**SCIENTIFIC MERIT FOR DoD FUNDED HUMAN RESARCH**

**Background and Instruction for Investigators**

Institutions conducting research funded by different federal agencies are required to comply with all relevant regulations and instructions for those agencies. DoD Instruction 3216.02 requires the IRB reviewing a DoD supported human research study to include in their considerations the "scientific merit" of the research. The requirements for scientific merit extend beyond the baseline determinations required for IRB review that "procedures … are consistent with sound research design and … do not unnecessarily expose subjects to risk.” Scientific merit review entails specific consideration of the alignment of the study design and procedures with the research questions or hypotheses, detailed consideration of scientific and statistical design, feasibility of successfully producing useful and generalizable results, and the value of the research in terms of the overall field in which the research is situated. As many of these issues are likely to be tied to the particular nuances of your field of research, they are probably beyond the ability of the IRB's reviewers to directly assess. In such cases, the IRB utilizes an outside reviewer or "consultant" to provide information and input to the review.

Because you are most familiar with the nature of your research and research field, the IRB asks that you provide a qualified person who is willing to act as a consultant for this review. A qualified person must be familiar with the scientific requirements of your research, and have no conflicts of interest in reviewing your study (for example, the consultant must not be part of your research team, or providing funding your study). Ideally, this will be a person with direct experience in overseeing or conducting human research similar to yours. The scientific merit reviewer will be asked to provide a CV or brief description of their background and experience with the types of research proposed. Per regulation, this consultant may need to be actively involved in the CU Boulder IRB discussion if the study involves higher levels of risk. For most studies, it would be sufficient to have this information provided to the committee using the attached Scientific Merit Letter.

Please provide the consultant with the attached Scientific Merit Letter template and instructions **(remove this guidance document)**. If desired, you may complete the basic background information on the form. The form itself should be on the letterhead of the consultant if possible, and signed by the consultant. When complete, the letter should be submitted directly to the CU Boulder IRB office by the consultant. However, we must receive the letter before the IRB will review your research study.

**REVIEW FOR SCIENTIFIC MERIT FOR DoD-FUNDED HUMAN RESEARCH**

**Instructions for Scientific Merit Consultant**

Greetings from the University of Colorado Boulder Institutional Review Board. CU Boulder has obtained funding from the DoD for a research study. Part of the requirements for providing IRB review for DoD-Funded research is that the IRB consider the "scientific merit" of the research. Scientific merit review entails specific consideration of the alignment of the study design and procedures with the research questions or hypotheses, detailed consideration of scientific and statistical design, feasibility of successfully producing useful and generalizable results, and the value of the research in terms of the overall field in which the research is situated. As many of these issues are likely to be tied to the particular nuances of the proposed field of research, they are probably beyond the ability of the IRB's reviewers to directly assess. We are asking for your help in reviewing the study.

More specifically, we are asking that you review the researcher’s study Protocol and complete the attached form. The checklist below addresses the specific issues that the DoD is interested in as a part of "scientific merit" for a human research study. Please let the committee know of any concerns you might have about the study, or any suggestions you have that might improve the study. These don’t have to be big concerns—we’d also like to know about less serious issues you may have. Please use as much room and as many pages as you like. If there is information missing or you are not able to make the determinations below, please work with the researcher to resolve any problems with the study.

If possible, we would appreciate it you could add your letterhead to the form and sign the document before you return it to us. Please also provide information about your background and experience, either in the location indicated below, or by attaching a copy of your CV.

Once you have completed the form, we would prefer that you send it back directly to the IRB, rather than giving it to the researcher. Please send the form to us by e-mail at irbadmin@colorado.edu.

Thank you very much for your help.

 **[Scientific Merit Consultant Letterhead]**

## **Scientific Merit Letter**

**[Date]**

Institutional Review Board

563 UCB

Boulder, CO 80309

Dear Committee members:

 I have reviewed [**name of PI**]’s human research protocol, **[title of research protocol],** with regard to the scientific merit of the research.

 I understand that [**name of PI**] proposes to **[brief description of research activities to take place].** Regarding scientific merit, I have made the following findings:

|  |
| --- |
| Are the objectives clearly stated to address the research question and hypothesis?  |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Have the investigators presented enough information to follow the logic behind the development of the project and where the project fits in the current or recognized standard of care, practice or state of the art?  |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Are gaps in the literature articulated in a manner that further supports the execution of the protocol?  |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Do the investigators’ and/or their collaborators’ CVs indicate that they have the expertise to execute the methods? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Will the proposed design enable the investigators to meet the objectives? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Are the requested data elements the “minimum necessary” to conduct the study? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Are the correct data elements being collected to meet the primary and secondary endpoints? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Are there data elements that might be useful to the project that the investigators are NOT collecting? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Are all of the necessary resources available (i.e., equipment, instrumentation, lab space, computing resources, etc.), or reasonably be obtainable? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Is there a data security/data management plan in place?  |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| If this is a greater than minimal risk study, then has a Research Monitor been identified, and is thatperson appropriately qualified, and have the time and resources to perform in this role? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Are endpoints provided? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Do the endpoints align with the objectives? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Is the proposed schedule for the study realistic? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Is the statistical analysis plan outlined in the protocol?  |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Are the endpoints used in the statistical analysis? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Are the inclusion and/or exclusion criteria appropriate to the nature of the research, subject population, etc.? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Is information provided that would suggest enrollment goals can be met? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| If applicable, are the controls appropriate? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| When appropriate, is a sample size calculation provided? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Has subject attrition been considered? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present |  |
| Reviewer's Comments:  |
| Have concepts such as missing data, intention to treat analysis, and stratification been addressed? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Has the team met with a statistician or do they have their own statistical support? |
| [ ] Present/Acceptable | [ ] Present/Not Acceptable | [ ] Not Present | [ ] Not Applicable |
| Reviewer's Comments:  |
| Do you believe that this study presents sufficient risk to participants that you should be personally involved in the Institutional Review Board’s discussion of this study? |
| [ ]  YES | [ ]  NO |  |  |
| Reviewer's Comments:  |

Other comments or suggestions:

**[If you have any other comments about this study that you believe would aid the Institutional Review Board in its review of this study, please add them here.]**

Sincerely,

**[name and title**

**agency/institution**

**contact information (email preferred)]**

**[Provide a brief description of your background and experience in conducting, reviewing or overseeing human research, OR include a copy of your CV with this letter when returning it to the IRB]**

Please return this form to the University of Colorado Boulder Institutional Review Board via email as attachment to irbadmin@colorado.edu.