



**Walter Reed Army Institute of Research
Standard Operating Procedure**



SOP Title	REVIEW OF HUMAN SUBJECTS RESEARCH BY THE FULLY CONVENED WRAIR INSTITUTIONAL REVIEW BOARD	SOP No.	UWS-HP- 628.02 Appendix C
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Note: This OPTIONAL sample template lists the main issues and questions that you should consider and evaluate during review of the protocol. Its purpose is to help you organize the review and remember what issues have and have not been addressed during the WRAIR IRB's review of the protocol, and for presenting the review to fellow IRB members at the start of the protocol's discussion. The most applicable Belmont Report principle is included next to each review item.

Appendix C

**WRAIR Institutional Review Board
Primary Reviewer Worksheet**

1. Purpose of study:

2. Summary (background, number of study arms, controls, IND, etc.):

3. Investigator(s) (Qualified? Conflict of interest?) [Beneficence] :

4. Study population and recruitment practices:
 - Includes vulnerable subjects? (children, etc.) [Respect for Persons]
 - Subject recruitment (who, where, how?) [Beneficence]
 - Payment or reimbursements (coercive?) [Beneficence]
 - Is subject selection likely to be equitable? [Justice]
 - Adequacy of procedures to protect vulnerable subjects [Respect for Persons]:

5. Informed consent process (written, surrogate, etc.) [Respect for Persons] :

6. Birth control [Beneficence] :

7. Genetic testing/tissue repository [Respect for Persons and Beneficence] :
 - Will the subjects or their doctors be given research results?
 - Are they informed of this before enrolling?

8. Cost (relative to non-research cost):
 - Will subjects understand increased cost? [Respect for Persons]



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Are subjects coerced to accept increased cost? [Beneficence]

9. Risks (relative to non-research alternative) [Beneficence]

Rate risk level as (1) minimal, (2) moderate, or (3) high:

Absolute Relative

Risks are minimized (appropriate control group?)

10. Potential benefit (direct for the subject versus altruism):

11. Risk/benefit analysis [Beneficence]:

Risks are minimized and reasonable in view of potential benefits.

12. Confidentiality [Respect for Persons]:

Provisions to protect privacy and confidentiality are adequate.

13. Data oversight [Beneficence]

How will data be monitored?

Stopping rules are explained and sufficiently detailed.

14. Consent document [Respect for Persons]

Accurately describes the essential elements in a way that is likely to be understood by the expected subject population

15. Primary Reviewer's recommendation for approval: