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| \\crdf.org\crdfiles\DER\Communications\Organizational Use Folders and Files\CRDF GLOBAL LOGOS\LOGOS\CRDF Global_logo_Tagline_V1.jpg | Guidelines for Projects 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 bioethics review prior to award activation. Following are instructions for the documentation required at this proposal stage.

**Human Subjects Activity**

Human subject activity includes any 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.

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

1. Documentation of Institutional Review Board (IRB) registration and Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services (HHS), Office of Human Research Protections[[1]](#footnote-1) (OHRP). This information must be submitted to CRDF Global using the **Bioethics Review Form** found in Appendix A.
2. Written approval from each responsible IRB or equivalent ethics committee; **OR** Written research exemption from each responsible IRB, or equivalent. The written approval or exemption notice must clearly include the name of the project (that matches information provided to CRDF Global) and period for which the approval/exemption is valid.

**Animal Subjects Activity**

Animal subject activity is defined as any activity that involves handling and/or care of live, vertebrate animals for research, testing, experimentation or educational purposes.

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

1. Documentation of certification by the Association for Assessment and Accreditation of Laboratory Animal Care International[[2]](#footnote-2) (AAALAC International). This information must be submitted to CRDF Global, using Bioethics Review Form found in Appendix A.

OR

1. Submission of the CRDF Global Summary Protocol Form (PSF), which collects details specific to the proposed animal usage, including type of animal(s), necessity and role in proposed research, and other relevant details (how obtained, housed, post-study, etc.).
2. 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.

**CRDF Global reserves the right to request additional information to ensure compliance with US regulations. Awards will not be issued for any projects involving human or animal subjects until these requirements are satisfied. CRDF Global may consider exceptions to these requirements for documented extenuating circumstances, as permitted by US regulation.**

APPENDIX A

Bioethics Review Form

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 bioethics review prior to award activation. The Principal Investigator (PI) must submit this form to CRDF Global within 2 weeks of receipt

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| Project Name: | |  | | | | | | | | |
| Principal Investigator (PI) Name: | |  | | | | | | | | |
| PI Contact Information: | | **Telephone:** | | | | | | **E-Mail:** | | |
| Institution Name: | |  | | | | | | | | |
| Institution Website: | |  | | | | | | | | |
| Does your project involve: | | Human Subjects | | Animal Subjects | | | | | Recombinant DNA | |
| ***If you checked the box for Human Subjects, you must submit the information below.***  ***To obtain these numbers (#), please visit OHRP website:*** [***https://www.hhs.gov/ohrp/irbs-and-assurances.html***](https://www.hhs.gov/ohrp/irbs-and-assurances.html) | | | | | | | | | | |
| OHRP IRB#: |  | | OHRP FWA#: | | | |  | | | |
| ***If you checked off the box for Animal Subjects above, you must check one of the options below.*** | | | | | | | | | | |
| AAALAC Accreditation: | | | | | | Yes  No | | | | |
| *All projects with human or animal subjects must submit either approval or exemption notice from their IRB or IACUC (as applicable).*  *The notice must include project name and, period for which approval/exemption is valid.* | | | | | | | | | | |
| IRB/IACUC Approval/Exemption Notice Attached: | | | | | | Yes  No | | | | |
| ***If you answered No above you must complete the following section, to the best of your knowledge*** | | | | | | | | | | |
| Date by which IRB Approval/Exemption notice will be submitted to CRDF Global: | | | | | | | | | | *MM-DD-YYYY* |
| Submitted By: | | | | | | | | | | |
|  | | | | |  |  | | | | |
| Name and Title | | | | |  | Date | | | | |

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)
2. [American Association for Accreditation of Laboratory Animal Care (AAALAC)](https://www.aaalac.org/accreditation/index.cfm) is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. [↑](#footnote-ref-2)