|  |  |
| --- | --- |
| **\\crdf.org\crdfiles\DER\Communications\Organizational Use Folders and Files\CRDF GLOBAL LOGOS\LOGOS\CRDF Global_logo_only_V1.jpg** | **Protocol Summary Form (PSF)****for Human Subjects Research** |
| Project Title |  |
| CRDF Global Proposal # |  |
| CRDF Global Program |  |
| [**Primary/Principal Investigator**](#pi) **(PI) and Institution Information.** For projects that include a collaborative team composed of more than one institute, please duplicate this entire table for each institution included in the project.  |
| Name (Last, First, Middle) |  |
| Institution & Department |  |
| City, Country |  |
| E-Mail Address |  |
| **Project Information** |
| Provide a brief description of the project: |
|  |
| Describe the portion of the project involving human subjects, including interactions with study subjects, collection of samples ([prospective](#prospective) or [retrospective](#retrospective)), and/or any procedures to be performed: |
|  |
| Will any employee of this institute, or any individual involved with the study: |
| 1. Participate in the [collection](#collection) of human data, information or biospecimens?
 | **YES** [ ]  | **NO** [ ]  |
| 1. Participate in the [handling](#handling) of human data, information or biospecimens?
 | **YES** [ ]  | **NO** [ ]  |
| 1. Interact directly with the study subjects?
 | **YES** [ ]  | **NO** [ ]  |
| 1. Have access to [personally identifiable information](#pii) of the study subjects?
 | **YES** [ ]  | **NO** [ ]  |
| If the answer to all of the above is “no,” please submit this form with your proposal application along with any institutional materials that will support the statements above. If the answer to any of the above is “yes,” please continue to complete the sections below. |
| **Ethics Review Information** |
| Does any project PI have, or plan to apply for, a [research ethics committee](#researchethics) approval for this study? | **YES** [ ]  | **NO** [ ]  |
| Please provide more information on the research ethics committee: |
| [ ]  Planning to apply | Ethics review entity: |  |
| [ ]  Application pending approval | Ethics review entity: |  | Application Date:  |  |
| [ ]  Approval received | Ethics review entity: |  | Approval Date: |  |
| Is the institutional research ethics committee registered with OHRP[[1]](#footnote-1)? | **YES** [ ]  | **NO** [ ]  |
| If no, please explain: |  |
| *I certify that the information above is true and accurate to the best of my knowledge. I understand that CRDF Global funds may not be used to support human subjects research beyond that described in this form and that any misrepresentation of research activities may result in forfeiture of the CRDF Global award and inability to participate in any future programs.* |
| Submitted By: |
|  |  |
| Signature |
| Name and Title |  | Date |

# **Glossary**

**Collection:** Collection is the process of finding and gathering information, human data, and/or physical biospecimens.

**Handling:** Handling is the process of using, analyzing, or working with information, human data, and/or physical biospecimens.

**OHRP:** US Office of Human Research Protections (OHRP). OHRP provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the US Government. Institutions involved in human subjects research must obtain the following registrations from OHRP:

**IORG:** IRB Organization (IORG).

**IRB:** Institutional Review Board (IRB).

**FWA**: Federalwide Assurance (FWA)

An institution must have an IRB Organization (IORG) with an Institutional Review Board (IRB) and Federalwide Assurance (FWA) registered with OHRP to receive CRDF Global support for research involving human subjects. Should circumstances prohibiting registration arise, CRDF will consider an exemption and/or alternative measures on a case by case basis. IRBs are operated by IRB Organization (IORG), and each IORG can register one or more IRBs with OHRP. An institution must have an FWA that designates at least one IRB registered with OHRP. An IRB is a committee that performs ethical review of proposed research. For more information about OHRP and how to register visit: <http://www.hhs.gov/ohrp/assurances/index.html>

**Personally Identifiable Information (PII)**: PII is any data that could potentially identify a specific individual. Examples include name, government ID number, address, and combinations of gender, age, or other demographic information in which the subject’s identity could be determined.

**Primacy/Principal Investigator (PI):** A PI is the primary individual responsible for the preparation, conduct, and administration of a research grant, training or public service project, contract, or other sponsored project in compliance with applicable laws, regulations, and institutional policy governing the conduct of sponsored research.

**Prospective Study:** A prospective study watches for outcomes, such as the development of a disease, during the study period and relates this to other factors such as suspected risk or protection factor(s). The study usually involves observing a cohort of subjects over an extended period of time.

**Research Ethics Committee**: A research ethics committee is formally designated by a research institution or a local governing body to ensure the protection of the rights, safety, and well-being of human subjects involved in a study and to provide public assurance of that protection by reviewing and approving/providing favorable opinion on the study protocol. Ethics committees exist under a variety of titles, including Research Ethics Committee, Institutional Review Board (IRB), Independent Ethics Committee (IEC), Ethics Review Board, Health Research Ethics Committee, etc.

**Retrospective Study:** A retrospective study looks backwards and examines exposures to suspected risk or protection factors resulting in an outcome of interest that has already occurred at the time the study is initiated,

1. The [Office for Human Research Protections (OHRP)](https://www.hhs.gov/ohrp/) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). [↑](#footnote-ref-1)