PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK

REVIEWER RESPONSIBILITIES: Create a "*Protection Of Human Subjects From Research Risk*" heading in your written critique (using upper and lower case letters as shown).
Federal regulations (45 CFR 46.120) require that the information provided in the application (Human Subjects section E or other sections of the application) must be evaluated with reference to the following four criteria:

(1) Risk To Subjects;

(2) Adequacy Of Protection Against Risks;

(3) Potential Benefits Of The Proposed Research To The Subjects And Others;

(4) Importance Of The Knowledge To Be Gained.

Evaluate the information provided in the application, and indicate whether the information is "Absent" or Protection Of Human Subjects From Research Risk is Acceptable or Unacceptable or that the proposed research is "Exempt".

Scoring Considerations:

If the Protection Of Human Subjects From Research Risk is Unacceptable it should be reflected in the priority score for scientific and technical merit assigned to the application. The negative impact on the score should reflect the seriousness of the human subjects concerns that are identified. Reviewers may also recommend limitations on the scope of the work proposed, imposition of restrictions, or elimination of objectionable (risky) procedures involving human subjects.

If the research risks are sufficiently serious and protections against the risks are so inadequate as to consider the proposed research unacceptable on ethical grounds, reviewers may recommend that no further consideration be given to the application and score the application as NRFC (Not Recommended for Further Consideration).

Your evaluation is independent of any other group who will review the research. (NIH policy no longer requires documentation of Institutional Review Board (IRB) approval at the time of the initial peer review http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html).

Absent If the applicant does not address any of the Human Subjects elements that are specifically required in the PHS 398 instructions, begin your comments in the Human Subjects section with the words "Human Subjects Information Absent" and call the Scientific Review Administrator. The application cannot be reviewed without this information.

Acceptable If the applicant has adequately and appropriately addressed the four Human subjects criteria and there are no concerns as defined in the glossary of terms, then, enter the words Acceptable risks and/or adequate protections.

Other issues related to the inclusion of human subjects, which are not concerns, may be communicated to the applicant or NIH staff in this section of your critique.

Unacceptable If the applicant has not adequately and appropriately addressed the four criteria in the application and/or you identify human subjects concerns, then, begin your comments with the words "Unacceptable Risks and/or Inadequate Protections." Document and specify the actual or potential issues that constitute the unacceptable risks or inadequate protections against risks.

Human subjects concerns (see Glossary) should be described in your reviews, whether or not you recommend that the application be scored.

Exempt: If the application indicates that the Human Subjects research is exempt from coverage by the regulations, then determine whether the information provided conforms to one of the categories of exempt research and whether the information justifies the exemption claimed. If it is exempt, state "Exempt" and specify which exemption or exemptions apply (see Glossary for list of Exemption categories).

If an exemption is claimed and you determine that the information provided does not justify the exemption, then, indicate Unacceptable and indicate why you have determined that the information provided does not justify the exemption.

Where is the human subjects information located in an application?

The PHS form 398 grant application requires that applicants provide information about human subjects involvement and protections from research risk in the RESEARCH PLAN and the Appendices (if applicable).