CFAR-Supported International Studies Checklist

DATE:

1. CFAR PRINCIPAL INVESTIGATOR'S NAME:

2. CFAR INSTITUTION:

3. CFAR GRANT NUMBER:

4. TITLE OF PROJECT:

5. COUNTRY OF PROJECT:

6. PROJECT FIELD SITE(S):

7. DOMESTIC PROJECT INVESTIGATOR*

Name:
Organization:
Address:
City, State, and Zip:
Phone:
Fax:
Email:

**If multiple investigators are involved, provide name of each key investigator. (Use additional sheets as necessary).*

8. Estimated TOTAL Dollar Award (Domestic AND Foreign)

8a. 1st Year
$

8b. 2nd Year (if applicable)
$

9. FOREIGN PRINCIPAL OR COLLABORATING INVESTIGATOR(S)^

Name:
Organization:
Address:
City and Country:
Phone:
Fax (if applicable):
Email:

**If multiple sites or countries are involved, provide contact info for each foreign site. (Use additional sheets as necessary).*

10. Estimated FOREIGN Dollar Award (Foreign Component ONLY)

10a. 1st Year
Site 1:$
Site 2:$(Please add additional as necessary)

10b. 2nd Year (if applicable)
Site 1:$
Site 2:$ (Please add additional as necessary)

11. HUMAN SUBJECTS INVOLVEMENT:

☐Yes ☐No (Skip to #12)

11a. Federalwide Assurance (FWA) for Foreign Performance Site(s):

☐ FWA Number(s) _____
☐ Pending (to be forwarded when obtained)

11b. CERTIFICATES of HUMAN SUBJECTS RESEARCH PROTECTION

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

11c. U.S. (DOMESTIC) IRB APPROVAL:

☐ IRB APPROVAL LETTER ATTACHED

_____ _____
U.S. IRB # *Approval Date*

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

11d. FOREIGN IRB/ETHICS APPROVAL:

☐ IRB APPROVAL LETTER ATTACHED

_____ _____
Foreign IRB # *Approval Date*

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

12. ANIMAL INVOLVEMENT:

☐Yes ☐No (Skip to #13)

12a. Office of Laboratory Animal Welfare (OLAW) for Foreign Performance Site:

☐ OLAW Number _____
☐ Pending (to be forwarded when obtained)

12b. U.S. Institutional Animal Care and Use Committee (IACUC) Approval:

☐ IACUC APPROVAL LETTER / DOCUMENTATION ATTACHED

_____ _____
U.S. IACUC # *Approval Date*

☐ EXEMPT (attach documentation)

12c. FOREIGN Institutional Animal Care and Use Committee (IACUC) Approval:

☐ IACUC APPROVAL LETTER / DOCUMENTATION ATTACHED

_____ _____
Foreign IACUC # *Approval Date*

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

☐ PENDING (to be forwarded when obtained)	

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CFAR-Funded International Studies Checklist *(continued)*

13. STUDY DESCRIPTION

The study description should be written in third person and in lay language. Indicate the **research objectives** (like an abstract from an R01 application), including what the project is trying to accomplish and briefly, how. Include information on the **study population** (number, age, gender, HIV status, study site, and nature of study participation). If **samples** are to be obtained, please describe the samples and how often they will be collected. Do not cut and paste abstract. *Use additional pages as needed.*

13a. Describe how **human subjects' protection** will be maintained including the informed consent process (language used, written or verbal consent, who obtains consent) and confidentiality.

14. Describe the **CFAR Cores** that will be used and the type of support that will be provided.	**15.** Describe any **NIH programs** (indicate PI, title and corresponding grant number) linked to this project. *This may help facilitate the approval process.*
☐ **16.** Copy of **project / grant application** attached	☐ **17. Related correspondence** attached (e.g. letters of collaboration or support)

Guidance for NIH Approval Process
For CFAR-Supported International Studies
Research Objectives Description

Purpose:
- To provide enough detail about the project to enable assessment and approval of the project in foreign countries.
- To serve as a record of the type of CFAR-associated projects taking place at international sites.

General guidance:
- Write in non-scientific terms (lay language).
- Write in the third person.

Format:
- Brief statement of project goal (1-3 sentences).
- Description of activities that will be carried out at the foreign site (1-2 paragraphs).

If substudy: If the pilot study is nested within another ongoing study (NIH or other), please provide, at minimum, the following information on that study: Study title, PI, grant number, funding agency, and existing IRB approvals. This could help speed up the approval process.

If renewal: For continuing research at previously approved sites, state in the first sentence that the research is a continuation which was previously approved.

If human subjects are involved include the following study details, as applicable:
- The demographics (age range, gender, etc.).
- The number of subjects (and how they will be recruited, if known).
- HIV status (positive, negative, both, or unknown).
- What participation will entail (clinic visit, questionnaire, blood sample, treatment, etc).
- How long subjects will participate (e.g., one clinic visit a month for a year).

Include details on human subjects protection and confidentiality:
- Statement on protection of welfare of humans subjects.
  - Describe informed consent and confidentiality procedures to be used.
  - e.g. "Informed consent for participation will be obtained from all human subjects and confidentiality of subjects will be protected, in compliance with NIH and in-country guidelines under the assurance number provided."

If human subjects data or samples are pre-collected:
- State that data/samples were collected under another project.
- State that data/samples are anonymous (if de-identified) or how confidentiality will be ensured if not anonymous.
- If data/samples collected under another project *and* are anonymous: State that the study is not considered "human subjects research" because data/samples were previously collected and anonymous, as determined by the IRB (note: no FWA is needed).

If animal subjects are involved, include:
- The species of animal
- A brief description of what they will be used for (e.g., "…using a mouse model…")

EXAMPLES

An example with human subjects:
This pilot study will be conducted to determine the factors that are associated with treatment failure of AIDS/HIV in Botswana. The researchers will evaluate the use of pill count records as a valid measure of adherence, describe adherence patterns to ARVs, and determine baseline treatment characteristics associated with treatment failure. Participants will be HIV-infected patients aged 18 and older on antiretroviral therapy for greater than 6 months who will be selected from the clinic population. Participation in this study will involve only one study visit that will coincide with the patient's regularly scheduled clinic visit. Patients who provide written informed consent will provide their medical card and access to their computerized data. The clinical and demographic data will be abstracted from the medical record in the IDCC by the study coordinator. Paper records will be maintained in a locked filing cabinet in a locked office and the computerized database will be password protected and maintained on a password protected computer. Data will be transferred to electronic records which will be delinked from the identifiers and only maintained using study ID numbers. The identifiable data will be maintained in a separate file that analysts will not be given access to.

An example using specimens:
The purpose of this grant is to establish an International Consortium to study a region on chromosome 1q that has repeatedly shown evidence for linkage to type 2 diabetes. This International Consortium will study DNA samples from Europeans, East Asians, Native American and African American populations. All samples in France have already been collected with appropriate bioethical approval and are anonymous. By densely genotyping this region using SNP technology and the information provided by the Hapmap, this Consortium will try to identify the genetic variations that predispose to type 2 diabetes.

An example with animal subjects:
The purpose of the project is to explore regional and temporal specificity of the GDNF depletion using tissue culture and transplantation of defined brain regions in mice. This project will test if the brain-specific alterations observed are caused by a loss of GDNF in the brain, or by interaction with peripheral organs; if the alterations persist in transplants of brain tissue, this suggests that peripheral organs play less of a role in the results than the growth factor loss in the brain.

A basic science example (no human or animal involvement)
Berberine and coptise are components of a Chinese herbal medicine (Coptis chinensis) that has been used to treat gastroenteritis for thousands of years. The PI has demonstrated that these components also have anti-tumor activity. The goal of this project is to confirm the relationship between coptise and berberine, the down-regulation of NCOA-5, and the impact on tumor activity. First, he will determine if berberine and coptise down-regulate NCOA-5 in a dose-dependent manner. In a complementary experiment, he will determine whether over-expression of NCOA-5 abolishes or diminishes the anti-tumor activity of berberine and coptise. Finally, he will determine whether deletion of NCOA-5 will sensitize cancer cells to berberine and coptise treatment. These experiments should further elucidate whether NCOA-5 serves as a cellular target for the components of this Chinese herb allowing it to act as an anti-tumor agent.