ORIENTATION AND GUIDE
MEMBERS OF SCIENTIFIC REVIEW GROUPS
THE CENTER FOR SCIENTIFIC REVIEW
****
SMALL BUSINESS INNOVATION RESEARCH
SMALL BUSINESS TECHNOLOGY TRANSFER RESEARCH
****

I. GENERAL PROGRAM DESCRIPTION

The Small Business Innovation Research (SBIR) program was established by the Small Business Research and Development Enhancement Act of 1992. Under this program, agencies of the Public Health Service (PHS), Department of Health and Human Services (HHS), and certain other federal agencies are required to reserve 2.5% of their current fiscal year extramural budgets for research or research and development (R/R&D). The Small Business Technology Transfer (STTR) program, currently in five federal agencies, was established by the Small Business Technology Transfer Act of 1992 (Public Law 102-564, Title II). Under this program, 0.15% of a federal agency's extramural R/R&D effort is reserved for awards to small business concerns and their non-profit research institution partners for cooperative research and development efforts.

The SBIR and STTR programs stimulate technological innovation in the private sector by strengthening the role of small business concerns in meeting federal research and development needs, increasing the commercial application of federally supported research results, and fostering and encouraging participation by socially and economically disadvantaged persons and women-owned small businesses in technological innovation. The STTR program further expands the goals through cooperative research and development carried out between small business concerns and research institutions.

In the past, NIH has issued separate SBIR and STTR Grant Solicitations. Because of the similarities between the two solicitations, both in research topics that may be of interest to small businesses and in application instructions, a single Omnibus Solicitation of the NIH, CDC, and FDA for SBIR/STTR Grant Applications will be issued for CY 2000 grant application receipt dates.

NOTE: The CDC and FDA participate ONLY in the SBIR program.

The single SBIR/STTR solicitation (PHS 2000-2) provides information about each program and is available on the NIH website (http://grants.nih.gov/grants/funding/sbirsttr1/index.htm). Appendix A from the Solicitation, "Instructions for SBIR and STTR Grant Applications", may be found at the end of this Guide to Reviewers.

The significant difference between the SBIR and STTR programs is that the STTR requires researchers at universities and other non-profit research institutions to have a formal collaboration with the small business concern and play a significant intellectual role in the conduct of each STTR project. Under the STTR program, the Principal Investigator may be from the small business concern or the research institution. The university-based Principal Investigator is not required to be employed by the small business concern.

A. SBIR/STTR PROGRAMS: THREE PHASES

PHASE I: Feasibility (Type 1 R41 and Type 1 R43 applications)

The objective of Phase I is to establish the technical merit and feasibility of the proposed R/R&D efforts and to determine the quality of performance of the small business grantee organization prior to providing further federal support in Phase II. *Preliminary data are not required.* SBIR Phase I awards normally may not exceed $100,000 total costs (direct costs, indirect costs, and negotiated fixed fee) for a period normally not to exceed 6 months. STTR Phase I awards normally may not exceed $100,000 total costs for a period of 1 year. For SBIR projects, the total amount of all contractual costs and consultant fees normally may not exceed 33% of the total costs requested. However, these levels for time and amount are guidelines, not ceilings; deviations are acceptable, if well justified.

PHASE II: Full R/R&D Effort (Type 2 R42 and Type 2 R44 applications)

The objective of Phase II is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I, scientific and technical merit, and commercial potential of the Phase II application. SBIR Phase II awards normally may not exceed $750,000 in total costs (direct costs, indirect costs, and negotiated fixed fee) for a period normally not to exceed 2 years. STTR Phase II awards normally may not exceed $500,000 total costs (direct costs, indirect costs, and negotiated fixed fee) for a period normally not to exceed 2 years. However, these levels for time and amount are guidelines, not ceilings; deviations are acceptable, if well justified.

Only Phase I grantees are eligible to obtain Phase II funding, and only one Phase II award may be made for a single SBIR/STTR project. Phase II applications may be submitted either before or after expiration of the Phase I budget period, except for those applicants electing to concurrently submit Phase I and Phase II applications under the Fast-Track procedures (Section I, Item B). Also, under special circumstances, requests for supplemental funds to existing Phase I grants or requests for an extension of the period of support with funds, may be considered. (*The above applies to NIH ONLY, as CDC and FDA do not make awards greater than the stated guidelines.*)

PHASE III: Commercialization

The objective of Phase III, where appropriate, is for the small business concern to pursue with non-SBIR/STTR funds (either federal or non-federal) the commercialization objectives resulting from the results of the research or R&D funded in Phases I and II. In some Federal agencies, Phase III may involve follow-on, non-SBIR/STTR funded R&D, or production contracts for products or processes intended for use by the U.S. Government.

B. FAST TRACK APPLICATIONS (Type I R42 and Type 1 R44 applications)

The NIH Fast Track program expedites the decision and award of SBIR and STTR Phase II funding for scientifically meritorious applications that have a high potential for commercialization. Fast Track incorporates a parallel review option, in which both Phase I and Phase II grant applications are submitted and reviewed together. As with other Phase I applications, preliminary data are not required. However, the Phase I portion of a Fast Track application must specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II work. In addition, a Fast Track application must present a brief (limited to ten pages) Product Development Plan that addresses these points:

· Company information, including size, specialization area(s), products with significant sales, history of previous federal and non-federal funding, regulatory experience, and history of experience with commercialization,

· Value of the SBIR or STTR project, including lay description of key technology objectives, current competition, and advantages compared with competing products or services,

· Commercialization plans, milestones, target dates, analyses of market size, and the estimated market share after the first year of sales and after five years of sales, and

· Patent status or other approaches to protecting intellectual property of the project.

In most cases, the Phase I and Phase II applications will be considered as a single submission, and will receive a single priority score. However, applications that do not meet these criteria may be redirected for review through the standard review procedures for Phase I applications, without consideration of the Phase II portion. In addition, the SRG may suggest other milestones that should be met prior to awarding of Phase II funding.

Applications selected for funding via the Fast Track initiative will have a reduced gap between Phase I funding and Phase II funding. Phase II funding will be awarded based on the project's scientific and technical merit, the awarding component's assessment of the Phase I progress report and determination that the Phase I goals were achieved, update and verification of the Product Development Plan, the project's potential for meeting the mission of the awarding component, potential for commercial success, and the availability of funds. Although a formal peer review of Phase I Fast Track progress is not required, awarding components may seek the advice of consultants prior to making a Phase II Fast Track award.

C. SIMPLIFIED BUDGETS

The National Institutes of Heath is employing these features of the Modular Grant Application and Award procedures under its SBIR/STTR programs:

· For applications requesting up to $100,000 total costs, **Budget Page 3** ("Budget for Phase I - Direct Costs ONLY") is **not** required. Only **Form Page 4** ("**Budget Justification**") **is** required. The review panel is instructed NOT to recommend changes in these "simplified" budgets.

· For applications requesting over $100,000 total costs, **Budget Page 3, with a detailed budget request, and Form Page 4, both are required**. The review panel is asked to comment on the appropriateness of these budgets and their justification, and to recommend budget changes where appropriate. If a review panel believes that a Phase II project can be accomplished within a shorter period of time than that proposed by the Principal Investigator, they may recommend that the amount and/or period of support be reduced accordingly.

Modules of $25,000 **do not apply** to SBIR and STTR applications.

D. RECEIPT DATES

SBIR and STTR Receipt Dates Phase I and Phase II	National Technical Merit Review	Advisory Council/ Board Review	Estimated Award Date
April 1, 2000	June/July	Sept/Oct	November
August 1, 2000	Oct/Nov	Jan/Feb	March
December 1, 2000*	Feb/March	May/June	July

* Applications to the Centers for Disease Control and Prevention may be submitted only on the December 1, 2000 receipt date. CDC and FDA do not participate in the STTR program.

II. METHOD OF SELECTION AND EVALUATION CRITERIA

Grant applications are subjected to a review process involving two sequential steps, both of which are required by law. The first step is performed by the Scientific Review Groups (SRGs), composed primarily of non-Federal scientists (from academia and industry) selected for their competence in particular scientific fields. The task of the SRGs is to evaluate SBIR/STTR applications for scientific and technical merit and potential for commercialization. The SBIR/STTR Phase I review criteria are listed in Section II, Item A. Each grant application generates a summary statement that includes a single rating and the written critiques of two or more assigned reviewers.

The second level of review is performed by the National Advisory Council or Board of the potential awarding component (Institute, Center, or other unit) to which the grant application is assigned. These groups, composed of scientists, physicians, and leaders in public affairs, are chosen for their expertise, interest, or activity in matters related to the awarding component's mission. If the council or board recommends an action other than that recommended by the SRG, the awarding component will send a letter to the Principal Investigator indicating the action and its rationale.

A. SBIR/STTR REVIEW CRITERIA

"Formulas" do not exist for calculating an individual reviewer's score on an application. However, in considering the scientific and technical merit of each application, reviewers, discussants, and other SRG members should consider the following criteria:

Significance

· Does this study address an important problem?

· Does the proposed project have commercial potential to lead to a marketable product or process?

· What may be the anticipated commercial and societal benefits of the proposed activity?

· If the aims of the application are achieved, how will scientific knowledge be advanced?

· Does the proposal lead to enabling technologies (e.g., instrumentation, software) for further discoveries?

· Will the technology have a competitive advantage over existing/alternate technologies that can meet the market needs?

Approach

· Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?

· Is the proposed plan a sound approach for establishing technical and commercial feasibility?

· Does the applicant acknowledge potential problem areas and consider alternative strategies?

· Are the milestones and evaluation procedures appropriate?

Innovation

Something new or improved, including research for development for new technologies, refinement of existing technologies, or development of new applications for existing technologies. For purposes of PHS programs, an example of "innovation" would be new medical or biological products, for improved value, efficiency, or costs.

· Does the project challenge existing paradigms or employ novel technologies, approaches or methodologies?

· Are the aims original and innovative?

Investigators

· Is the Principal Investigator capable of coordinating and managing the proposed SBIR/STTR?

· Is the work proposed appropriate to the experience level of the Principal Investigator and other researchers, including consultants and sub-awardees (if any)?

Environment

· Is there sufficient access to resources (e.g., equipment, facilities)?

· Does the scientific and technological environment in which the work will be done contribute to the probability of success?

· Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

Gender, Minority, and Children Subjects (if applicable)

· For applications involving the use of human subjects, does the experimental design include adequate plans to include both genders, as well as minorities and their subgroups, as appropriate for the scientific goals of the research?

· Are plans for the recruitment and retention of subjects adequate?

Phase II Applications (Type 2 R42 and type 2 R44 applications)

· In addition to the above criteria, to what degree was progress toward the Phase I objectives met and feasibility demonstrated in providing a solid foundation for the proposed Phase II activity?

Phase I/Phase II Fast Track Applications (Type 1 R42 and type 1 R44 applications)

For Phase I/Phase II Fast Track applications, the following additional criteria should be applied:

· Does the Phase I application specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II?

· Did the applicant submit a concise Product Development Plan that adequately addresses the four areas listed in Section I, Item B?

· To what extent was the applicant able to obtain letters of interest, additional funding commitments, and/or resources from the private sector or non-SBIR/STTR funding sources that would enhance the likelihood for commercialization?

· Does the project carry a high degree of commercial potential, as described in the Product Development Plan? Commercial potential is an important review criterion and should be factored into the priority score.

Amended (revised) applications (numbers ending in A1 or A2)

For amended applications, the following additional points should be determined:

· Are the responses to comments from the previous Study Section adequate?

· Are the improvements in the revised application appropriate?

B. OTHER CRITERIA CONSIDERED

Because the following considerations and issues do not constitute review criteria, they are discussed after the application has been assigned a priority score. These issues therefore **do NOT affect the scientific and technical merit evaluation**, and comments on these topics are included as Administrative Notes in the summary statement.

The overall budget

· On applications requesting up to $100,000 total costs, is the overall budget realistic and justified in terms of the aims and methods proposed?

· On applications requesting over $100,000 total costs, is each budget category realistic and justified in terms of the aims and methods?

· Is the percent effort listed for the Principal Investigator appropriate for the work proposed?

Biohazards

· Is the use of materials or procedures that are potentially hazardous to research personnel proposed? Is the proposed protection adequate?

Human subjects

· If human subjects are involved, are the plans proposed for their protection adequate?

· If exemptions are claimed, are they appropriate for the work proposed?

· If no exemptions are claimed, are the applicant's responses to the six (or seven) required points (Appendix A, Section G) appropriate?

· Are the risks to the subjects reasonable in relation to the anticipated benefits to the subjects and/or in relation to the importance of the knowledge that reasonably may be expected to result from the research?

Animal welfare

· If vertebrate animals are involved, are adequate plans proposed for their care and use?

· Are the applicant's responses to the five required points (Appendix A, Section H) appropriate?

· Will the procedures be limited to those that are unavoidable in the conduct of scientifically sound research?

The applicant organization

· Is the small business authentic and reasonably structured, and does the small business control the research space?

· Are the relationships of the key personnel to the small business and to other institutions reasonable for the work proposed?

III. REVIEW PROCEDURES

A. STREAMLINING

For the review of SBIR and STTR research grant applications, a streamlined procedure is employed to identify applications that rank in the upper (more meritorious) or lower (less meritorious) half of those assigned to an SRG. This procedure is described in the document "Streamlined Review Procedures Used in CSR" (http://www.csr.nih.gov/REVIEW/streamln.htm). Prior to the SRG meeting, reviewers are asked to identify applications that in their opinion rank in the lower half and consequently should not be discussed at the meeting. The Scientific Review Administrator (SRA) compiles a list of those applications receiving two or more votes for placement in the lower half, and sends it to SRG members before the meeting. At the beginning of the meeting, the list is read aloud for final concurrence by the entire SRG. However, **at any time**, any SRG member may disagree and identify an application that he/she believes is in the upper half and, therefore, should receive full discussion. If any member of the SRG questions the rating or wishes to comment on an application, the SRG will discuss

and consider it in the normal sequence of review.

In accordance with federal regulations, the Principal Investigator clearly must be responsible for the scientific and technical direction of the project. When the Principal Investigator does not have sufficient qualifications to assume this role, the application should be streamlined.

B. SCORING

The Chairperson of the SRG introduces each application in the upper half, calls upon the reviewers assigned by the SRA, and asks them to present their written comments. The assigned discussants then are called on for their comments and group discussion follows. After sufficient discussion the Chairperson calls for a priority rating to be assigned to the application. However, if the SRG determines that the application being discussed should be placed in the lower half, it may recommend that the application not be scored. This decision requires unanimous agreement of the SRG.

For applications that are scored, each member records on his/her scoring sheet a numerical rating that reflects his/her opinion of the merit of the application. A score of 1.0 signifies the highest scientific and/or technical merit. Under the currently employed streamlining procedures, a rating of 3.0 is considered the median score for the cohort of applications that an SRG reviews. If a reviewer believes that a scored application ranks in the lower half of applications generally considered by that study section, that reviewer may assign a score greater than the median (3.0) to the application. Numerical scores are assigned in increments of 0.1. Abstaining members do not assign a numerical rating and are not counted in calculating the average of the individual ratings.

C. OTHER MOTIONS

Deferral. An application may be deferred because of insufficient information to make a recommendation. The applicant may be requested to submit additional information, or a project site visit (applicable to Phase II applications only) may be recommended.

Not Recommending for Further Consideration. Only if gravely hazardous or unethical procedures are involved, may the SRG recommend the application for "no further consideration". This decision is made by majority vote of the SRG. Concerns regarding human subjects, animal welfare, or biohazards must be included in the summary statement.

D. FAST TRACK APPLICATIONS

In most cases, a single score should be assigned to a Fast Track application to reflect the reviewers' enthusiasm for the entire project. The SRG should evaluate the goals that will be achieved during Phase I, the ability of the applicant to demonstrate their achievement in a convincing way, and discuss their appropriateness for determining feasibility. The SRG also may recommend additional milestones. In some cases, the SRG may review and score only the Phase I portion of a Fast Track application, if:

· the application does not include a Product Development Plan that includes the four items listed in Section I, Item B,

· the application does not contain clear, measurable Phase I goals that are appropriate for demonstrating feasibility, or

· the Phase II project is significantly less meritorious than the Phase I project.

If the SRG takes such action, only material included in the Phase I portion of the application may be used in determining the priority score; the action should be explained fully in the critique, and comments on the Phase II work plan are not needed.

IV. CONFIDENTIALITY AND COMMUNICATION WITH INVESTIGATORS

All materials pertinent to the applications being reviewed are privileged communications prepared for use only by consultants and NIH staff, and should not be shown to other individuals or discussed with others. No direct communication should occur between SRG members and investigators. Reviewers' requests for additional information, telephone inquiries or correspondence should be directed to the SRA, who handles all communications with investigators. Consultants are required to leave all review materials with the SRA at the conclusion of the review meeting (except material already in the public domain, e.g., reprints).

Under no circumstances should consultants advise investigators or other individuals of recommendations or discuss the review proceedings with them, because investigators may be led into unwise actions on the basis of premature or erroneous information. Such advice also represents an unfair intrusion into the privileged nature of the proceedings and invades the privacy of applicants as well as consultants serving on review committees. A breach of confidentiality could result in disclosure of trade secrets or other proprietary information (commercial as well as financial), deter qualified consultants from serving on review committees, and inhibit those who do so from engaging in free and full discussion of recommendations during the official review process.

V. CONFLICTS OF INTEREST

A conflict of interest in scientific peer review exists when a reviewer has an interest in an application or a proposal and that interest may bias or give the appearance of biasing his or her review of it on grounds other than those specified in the review criteria. A reviewer who has a real conflict of interest with an application or proposal may not participate in its review. In addition, appearance of a conflict of interest should be avoided whenever possible; however, if it is established that no real conflict of interest exists and the Scientific Review Administrator [SRA] determines that the integrity of the process would not be impaired, then the individual in question may participate in the review.

The SRA is responsible for resolving any questions about the participation of reviewers; however, reviewers are most familiar with their own situations. The reviewer is personally responsible for: (1) bringing to the attention of the SRA any conflict of interest situations that may pertain, whether real or apparent, (2) identifying on the pre-meeting and post-meeting Conflict of Interest and Confidentiality Certification Forms any applications with which he/she has a conflict of interest, and (3) certifying on the Conflict of Interest and Confidentiality Certification Forms that he/she will not be and has not been involved in the review of any grant application where his/her participation constitutes a conflict of interest, nor will he/she disclose any matters related to the review proceedings. In addition, the NIH may determine that a particular situation involves a conflict of interest and require that the potential reviewer not be involved in the review of the application(s) or proposal(s) in question.

The following guidance, derived from 42 CFR Part 52h, will assist the reviewer in determining whether he/she is faced with a real or apparent conflict of interest. The guidance is not all-inclusive, due to the nature of the conflict of interest subject matter. The SRA is responsible for resolving any questions about the participation of reviewers.

A. BASES FOR CONFLICTS OF INTEREST

Several bases exist for a real conflict of interest: employment, financial benefit, and personal or professional reasons. If applicable, any one of these may suffice to disqualify a reviewer from participating in the review of an application or proposal.

Employment A reviewer who is a salaried employee, officer, director, trustee, or partner, whether full- or part-time, of the applicant institution or offeror, or who is negotiating with the applicant organization for employment shall generally be considered to have a conflict of interest with regard to applications/proposals from that organization. However, in large organizations or multi-component organizations circumstances may exist such that the components are sufficiently independent to permit an employee of one component to review an application/proposal from another component without a real conflict of interest. Membership on a scientific review group does not make an individual an employee or officer of the Federal Government.

Financial Benefit: A conflict of interest exists: (1) when a reviewer has received or could receive direct financial benefit of any amount, other than from employment, from an applicant institution, offeror, or principal investigator related to the application or proposal under review, or (2) when a reviewer has received or could receive a financial benefit that, although clearly unrelated to the application or proposal under review, has a value of $5,000 or more per year. Regardless of the level of financial involvement, if the individual is unable to provide objective advice, he/she must recuse him/herself from the review of the application or proposal at issue.

Relatives or Associates: A conflict of interest exists if a close relative or professional associate of a reviewer submits an application or proposal, or receives or could receive financial benefits from or provides financial benefits to an applicant or offeror. In such a case, the financial benefits will be treated as the reviewer's financial benefits. A close relative is defined as a parent, spouse/domestic partner, or son or daughter. A professional associate is defined as any colleague, scientific mentor, or student with whom the reviewer is currently conducting research or other professional activities, or with whom the reviewer has personally worked within three years of the date of the review.

Standing Review Group Membership: When a scientific review group meets regularly, a relationship exists among the individual members; therefore, the group as a whole may not be objective in evaluating the work of one of its members. In such a case, the member's application or proposal will be reviewed by another review group to insure that an objective review is obtained.

Longstanding Disagreements: A conflict of interest exists when a potential reviewer has longstanding scientific or personal differences with an applicant.

B. APPEARANCE OF CONFLICT OF INTEREST

When an appearance of conflict of interest exists, but the grounds for disqualifying the reviewer are insufficient, the government official in charge of the review will document: (1) that no real conflict of interest exists, and (2) that, at the time of the review, no practical alternative exists for obtaining the necessary scientific advice from the reviewer with the apparent conflict.

C. PEER REVIEW CONSULTANTS - Individuals Named In Applications/Proposals Who Are Not From the Applicant Institution

In the past, the requirements of the conflict of interest statutes and regulations that apply to federal employees have been applied unnecessarily to all peer review consultants (i.e., study section and other scientific review group [SRG] members). No longer applying those statutes and regulations allows a shift in focus of conflict of interest regulations from institutional conflicts to conflicts involving the individual. In the interest of uniform review policies across the ICs, the following clarifications of this policy are presented. The following applies to all peer review consultants who are not federal employees.

A Principal Investigator (PI) may submit an application/proposal naming a participating individual from another institution. It is hereby determined that the relationship between such a named participating individual and the applicant institution does not constitute a conflict of interest. Consequently, (1) that named individual may review other applications/proposals from the applicant (i.e., PI's) institution; and (2) other individuals from the institution of the named individual may be used as reviewers for the PI's application/proposal, as long as any real or apparent conflict of interest is resolved. The SRA will document that no conflict of interest exists.

In addition, if an individual supplies a resource or service to an applicant, and that resource or service is freely available to anyone in the scientific community, neither the institution nor the individual supplying the resource is in conflict, as long as any real or apparent conflict of interest is resolved.

VI. GUIDE FOR PREPARING PRELIMINARY COMMENTS

Reviewers assigned to critique an application should follow this recommended outline when preparing written reviews of SBIR, STTR, and Fast Track applications:

CRITIQUE: Provide a comprehensive evaluation of the strengths and weaknesses of the application. Address each of the major review criteria described in Section II, Item A (Significance, Approach, Innovation, Investigators, and Environment), using a separate subheading for each. If applicable, also evaluate the special criteria for Phase II applications, Fast Track applications, and/or amended applications (Section II, Item A). If applicable, also include a subheading Gender, Minority, and Children Subjects to address the following:

· Using the categories "1" to "4" below, assess the proposed plans to include men and women, children (individuals under the age of 21), as well as minorities and their subgroups, as appropriate for the scientific goals of the research. Clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention and preventive strategies, diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

Category	Gender (G)	Minority (M)	Children (C)
1	Both Genders	Minority & non-minority	Children & adults
2	Only Women	Only minority	Only children
3	Only Men	Only non-minority	No children included
4	Gender Unknown	Minority representation unknown	Representation of children unknown

· Evaluate the acceptability of the proposed plans as "A" (acceptable) or "U" (unacceptable). Consider an Unacceptable rating as a weakness or deficiency in the design of the project, and reflect it in the overall score.

· Assess the plans for the recruitment and retention of subjects.

· Determine whether the research is a Phase III clinical trial. An NIH-defined clinical trial is a broadly based, prosepective, Phase III clinical investigation comparing interventions or treatments whose trial outcome would lead to a change in standard of care or health policy.

Reviewers should address these additional categories, if applicable, under separate headings:

HUMAN SUBJECTS: Where an application involves activities that could have an adverse effect on humans, animals, or the environment, express any comments or concerns about the adequacy of the proposed means for protecting against or minimizing such effects. Discuss the appropriateness of the applicant's responses to the six (or seven) required points (Appendix A, Item G).

ANIMAL WELFARE: Express any comments or concerns about the appropriateness of the applicant's responses to the five required points (Appendix A, Item H).

BIOHAZARDS: Note any materials or procedures that are potentially hazardous to research personnel and comment on the adequacy of the protection measures proposed.

OVERALL EVALUATION: Provide an overall evaluation of the strengths and weaknesses of the application and a preliminary recommendation of an overall level of scientific and/or technical merit.

BUDGET

· Assess whether the percent effort listed for the Principal Investigator is appropriate for the work proposed.

· For applications requesting up to $100,000 total costs, determine whether the overall budget is realistic and justified in terms of the aims and methods.

· For applications requesting over $100,000 total costs, provide justification for any modification in time or amount that you recommend.

Last Updated: April 5, 2000