

# Guidelines for Reviewers

## Small Business Innovation Research (SBIR) Small Business Technology Transfer Research (STTR)

The Center for Scientific Review  
National Institutes of Health

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#### New Features:

- ❖ Instructions and forms for SBIR and STTR applications appear in the Application for a Public Health Service Grant<sup>1</sup> (PHS 398; revised 05/2001), and in the Omnibus Solicitation of the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration for Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grant Applications<sup>2</sup> (PHS 2001-2).
- ❖ SBIR/STTR applications received for the August 1, 2001 receipt date may use instructions and forms from either PHS 398<sup>1</sup> or PHS 2001-2.<sup>2</sup>

#### I. General Program Description

The objectives of the SBIR Program include stimulating technological innovation in the private sector, strengthening the role of small business in meeting Federal R/R&D needs, increasing private sector commercialization of innovations developed through Federal SBIR R&D, increasing small business participation in Federal R/R&D, and fostering and encouraging participation by socially and economically disadvantaged small business concerns and women-owned business concerns in the SBIR program. The STTR program further expands the goals through cooperative research and development carried out between small business concerns and research institutions.

<sup>1,2</sup> Reviewers should refer to the Application for a Public Health Service Grant (PHS 398; <ftp://grants.nih.gov/forms/phs398.pdf> and <http://grants.nih.gov/grants/funding/phs398/phs398.html>), and to the Omnibus Solicitation of the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration for Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grant Applications (PHS 2001-2) (<http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf>) or ([http://grants.nih.gov/grants/funding/sbirsttr1/PHS2001-2\\_Full\\_with\\_Topics.pdf](http://grants.nih.gov/grants/funding/sbirsttr1/PHS2001-2_Full_with_Topics.pdf)) for additional information.

The SBIR and STTR programs differ in significant ways. First, the STTR program requires the small business: (1) to have a formal collaboration with researchers at universities or other non-profit research institutions, and (2) to play a significant intellectual role in the conduct of the STTR project. Also, only the SBIR program stipulates that the Principal Investigator (PI) must have his/her primary employment with the small business. Therefore, the PI on an STTR may be from the small business or the research institution *as long as (s)he has a formal appointment with or commitment to the applicant small business, which is characterized by an official relationship between the small business and the PI.*

## 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/scientific 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<sup>3</sup> for a period normally not to exceed 6 months. The total amount of all contractual costs and consultant fees normally may not exceed 33% of the total costs requested.
- ❖ STTR Phase I awards normally may not exceed \$100,000 total costs<sup>3</sup> for a period of 1 year.
- ❖ These award levels for duration and total costs are statutory guidelines, not ceilings. Deviations from the guidelines are acceptable, but must be justified.
- ❖ For STTR awards at least 40% of the work must be performed by the small business and at least 30% by the research institution.

### 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. Evaluation is based on the results of Phase I, scientific/technical merit, and commercial potential/societal impact of the Phase II application. Reviewers may access additional information on Phase II.<sup>4</sup>

**Beginning with CY2001, all Phase II SBIR/STTR applications must include a succinct "Product Development Plan" (PDP)(Section I.C) within the application.<sup>5</sup>**

- ❖ SBIR Phase II awards normally may not exceed \$750,000 in total costs<sup>3</sup> for a period normally not to exceed 2 years. The sum of the consultant costs and contractual costs normally may not exceed 50% of the total costs requested.
- ❖ STTR Phase II awards normally may not exceed \$500,000 total costs<sup>3</sup> for a period normally not to exceed 2 years.
- ❖ These award levels for duration and total costs are statutory guidelines, not ceilings. Deviations from the guidelines are acceptable, but must be justified.
- ❖ For an STTR award, at least 40% of the work must be performed by the small business and at least 30% by the research institution.

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<sup>3</sup> Total costs are the sum of direct costs, indirect costs, and negotiated fixed fee.

<sup>4</sup> Reviewers should refer to the SBIR Phase II Grant Application Major Policy Changes and Program Reminders (<http://grants.nih.gov/grants/funding/sbir2/polchng.htm>), the SBIR Phase II Grant Application Introduction and Instructions (<http://grants.nih.gov/grants/funding/sbir2/intro.htm>), and the STTR Phase II Grant Application Instructions (<http://grants.nih.gov/grants/funding/str2/intro.html>) for additional information.

<sup>5</sup> For SBIR/STTR applications submitted on PHS 2001-2 forms, the Product Development Plan should be included as part of the Research Plan, after the Significance section, and is excluded from the 25-page limit. For SBIR/STTR applications submitted on PHS 398 forms, the Product Development Plan should be included as Section J.

## B. Fast-Track Applications (type 1 R42 and type 1 R44 applications)

The NIH Fast-Track mechanism expedites the award of SBIR and STTR Phase II funding for scientifically meritorious applications that have a high potential for commercialization.<sup>6</sup> Fast Track incorporates a parallel review option, in which the Phase I and Phase II grant applications are submitted and reviewed together. Preliminary data are not required, but the Phase I of a Fast Track must specify clear, measurable milestones that should be achieved prior to initiating Phase II work.

**All Fast Track applications must include a succinct "Product Development Plan" (PDP)(Section I.C) within the Phase II application.<sup>5</sup>**

## C. Product Development Plans

Product Development Plans (limited to ten pages) should address:

- ❖ Company information: including size; specialization area(s); products with significant sales; and history of previous federal and non-federal funding, regulatory experience, and subsequent commercialization<sup>6</sup>.
- ❖ Value of the SBIR/STTR project, including lay description of key technology objectives, current competition, and advantages compared to competing products or services.
- ❖ Commercialization plans, milestones, target dates, analyses of market size and estimated market share after first year sales and after five years.
- ❖ Patent status or other protection of project intellectual property.

## D. Budgets

### Modular budgets (requests up to \$100,000 total costs<sup>3</sup>)

The NIH is employing features of the Modular Grant Application and Award procedures under its SBIR/STTR programs for SBIR/STTR applications requesting up to \$100,000 in total costs<sup>3</sup>. For modular SBIR applications, only the "Budget Justification Page" is required.<sup>7</sup> For modular STTR applications, the "Budget of Research Institution for Phase I" plus the "Budget Justification" are required. Reviewers should evaluate these modular budgets on the basis of a general, expert estimate of the total costs and resources required to carry out the proposed research in the requested period, rather than on the basis of detailed categorical costs. Review panel recommendations for SBIR/STTR modular budgets need not conform to modules of \$25,000.

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<sup>6</sup> Commercialization is defined in PHS 398 and PHS 2001-2 as "[t]he process of developing markets and producing and delivering products for sale (whether by the originating party or by others); as used here, commercialization includes both government and private sector markets."

<sup>7</sup> For modular SBIR budgets submitted on PHS 2001-2 forms, the "Budget Justification Page" (Form Page 5) is required, but the "Budget for Phase I - Direct Costs Only" (Form Page 3) is NOT required. For modular SBIR budgets submitted on PHS 398 forms, the "Modular Budget Format Page" is required, but the "Detailed Budget for Initial Budget Period" (Form Page 4) and the "Budget for Entire Proposed Project Period" (Form Page 5) are NOT required. For modular STTR budgets submitted on PHS 2001-2 forms, the "Budget of Applicant Organization for Phase I-Direct Costs Only" (Form page 3) is NOT required. For modular STTR budgets submitted on PHS 398 forms, the "Modular Budget Format Page" and the "Budget of Research Institution" (STTR Research Institution Budget Form Page) are required, but the "Detailed Budget for Initial Budget Period" (Form Page 4) and the "Budget for Entire Proposed Project Period" (Form Page 5) are NOT required.

## Multi-year Phase I budgets

Multi-year Phase I budget requests that exceed the normal guidelines in terms of amount and duration are allowable for certain SBIR/STTR projects,<sup>8</sup> if the requests are well justified or stipulated in a specific Program Announcement.

## Just-in-Time Considerations

All Phase I budgets must itemize and justify requests that exceed the following: 1) \$15,000 for total equipments costs; 2) \$15,000 for total supplies; 3) \$5,000 for all travel; and 4) \$5,000 for all Other Expenses. Information for other items in a Phase I application<sup>9</sup> may be requested by the awarding component if the likelihood exists for the application to be funded.

## II. Review Procedures

Grant applications submitted to NIH are subjected to a peer review process involving two sequential steps that are required by law. The first step is performed by the Scientific Review Groups (SRGs), composed primarily of non-federal scientists, physicians, and engineers (from academia and industry) who are selected for their expertise and stature in particular scientific fields. The Scientific Review Administrator (SRA) is the designated government official responsible for ensuring that each application receives a fair review, according to NIH policy. The second step is performed by the National Advisory Council or Board of the potential awarding component to which the grant application is assigned.

The first task of the SRGs is to make a recommendation for each application on the basis of the SRG's evaluation of the application's scientific and technical merit, potential for commercialization and/or societal benefit.<sup>10</sup> The second task of the SRGs is to make budget recommendations concerning time and dollar amounts that are appropriate for the work proposed.<sup>10</sup>

### A. Streamlining

NIH uses a numerical scoring range from 100 (most meritorious) to 500, and a streamlining procedure<sup>11</sup> to determine those applications that the SRG considers to be in the "upper" and "lower" halves. Applications in the "upper half" are discussed by the SRG and *generally* receive a score between 100 and 300; applications that generally would have received a score between 300 and 500 are not discussed and receive an "unscored" designation. At *any* time during the meeting, *any* SRG member may identify an application that (s)he believes should be discussed and scored.

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

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<sup>8</sup> Instructions to applicants submitting multi-year Phase I budgets on PHS 2001-2 forms are available on the Internet at <http://grants.nih.gov/grants/funding/sbir.htm>.

<sup>9</sup> Information on institutional base salary for personnel, salaries requested, fringe benefits, total personnel costs requested, and Other Support is NOT required at the time an SBIR/STTR application is submitted.

<sup>10</sup> Reviewers may refer to the document "Review Procedures for Scientific Group Meetings" for additional information at <http://www.csr.nih.gov/guidelines/proc.htm>.

<sup>11</sup> The streamlining procedure for NIH is described in the document entitled "[Streamlined Review Procedures Used in CSR](http://www.csr.nih.gov/REVIEW/streamln.htm)" at <http://www.csr.nih.gov/REVIEW/streamln.htm>.

## B. Scoring

For applications that are not streamlined, each member records on a scoring sheet a numerical rating that reflects his/her opinion of the merit of each application. Numerical scores are assigned by reviewers in increments of 0.1. In special circumstances, a member may record a non-numerical rating such as NP (Not Present), AB (Abstention), or CF (Conflict of Interest).

**Deferral.** An application may be deferred if insufficient information exists to make a recommendation. The applicant may be requested to submit additional information, or in special cases a project site visit (applicable to Phase II applications only) may be recommended.

**Not Recommending for Further Consideration.**<sup>12</sup> The SRG may recommend an application for "no further consideration" in rare cases where 1) the application lacks significant and substantial merit, or 2) research risks are sufficiently serious and protections against the risks are so inadequate as to consider the proposed research unacceptable on ethical grounds. The decision for "NRFC" must be made by majority vote of the SRG.

## C. 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 1) evaluate the goals that will be achieved during Phase I and the ability of the applicant to demonstrate their achievement in a convincing way, and 2) discuss their appropriateness for determining feasibility. *The SRG also may recommend additional milestones that should be achieved before progressing to the Phase II project.* 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.C,
- ❖ 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 scores only the Phase I, then only material from the Phase I application may be used in determining the priority score.

## III. Conflict of Interest

A conflict of interest in scientific peer review exists when a reviewer has an interest in an application that may bias or give the appearance of biasing his/her review of it on grounds other than those specified in the review criteria. All reviewers must read the "NIH Conflict of Interest, Confidentiality, and Non-Disclosure Rules and Information for Reviewers of Grant Applications and R&D Contract Proposals" and submit a completed, signed "NIH Pre-Review Certification Form Regarding Conflict of Interest, Confidentiality, and Non-Disclosure for Reviewers of Grant Applications and R&D Contract Proposals" before participating in peer review. A reviewer who has a conflict of interest with an application may not participate in its review, and the appearance of a conflict of interest should be avoided whenever possible.

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<sup>12</sup> Reviewers should refer to the OER Policy Statement 1996-04, "Fundability of Grant Applications Designated as Unscored or Not Recommended for Further Consideration" at [http://odoerdb2.od.nih.gov/oer/policies/oer\\_announce\\_1996\\_04.htm](http://odoerdb2.od.nih.gov/oer/policies/oer_announce_1996_04.htm) for additional information.

An SRG may not review an application if:

- ❖ One of its members, or a member's close relative,<sup>13</sup> is the PI or is listed on the budget page in any capacity;
- ❖ One of its members is an owner, officer, or employee in the small business submitting the application; or
- ❖ A member's close professional associate<sup>14</sup> is the PI or is responsible for conducting a significant portion of, or has significant intellectual input into, the planned research.

An SRG member must leave the room during the discussion of an application:

- ❖ Submitted by a small business from whom the member has received or could receive direct financial benefit—of any amount—that is related to the project under review but is not derived from employment;
- ❖ Submitted by a small business from whom the member has received or could receive a financial benefit that has a value of \$5,000 or more per year and is clearly unrelated to the project under review;
- ❖ Submitted by an applicant or small business with whom the member has longstanding scientific or personal differences that may be viewed as biasing the member's judgment;
- ❖ Submitted by a major competitor of the member; or
- ❖ If the member feels unable to provide objective advice.

The SRA is responsible for determining whether the participation of particular reviewers is appropriate, and for answering all questions about conflicts of interest.

#### **IV. Confidentiality**

All materials pertinent to the applications being reviewed are privileged communications prepared for use only by NIH consultants and NIH staff, and should not be shown to, or discussed with, other individuals. Nor should direct communication occur between reviewers and investigators. Reviewers' requests for additional information, telephone inquiries or correspondence should be directed to the SRA. Reviewers are required to leave all review materials with the SRA at the conclusion of the review meeting (except materials that are already in the public domain, e.g., reprints).

In accordance with NIH policy,<sup>15</sup> all applications for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

#### **V. Scientific Misconduct**

It is vital that reviewers not make allegations of potential misconduct at the study section meeting or in their critiques. Such concerns must be brought to the attention of the SRA in a confidential manner, preferably before the study section meets.

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<sup>13</sup> A close relative is defined as a parent, spouse/domestic partner, son or daughter.

<sup>14</sup> 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. The determination of a close professional association is a matter of judgment on the part of the SRA.

<sup>15</sup> The NIH Guide Notice OD-00-004, namely "URL's in Applications, Proposals, or Appendices," at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-004.html>, presents the NIH URL policy.

## VI. Writing Your Review

"Formulae" do not exist for calculating an individual reviewer's score on an application. Rather, reviewers should balance the strengths and weaknesses of each application, using the criteria below.

### A. All SBIR/STTR Applications (all R41, R42, R43, and R44 applications)

#### 1. Significance.

- ❖ Does the proposed project have commercial potential to lead to a marketable product or process? Does this study address an important problem?
- ❖ 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?

#### 2. 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?

#### 3. Innovation.<sup>16</sup>

- ❖ Does the project challenge existing paradigms or employ novel technologies, approaches or methodologies?
- ❖ Are the aims original and innovative?

#### 4. Investigators.

- ❖ Is the Principal Investigator capable of coordinating and managing the proposed project?
- ❖ Is the work proposed appropriate to the experience level of the Principal Investigator and other researchers, including consultants and sub-awardees (if any)?
- ❖ Are the relationships of the key personnel to the small business and to other institutions appropriate for the work proposed?

#### 5. 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?

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<sup>16</sup> Innovation is defined in PHS 2001-2 and PHS 398 as "Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of 'innovation' would be new medical or biological products, for improved value, efficiency, or costs."

**B. Additional Criteria for Phase II Applications (type 2 R42 and type 2 R44 applications)**

- ❖ How well did the applicant demonstrate progress toward meeting the Phase I objectives, demonstrating feasibility, and providing a solid foundation for the proposed Phase II activity?
- ❖ Did the applicant submit a concise Product Development Plan that adequately addresses the four areas described in Section I.C?
- ❖ Does the project carry a high degree of commercial potential, as described in the Product Development Plan?

**C. Additional Criteria for Fast Track Applications (type 1 R42 and type 1 R44 applications)**

- ❖ Does the Phase I application specify clear, appropriate 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 described in Section I.C?
- ❖ 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?

**D. Additional Criteria for Amended Applications (applications with -A1 or -A2 suffixes)**

- ❖ Are the responses to comments from the previous SRG review adequate?
- ❖ Do the changes improve the revised application?

**E. Additional Criteria for Applications Involving Human Subjects Research**

In accordance with NIH policy, the following five subheadings should be addressed in critiques of applications that propose the use of human subjects,<sup>17</sup> and considerations of these points may impact the priority score.

1. Protection of Human Subjects from Research Risks<sup>18</sup> — *for all studies involving human subjects*
  - ❖ If an exemption is claimed, is it appropriate for the work proposed? If no exemption is claimed are the applicant's responses to the six required points<sup>17</sup> appropriate?
  - ❖ Are human subjects placed at risk by the proposed study? If so, are the risks reasonable in relation to the anticipated benefits to the subjects and others? Are the risks reasonable in relation to the importance of the knowledge that reasonably may be expected to be gained?
  - ❖ Are the plans proposed for the protection of human subjects adequate? If not, explain under a new heading "Concerns (unacceptable risks and/or inadequate protections)".
2. Data and Safety Monitoring Plan<sup>18</sup> — *for clinical trials only*
  - ❖ Does the applicant describe a Data and Safety Monitoring Plan that defines the general structure of the monitoring entity and mechanisms for reporting Adverse Events to the NIH and the IRB?

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<sup>17</sup> Reviewers should refer to the document "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications" at [http://grants.nih.gov/grants/peer/hs\\_review\\_inst.pdf](http://grants.nih.gov/grants/peer/hs_review_inst.pdf).

<sup>18</sup> Instructions to applicants concerning Human Subjects, and the six required points, are presented on pgs. 18-22, PHS 398 (<ftp://grants.nih.gov/forms/phs398.pdf>) and on pgs. A-17 to A-24, Appendix A, PHS 2001-2 (<http://grants.nih.gov/grants/funding/sbirsttr1/Appendix%20A%20-520Instruct.pdf>). Applicant organizations are NOT required to submit an Assurance or IRB approval at the time an application is submitted. An assurance number issued to a collaborator or contractor is not sufficient.

3. Inclusion of Women Plan<sup>18</sup> — *for clinical research*<sup>19</sup> *only*

- ❖ Does the applicant propose a plan for the inclusion of both genders that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent?
- ❖ Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?

4. Inclusion of Minorities Plan<sup>18</sup> — *for clinical research*<sup>18</sup> *only*

- ❖ Does the applicant propose a plan for the inclusion of minorities that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent?
- ❖ Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?

5. Inclusion of Children Plan<sup>18</sup> — *for all studies involving human subjects*

- ❖ Does the applicant describe an acceptable plan in which the representation of children of all ages (under the age of 21) is scientifically appropriate and recruitment/retention is addressed realistically? If not, does the applicant provide an appropriate justification for their exclusion?

Human Subjects Codes: Reviewers should use the categories "1" to "4" below to summarize the proposed plans for including men and women, children of all ages (under the age of 21), and minorities and their subgroups, as appropriate for the scientific goals of the research. In addition, they should evaluate the proposed plans as "A" (acceptable) or "U" (unacceptable).<sup>20</sup>

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

**F. Additional Criteria**

Biohazards — *may impact the priority score*

- ❖ Is the use of materials or procedures that are potentially hazardous to research personnel and/or the environment proposed?
- ❖ Is the proposed protection adequate?

<sup>19</sup> The 1997 Report of the NIH Director's Panel on Clinical Research (<http://www.nih.gov/news/crp/97report/execsum.htm>) adopted the following definition of Clinical Research: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens or cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies, (2) Epidemiologic and behavioral studies, and (3) Outcomes research and health services research.

<sup>20</sup> For example, proposed studies that involve men and women (over the age of 21), with only minority representation, would be designated "G1, M2, C3". If the reviewers found the representation of these groups to be scientifically acceptable, the studies would be designated "G1A, M2A, C3A". However, if the reviewers found the absence of non-minority subjects to be unacceptable in terms of the study design, the studies would be designated "G1A, M2U, C3A".

Animal Welfare<sup>21</sup> — *may impact the priority score*

- ❖ If vertebrate animals are involved, are adequate plans proposed for their care and use?
- ❖ Are the applicant's responses to the five required points<sup>21</sup> appropriate?
- ❖ Will the procedures be limited to those that are unavoidable in the conduct of scientifically sound research?

Budget — *should NOT impact the priority score*

- ❖ For all applications, is the percent effort listed for the PI appropriate for the work proposed?
- ❖ On applications requesting up to \$100,000 total costs,<sup>3</sup> is the overall budget realistic and justified in terms of the aims and methods proposed?
- ❖ On applications requesting over \$100,000 in total costs,<sup>3</sup> is each budget category realistic and justified in terms of the aims and methods? Reviewers should provide justification for any modification in time or amount that they recommend.

**G. Guide for Preparing Critiques**

Follow the outline below and use the review criteria (Sections VI.A-F) to provide a comprehensive evaluation of the application's strengths and weakness. Written comments are included virtually verbatim in summary statements that are sent to the applicants and NIH staff, so the use of personal identifiers or offensive comments should be avoided.

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**Critique**<sup>22</sup>

**Significance**<sup>23</sup>: all applications

**Approach**: all applications

**Innovation**: all applications

**Investigators**: all applications

**Environment**: all applications

**Progress in Phase I**: Phase II applications only

**Response to Previous Review**: amended applications only

**Product Development Plan**: Phase II and Fast Track applications only

**Protection of Human Subjects from Research Risks**: all applications involving human subjects

**Data and Safety Monitoring Plan**: clinical trials only

**Inclusion of Women Plan**: all applications involving clinical research

**Inclusion of Minorities Plan**: all applications involving clinical research

**Inclusion of Children Plan**: all applications involving human subjects

**Human Subjects Codes**: all applications involving human subjects

**Animal Welfare**: all applications involving vertebrate animals

**Biohazards**: only if a comment is warranted

**Overall Evaluation**: For each application, provide an overall evaluation of its strengths and weaknesses and a preliminary recommendation of its overall scientific and/or technical merit.

**Budget**: all applications

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<sup>21</sup> Instructions to applicants concerning Animal Welfare, including the five required points, are presented on pg. 88 of PHS 398 at <http://grants.nih.gov/forms/phs398.pdf> and on page A-24 in Appendix A, PHS 2001-2 at <http://grants.nih.gov/grants/funding/sbirsttr1/Appendix%20A%20-%20Instruct.pdf>. Applicant organizations that do not have an animal welfare Assurance on file with OLAW are NOT required to submit an Assurance or IACUC approval at the time an application is submitted. An assurance number issued to a collaborator or contractor is not sufficient.

<sup>22</sup> Descriptions based on the applicant's abstract are no longer necessary in reviewers' written critiques.

<sup>23</sup> Reviewers should address commercial potential as part of the Significance section.