, and Children.*** When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

***Vertebrate Animals.*** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information, see <http://grants.nih.gov/grants/olaw/VASchecklist.pdf>.

***Biohazards.*** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

***Resubmission Applications*** When reviewing a Resubmission application (formerly called an amended application), the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

***Renewal Applications.*** When reviewing a Renewal application (formerly called a competing continuation application), the committee will consider the progress made in the last funding period.

***Revision Applications.*** When reviewing a Revision application (formerly called a competing supplement application), the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

### **Additional Review Considerations**

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

***Select Agents Research.*** Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor

possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

**Resource Sharing Plans.** Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:

- Data Sharing Plan ([http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm));
- Sharing Model Organisms (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>);
- Genome Wide Association Studies (GWAS) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>).

**Budget and Period Support** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

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