

Scientific Review Checklist for Research Protocols

Date:

Reviewer (name):

Title of Project:

NAMRU-SA Lead Investigator (name):

Principal Investigator, if different from above (name):

Part A – Significance

Please verify that the investigator has provided adequate information in the following areas:

	Yes	No	NA
a. Is the research innovative?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Is there military relevance to the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Does this study address a problem of scientific and/or practical importance?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Does the protocol define the underlying basic research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Does the protocol explain how the project will be a significant addition to the body of knowledge?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Other (please describe)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

Part B – Rationale/Approach & Design

	Yes	No	NA
a. Is there a clearly stated hypothesis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Is the number of objectives reasonable such that the scope of research is appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Are the research procedures adequately defined and are they valid?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Does the strength of the scientific design and methodology support the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Do the endpoints (i.e. methods, data collection) match the objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Are adequate measures described in the protocol to minimize investigator bias?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Are there appropriate references or SOPs to ensure that research assays will generate valid data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Is the investigator's evaluation of the relevant literature or discussion of previous studies (if available) thorough and accurate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Are the proposed methods and assays appropriate for the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Is the statistical analysis plan reasonable and detailed (when appropriate)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. Is there a description of the data analysis plan with appropriate statistical tests? (The data analysis plan should be consistent with the study objectives.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. Are the conceptual framework, design, methods and analyses adequately developed, well-integrated and appropriate to the aims for the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. Does the Investigator acknowledge potential problem areas and consider alternative tactics?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n. Is data analysis plan consistent with the study objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o. Is there rationale for the proposed number of subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. Where appropriate, are there details to explain how missing data will be addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
q. Other (please describe)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments or Concerns:

Part C – Investigator

- | | Yes | No | NA |
|---|--------------------------|--------------------------|--------------------------|
| a. Is the investigator appropriately trained to conduct this study? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Is the work proposed appropriate to the experience level of the principal investigator and associates? | | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Other (please describe) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments or Concerns:

Part D – Environment

I have personally reviewed:

- | | Yes | No | NA |
|---|--------------------------|--------------------------|--------------------------|
| a. Does the scientific environment in which the study will be done contribute to the probability of success? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Does the proposed study take advantage of the unique features of the scientific environment or employ useful collaborative arrangements? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Are the facilities appropriate? | | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Other (please describe) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Comments or Concerns:

Part E – Reviewer Recommendation

Recommended SRB Action (*check one*):

- Approve as submitted
- Modifications required to secure approval described below
- Disapprove for the reasons described below

Comments or Concerns:

 Signature of Reviewer

 Date

 Signature of SRB Chair

 Date