CFAR CLINICAL RESEARCH STUDIES

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, prisoners, individuals who are unable to provide informed consent, etc.)
- Studies with populations with additional considerations for **confidentiality and safety** (transgender, sex workers, refugees, etc.)
- Studies involving **behavioral interventions** (above minimal risk)

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