DATE:

CFAR Clinical Research Studies Checklist

For Studies Above Minimal Risk

1. CFAR INSTITUTION:	2. CFAR GRANT NUMBER:

3. CFAR PROJECT INVESTIGATOR'S NAME:

4. TITLE OF PROJECT:

5. TOTAL Dollar Award $

6. HUMAN SUBJECTS CERTIFICATIONS

☐ ATTACHED (for all key personnel)
☐ PARTIALLY ATTACHED (some personnel)
☐ PENDING (to be forwarded after training)

7. IRB APPROVAL:

☐ IRB APPROVAL LETTER ATTACHED

_____ _____
IRB # *Approval Date*

☐ PENDING (to be forwarded)
☐ EXEMPT (attach documentation)

8. Federal Wide Assurance (FWA)
For each performance site:

☐ Institution FWA Number
☐ Other FWA # _____

9. Protocol:

☐ Draft Protocol attached
(Final protocol to be forwarded)

☐ Final Protocol attached

10. Informed Consent:

☐ Draft Document attached
(Final document to be forwarded)

☐ Final Document attached

11. Data Safety and Monitoring*:

☐ DSMP (Data Safety Monitoring Plan) description included

☐ DSMB (Data Safety Monitoring Board) description included

*Note: DSMP or DSMB required

12. Explain how the Project PI will handle and report **serious adverse events (SAEs).**

13. ☐ Copy of **project / grant application** attached

14. ☐ **Biosketches/CV** attached

15. ☐ If the project involves **International collaboration**, please also fill out the international checklist form

☐ N/A (**Domestic** only)

CFAR CLINICAL RESEARCH STUDIES

NIH definition of a **Clinical Trial** (NOT-OD-15-015)- A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

For clinical studies that also have an international component, please also submit the CFAR International Studies Checklist. **International components of a project cannot be initiated without International Clearance.**

I. Studies that cannot be funded through the CFAR

- Any clinical trial as defined above
- Studies involving new drugs, treatments, or devices

II. Studies that can be funded via CFAR but require additional NIH review

- Studies involving **new ways of using known drugs, treatments, or devices** (allowed on a case-by-case basis)
- Studies that are deemed **above minimal risk** by the Institutional IRB
- Studies involving **vulnerable populations** (children, pregnant women, transgender, sex workers, prisoners, refugees, individuals who are unable to provide informed consent, etc.)
- Studies involving **behavioral interventions** (above minimal risk)

For studies in this category, please send the clinical research protocol and informed consent documents. **Consultation with the Clinical Core is encouraged to ensure completeness of documents prior to submitting to NIH. No human subject work may be initiated until clinical approval is received.**

III. Studies that do not require additional NIH review

Research activities that do not include vulnerable populations (see Category II above) and present **no more than minimal risk** to human subjects as described in the OHRP Expedited Review Categories. Examples include but are not limited to the following:

- routine blood draws
- non-invasive procedures routinely employed in clinical practice (e.g. ultrasound, MRI)
- surveys, focus groups

For studies in this category, please include IRB approval dates in the annual progress report.