**Guidelines for Proposals Involving Human and/or Animal Research Subjects**

CRDF Global is committed to ensuring that projects involving human or animal research are conducted in accordance with all applicable regulations and ethical guidelines. All projects recommended for award that involve human or animal subjects will undergo a review by the CRDF Global Bioethics Review Committee (BRC) prior to Award request. Following are instructions for the documentation required at this proposal stage.

**Human Subjects**

Projects involving research with human subjects must ensure that subjects are protected from research risks in conformance with all applicable regulations and ethical guidelines. Human subject research is defined as an activity that involves obtaining information about living individuals by an intervention or interaction with said individuals. Activities classified as human subjects range from the undertaking of clinical trials, to conducting verbal or written surveys of study participants.

Each principal institution (e.g. each institute in a joint collaboration) represented on a proposal involving human subjects must include a CRDF Global Summary Protocol Form (PSF): Human Subjects (Short Form), to be uploaded separately from the proposal during electronic submission. The PSF collects details specific to the proposed human involvement: type of human interaction, consent and de-identification protocols, and ethical committee approvals.

Prior to award initiation by CRDF Global, all projects involving human subjects must submit:

1. Written approval from each responsible Institutional Review Board (IRB) or equivalent ethics committee; OR Written research exemption from each responsible IRB, or equivalent.[1]
2. Documentation of IRB registration and Federalwide Assurance (FWA) filed with the U.S. Department of Health and Human Services (HHS), Office of Human Research Protections (OHRP) prior to the commencement of any research.

Supporting documents (IRB/equivalent) are not required at the time of proposal submission. At the proposal stage only the PSF is required. Upon finalist award selection, CRDF Global will provide guidance on specific supporting documentation required.

**Animals Subjects or Animal Biomaterials**

Projects involving research with animal subjects must demonstrate that subjects are protected from research risks in conformance with all applicable regulations and ethical guidelines. Projects involving animal subjects are those that include handling and/or care of live, vertebrate animals for research, testing, experimentation or educational purposes.

Each principal institution (e.g. each institute in a joint collaboration) represented on a proposal involving animal subjects must include a CRDF Global Summary Protocol Form (PSF): Animal Subjects, to be uploaded separately from the proposal during electronic submission. The PSF collects details specific to the proposed animal usage: type of animal(s), necessity and role in proposed research, and other relevant details (how obtained, housed, post-study, etc.).
Prior to award initiation by CRDF Global, all projects involving animal subjects must submit:

1. Written approval from each responsible Institutional Animal Care and Use Committee (IACUC), or equivalent ethics committee OR Written research exemption from each responsible IACUC, or equivalent.[2]

Supporting documents (IACUC/equivalent) are not required at the time of proposal submission. At the proposal stage only the PSF is required. Upon finalist award selection, CRDF Global will provide guidance on specific supporting documentation required.

[1] If no IRB approval or waiver is provided, CRDF Global may decline to support the project

[2] If no IACUC approval or waiver is provided, CRDF Global may decline to support the project