*If a Pilot Application will have two foreign sites, complete this form for EACH research site. Please use this guidance on definition of a foreign component for the Foreign Clearance Form.*

**Definition of Foreign Component for Foreign Clearance Form:** *Definition of foreign component: The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are: collaborations with investigators at a foreign site anticipated to result in co-authorship; use of facilities or instrumentation at a foreign site; or receipt of financial support or resources from a foreign entity. Foreign travel for consultation is not considered a foreign component.*

**Foreign Site Information**

|  |  |
| --- | --- |
| **Principal Investigator Name:** |  |
| **Project Title:** |  |
| **Institution:** | This is the institution that will be administering the award |
| **Foreign Research Site:** | Location of foreign research activities |
| **Point of Contact for Research Site:** | Name, organization, address, email, and phone number |

**Introduction (3-4 sentences):**

**Provide a simple description of the overall goals of the project including the work that will be done at the foreign site. Indicate if any of the NIAID grant funds will be sent to the foreign site.**

The goals of this project are…

To achieve these goals, the investigator will collaborate with…

$X of grant funds will be sent to the site for these studies.

**Foreign component (3-4 sentences):**

**Describe the specific role of the foreign site (i.e. conduct critical experiments?, conduct data analyses?, provide consultations?, provide samples?, study human and/or animal populations?, conduct observational or interventional clinical trials?, collect samples and/or data to be brought to the US?).**

The site will…

**Human Subjects (1 word or 1 sentence per bullet):**

* **Parent Study IRB approval**
  + **IRB approval number for parent study:** #
  + **IRB approval date:** DD-MMM-YYYY
  + **Human Subject Assurance Number:** #
* **Does this study require a modification to the IRB approval of a parent study (Yes or No)?**
  + **?**
* **Will existing samples from human subjects will be used: (Yes or No)?**
  + **?**
  + **How many subjects provided the existing samples to be used?** #
* **Will human subjects be recruited (Yes or No)**
  + **?**
  + **Number of human subjects that will be recruited:** #
* **Population parameters:**
  + **Gender:** # males, # females
  + **Age Group:** ages # - #
  + **Race/Ethnicity:** # Caucasian subjects, # subjects of African ancestry, # subjects of Asian ancestry, etc.
* **Sample collection will include:**
  + **Blood:** Yes or No
  + **Urine:** Yes or No
  + **Tissues:** Yes or No
  + **Other samples (describe):** ?
* **Sample collection will be completed in how many visits:** #
* **Will samples be de-identified (Yes or No)? If No, describe how they will be protected.**
  + ?
* **Will local IRB approval be obtained prior to engaging in any research involving human subjects (Yes or No)? If No, describe alternate approvals being sought or state why local IRB approval is not required.**
  + ?
* **Will informed consent be obtained prior to engaging in any research involving human subjects (Yes or No)? If No, describe alternate approvals/consents being sought or state why informed consent is not required.**
  + ?
* **Will samples be brought back to the US (Yes or No)?**
  + ?
* **Will data be brought back to the US (Yes or No)?**
  + ?

**Animal Subjects (1 word or 1 sentence per bullet):**

* **Parent study IACUC approval**
  + **IACUC approval number for parent study:** #
  + **IACUC approval date:** DD-MMM-YYYY

**Animal Welfare Assurance Number:** #

* **Does this study require a modification to the IACUC approval of a parent study (Yes or No)?**
  + **?**
* **Will existing samples from animal subjects will be used: (Yes or No)?**
  + **?**
  + **How many animal subjects provided the existing samples to be used?** #
* **Will vertebrate animals be collected (Yes or No)?**
  + **?**
* **Species of animals (e.g. rats, mice, rabbits, monkeys):** ?
* **Animal parameters:**
  + **Total number of animals:** #
  + **Gender:** # males, # females
  + **Age range:** # - # weeks/ months/ years
  + **Lab strain (e.g. Sprague-Dawley rats, Balb/C mice):** ?
  + **Wild animals procured in country (e.g. Rhesus monkeys from a reserve):** ?
* **What will be done to them or with them and how often?**
  + ?
* **What are the follow-ups?**
  + ?
* **What will be their fate at the end of the experiments – will they be euthanized?**
  + ?
* **Will in-country clearances be obtained prior to engaging in any animal research (Yes or No)? If No, describe alternate approvals or state why in-country clearances are not required.**
  + ?
* **Will samples be brought back to the US (Yes or No)?**
  + ?
* **Will data be brought back to the US (Yes or No)?**
  + ?