# WorldFish Animal Care and Welfare Policy

Version 1.0.0
1 June 2019

| Document Summary | |
|---|---|
| Policy Title | Animal Care and Welfare Policy<br>(replaces Animal Care and Welfare Policy, 2004) |
| Policy Owner | Global Research |
| Policy Sponsor | Director of Aquaculture and Fisheries Sciences |
| Responsible Office | Global Research |
| Effective date | 18th Nov 2019. |
| Last updated | |
| To be reviewed | |

| Version Control Tracking | | | |
|---|---|---|---|
| Issue Date | Summary of Changes | Distribution | Version Number |
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## 1. Purpose

The mission of WorldFish is to provide technical and policy solutions to improve the lives of present and future generations of people in developing countries who depend on fish and other living aquatic resources. We work to achieve this through world leading and relevant research, partnerships, capacity building and policy support. In the conduct of its research and development, WorldFish researchers will sometimes need to exercise a degree of control over the fish and other living aquatic animals they study, for instance, to identify them in some way, or to subject them to treatments (e.g. nutritional, managerial, hormonal, disease challenges). In extreme cases, fish may have to be killed as part of the studies.

Our values as an organisation encompass:

Integrity and trust

Fairness and equity

Excellence and Innovation

Teamwork and Partnership

Our aim as an organisation is to ensure that all our work is done in an ethical manner. Our obligations in research are to the animals and to the quality of our research, and our legal obligations in each of the countries that we conduct research.

We at WorldFish recognise that fish can detect and react to noxious stimuli or pain. For example, behavioural avoidance responses are often displayed by fish in circumstances that might be expected to involve pain. In addition to concerns about the effect of pain itself, WorldFish recognises that injury or stress to a fish results in poor welfare where there is impairment of function, or increased susceptibility to disease, thus reducing productivity.

## 2. Scope

This policy applies to all scientific staff including primary investigators, project leaders, research technicians and research assistants; staff handling finfish that are employed by WorldFish; and any contractors or third parties that may be collaborating with WorldFish.

Project Partners and funding agencies must be aware of and agree to comply with the WorldFish Animal Care and Welfare Policy.

## 3. Definitions

**Fish** is used in a broad sense, to include invertebrate (if the laws of the country prescribe) as well as vertebrate aquatic animals.

**Care** refers to: (i) the attitude of being concerned with and paying appropriate attention to, and (ii) the acts of looking after, making provision for and protecting someone or something, in our case an aquatic animal.

The **welfare** of an animal refers to its quality of life (e.g. health, general wellbeing, comfort with its surroundings, opportunity to display its natural behaviour, longevity).

**Excessive pain or discomfort** means that which exceeds a perceived lower degree of pain, and that can be reduced by following a practical alternate approach.

**Unnecessary pain or discomfort** means that which is needless because it can be avoided by following a practical alternative approach that can altogether eliminate pain.

**The 3Rs** (Replacement, Reduction and Refinement) provide a framework for humane Fish Use Activities.
Replacement: methods which avoid or replace the use of animals
Reduction: methods which minimise the number of animals used
Refinement: methods which minimise animal suffering and improve welfare

**Ethical principles** pertain to moral views, to judgments about what is good or bad, or right or wrong in conduct.

The **Principal Investigator** is the leader of a team responsible for the conduct of a Fish Use Activity. It is the principal investigator who is responsible for obtaining approval to undertake Fish Use Activities, where required by the WorldFish Animal Care and Welfare Policy.

The **Project Leader** is the person in overall charge of the planning and execution of a particular project. A project may involve multiple Fish Use Activities.

The **Site Manager** oversees the operation and maintenance of physical facilities; such as ponds, equipment, and materials; and/or staff involved in Fish Use Activities at given site.

An **Animal Ethics Committee (AEC)** is an Institutional Animal Care and Use Committee (IACUC) with responsibility for the review, approval and monitoring of Fish Use Activities, in accordance with laws and an institution's policies.

**Fish Use Activities** are research, experimental, selective breeding, educational or other activities involving the use of fish.

**Scientific Purpose** is all those purposes which aim to acquire, develop or demonstrate knowledge or techniques in any area of science including teaching, field trials, environmental studies, research, diagnosis, product testing, and the production of biological products

The **OIE Aquatic Animal Health Code** is an international code that is produced and routinely reviewed by the World Organisation for Animal Health (OIE).

**WorldFish Standard Operating Procedure (WSOP)** is a detailed description of a standardised procedure or process approved by the WorldFish Director of Aquaculture and Fisheries Sciences

Herein **WorldFish Staff** includes people employed by WorldFish and any contractors or individuals from third parties that are collaborating with WorldFish

**Partners** are organisations and institutions that collaborate with WorldFish

## 4. Guiding Principles

- Humans have ethical duties towards animals.
- Ethical principles go beyond feelings, they may be based on reason (e.g. a particular treatment that results in pain to an animal may be justified if in turn it results in a magnified benefit to itself, to its own kind, or to members of other species, including our own).
- The respectful treatment of wild and captive fish in field research is both an ethical and a scientific necessity.
- WorldFish promotes a culture of respect towards the animals with which it works, including when undertaking activities with partner organizations.
- Fish Use Activities involving WorldFish conform to accepted international standards of animal care, welfare and ethics.

## 5. Policy Statements

- The exposure of fish under the care of WorldFish to excessive or unnecessary pain or discomfort must be avoided where practical.
- For Fish Use Activities involving WorldFish where there is modification of the animal's environment, physiology and/or behaviour, and where there are steps or procedures that will cause stress, physical trauma, harm, or death; approval by an Animal Ethics Committee must be obtained prior to the commencement of Fish Use Activities.
- All Fish Use Activities must be conducted in accordance with:
    - the laws of all relevant country(ies)
    - contractual obligations with partners and funding agencies
    - the principles of the 3Rs
    - the requirements of journals in which research is intended to be published.
- All Fish Use Activities involving WorldFish staff must have an identified Principal Investigator.
- All Fish Use Activities that receive approval by an Animal Ethic Committee must be implemented in accordance with the approved methods and any additional conditions specified by the relevant Animal Ethics Committee.

- On the commencement of their employment, all WorldFish staff will be made aware of, and agree to, their obligation to adhere to the WorldFish Animal Care and Welfare Policy.

- If there are any experiments or studies that are being conducted on animals, without the approval of an Animal Ethics Committee, then the Project Leaders and the Director of Aquaculture and Fisheries Science should be notified immediately.

- When possible, WorldFish will encourage its partners to adopt acceptable international standards with respect to animal welfare.

- WorldFish encourages staff to escalate any issues that are not in keeping with the WorldFish Animal Care and Welfare Policy (see below).

## 6. Responsibilities

The **Executive Team** are responsible for:

- approving changes to the WorldFish Animal Care and Welfare Policy
- ensuring that this policy conforms with the mission, values, aims and obligations of WorldFish.

The **WorldFish Director of Aquaculture and Fisheries Sciences** is responsible for ensuring that:

- WorldFish Standard Operating Procedures are reviewed on an annual basis and, where possible, conform with the OIE Aquatic Animal Code
- WorldFish Standard Operating Procedures are readily available to all staff on FishNet
- avenues to obtain approval from an Animal Ethics Committee are available for all Fish Use Activities requiring such approval
- any concerns raised by staff relating to animal cruelty and abuse are investigated
- informing the Director of Human Resources and Administration and, if appropriate, the Director General of any breaches of the WorldFish Animal Care and Welfare Policy by WorldFish staff
- informing the Director General of any breaches of the WorldFish Animal Care and Welfare Policy by partner organisations

The **Director of Human Resources and Administration** is responsible for ensuring that:

- all new staff are made aware of their obligations under the WorldFish Animal Care and Welfare Policy as part of the onboarding process
- ensuring that appropriate disciplinary action is taken against staff that breach the WorldFish Animal Care and Welfare Policy in accordance with WorldFish Human Resource policies and contracts

It is the responsibility of **WorldFish Project Leaders** to ensure that Fish Use Activities undertaken as part of the project:

- are identified when the project is at a conceptual stage and any costs and time associated with the need for Animal Ethics approval are planned for
- are identified in WorldFish's project management system (currently Monitoring, Evaluation and Learning; MEL)

- have a nominated Principal Investigator who is aware of, and agrees to, their responsibilities under the WorldFish Animal Care and Welfare Policy

The **Principal Investigator** of a Fish Use Activity is responsible for:

- ensuring that the Fish Use Activity is conducted in accordance with the WorldFish Animal Care and Welfare Policy - including, if required, the submission of an application for approval to conduct the Fish Use Activity to an Animal Ethics Committee
- ensuring that the Fish Use Activity is conducted in accordance relevant WorldFish Standard Operating Procedures
- ensuring that all participants, including partners, in the Fish Use Activity are made aware of their responsibilities with respect to the WorldFish Animal Care and Welfare Policy
- ensuring all relevant steps in the animal ethics approval process are appropriately recorded in WorldFish's project management system in a timely manner

All **WorldFish Staff** are responsible for:

- complying with, the WorldFish Animal Care and Welfare Policy
- complying with, the relevant animal welfare Codes of Practice and regulations in countries in which they are undertaking Fish Use Activities (refer to Section 7)
- raising any concerns relating to animal cruelty or abuse, or breaches of the WorldFish Animal Care and Welfare Policy with the Principal Investigator, and, if appropriate, the Project Leader, WorldFish Director of Aquaculture and Fisheries Sciences or the Director General.

**Site Managers** are responsible for:

- ensuring that all people undertaking Fish Use Activities on the site are aware of their responsibilities under the WorldFish Animal Care and Welfare Policy
- ensuring that all people undertaking Fish Use Activities on the site are trained in the activities that they need to perform in accordance with relevant WorldFish Standard Operating Procedures

**Project Partners and funding agencies** must:

- be aware of, agree to and comply with the WorldFish Animal Care and Welfare Policy
- ensure their staff are aware of their obligations under the WorldFish Animal Care and Welfare Policy

# WORLDFISH POLICY ON ETHICS OF RESEARCH INVOLVING PEOPLE

## 1. General information

Version: 1 (approved by WorldFish BoT on 28 February 2017)

Executive Sponsor: Michael Phillips, Director – Aquaculture and Fisheries Science

Policy Owner: Director, Aquaculture and Fisheries Science

Responsible Office: Research Support Hub

Effective Date: 1 March 2017

## 2. Purpose

The WorldFish mission is to 'reduce poverty and hunger by improving fisheries and aquaculture'. The values WorldFish has adopted to pursue its mission are those of integrity, trust, fairness and equity, excellence and teamwork. This Policy sets the framework for operating within the values of WorldFish when undertaking research that involves people, and establishes assurances that international and national treaties and regulations are complied with.

## 3. Scope

This Policy applies to all research activities involving people, regardless of source of funding, or the partnerships that WorldFish enters into. It equally applies to the partners and service providers that we work with if these do not have a commensurate policy acceptable to WorldFish. The policy underpins any specific operational guidance drawn up by WorldFish Country Offices or regional programs.

This Policy applies to research involving people as subjects or as partners in research, whether in the form of socio-economic surveys, interviews, focus group discussions, participant observation, or multi-stakeholder dialogue and participatory action and learning.

## 4. Policy Statement

While leading or participating in research activities that involve people, WorldFish researchers must operate within the values of WorldFish and establish assurances that national treaties and regulations regarding ethics in research are complied with.

## 5. Procedures

Research plans involving human subjects must be approved by the WorldFish Research Ethics Review Panel.

Research plans must be implemented in compliance with national law regarding research with human subjects.

Research participants must be informed of the nature and purpose of the research, the methods used and the time taken, and consulted on their willingness to participate.

Research data should be handled in a way that protects the well-being of people by not harming their safety, dignity or privacy.

Staff should take all possible steps to ensure safety and security of themselves, the partners we work with, and the people with whom we engage through our research.

## 6. Responsibilities

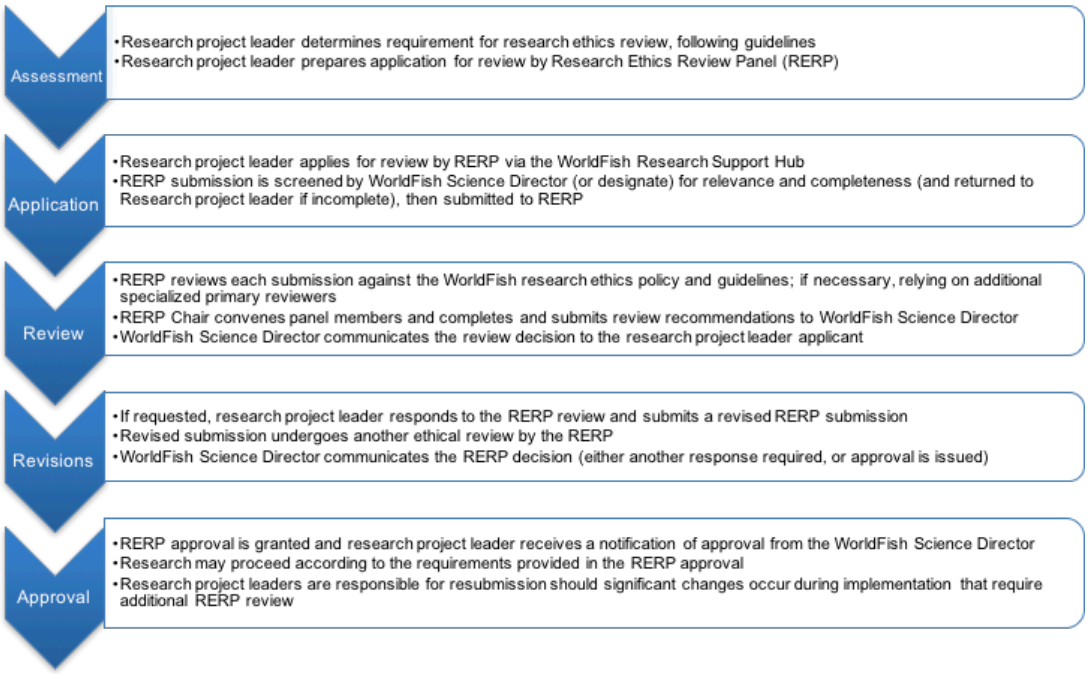
This Policy is implemented through a Research Ethics Review Panel (RERP). The RERP is an autonomous Panel with final approval authority. It is independent of any undue influence, independent of all members of research teams involved in conducting the research under review, transparent in its functioning, and qualified in the field of ethical research conduct.

The RERP is appointed by the Director General, who also approves its terms of reference and operational procedures and may modify these as necessary to ensure effective and efficient operations. The RERP will liaise with the Director – Aquaculture and Fisheries Science as required, and will be supported by a Secretary within the Research Support Hub.

Project leaders are responsible for developing and submitting applications for ethics approval by the RERP, and for ensuring implementation is in accord with agreed plans.

The RERP reviews applications for ethics approval with the purpose of ensuring that research plans are in compliance with the Policy and appropriate to the context, including adequate measures to identify and manage risk. In the case that research plans involve clinical trials or any form of medical research, prior approval from the review board of a national authority or partner institution duly qualified in the medical or public health research domain is required.

## 7. Process Map




## 8. Definitions and Acronyms

A list of commonly used definitions and acronyms is provided as Attachment 4.

## 9. References and Associated Policies

The Policy is supported by a set of general Guidelines for implementation (Attachment 1) and Principles to guide research staff regarding research involving local communities (Attachment 2).

This Policy complements other WorldFish policies related to research conduct including child protection; intellectual property rights and management of aquatic genetic resources; engagement in technology transfer activities; animal care and welfare; and gender research; as well as guidelines relating to photography and video, and social media. A list of relevant legal instruments, policies and guidelines is included as Attachment 3.

ATTACHMENT 1: **GUIDELINES FOR IMPLEMENTATION OF WORLDFISH POLICY ON ETHICS OF RESEARCH INVOLVING PEOPLE**[1]

The following points of guidance are intended to provide a reference in designing and implementing research in accord with the WorldFish Policy on Ethics of Research Involving People:

- ***Compliance with national law regarding research.*** Each country has different rules of engagement for international institutions and researchers when undertaking research involving their citizens. The Country Program must develop a good understanding of applicable international, regional and national regulations and procedures, as well as the time frame involved for the process of any approvals that may be necessary. The Country Program should also be able to advise on any WorldFish country-specific community engagement guidelines, and relevant local policies, customs and norms.

- ***Working with partners.*** If partners or third parties are engaged to interact with communities on behalf of WorldFish, they must be adequately briefed on their role under this Policy, including when securing permissions of any kind on our behalf, by following the appropriate procedures in a timely manner and with the same rigor as expected from a WorldFish researcher. The partner remains liable and guarantees the performance of the third party to operate within this policy when entering into an Agreement with WorldFish.

- ***Prior informed consent.*** Before undertaking research activities, researchers will ensure that participants are informed of the nature and purpose of the research, the methods used and the time taken, and consulted on their willingness to participate. They should be made aware that their participation is voluntary and that they can withdraw at any time. They should be provided the opportunity to ask questions about the research. They need to be assured that their anonymity and confidentiality will be safeguarded, unless they explicitly agree to be identified. There are multiple methods to obtain written or verbal informed consent; the review process is designed to ensure that appropriate methods are adopted based on the research context.

- ***Anonymity and confidentiality.*** Research data should be handled in a way that protects the well-being of people by not harming their safety, dignity or privacy. Data needs to be adequately protected during storage to prevent losses and ensure that the identity of participants cannot be traced to the source by researchers analyzing the data. All data (including records of interviews and informed consent forms) should be kept in a secure archive. In the case that individuals explicitly agree to be identified in communications resulting from the research, this should only be done so where there is a sound rationale in support of the research objectives.

- ***Risks and benefits.*** Staff and partners working with local communities or other stakeholders on our behalf should be vigilant of potential risks from the research undertaken and potential negative responses or unintended effects. Staff should take all possible steps to ensure safety and security of themselves, the partners we work with, and the people with whom we engage through our research. Participants need to be informed of possible risks and benefits from the research. No research with people is completely free of risks; the responsibility of researchers is to ensure that risks are identified, that these risks are reasonable in relation to the expected benefits, and that there are measures in place to manage these risks.

[1] Standard forms will be developed and updated as needed, to ease submission and assessment of RERP applications in accordance with these Guidelines. These forms will be subject to approval by the Director General.

ATTACHMENT 2. **WORLDFISH PRINCIPLES FOR ETHICAL CONDUCT OF RESEARCH INVOLVING LOCAL COMMUNITIES**

## 1 Preamble

Researchers at WorldFish are accountable towards those involved in or affected by our research. This document is not intended to provide an exhaustive list of rigid rules that apply to all circumstances encountered during research. The project leader or members of the research team will have to make carefully considered ethical choices, based on these Principles, and in line with the WorldFish Policy and on their knowledge and judgment. They must be prepared to explain the assumptions, facts and issues on which these choices were made.

## 2 Objective

The objective of these Principles is to reiterate our commitment to accountability, fairness, accuracy and integrity in our research practice. It is intended to ensure that any adverse effects of research undertaken by WorldFish are reduced to the greatest extent possible, and that local communities, individuals and groups have a clear choice regarding their participation in research. Additionally, these Principles aim to facilitate ethical conduct in relationships between WorldFish and our partners, including enabling people to conduct research in their own communities, for their own use, and for the benefit of the entire community.

## 3 Principles

**We work in partnership**: WorldFish engages in partnerships for long term goals and takes a proactive approach to nurturing relationships based on respect, trust, reciprocity and mutual understanding. Conflict resolution is part of this. Results of the engagement should be mutually beneficial and equitable, and shared in ways that are culturally acceptable and consistent with the WorldFish Policy.

**We use participatory approaches:** Where participatory approaches are adopted, they should enable stakeholders and partners to be involved in the design, management, implementation, analysis and application of research to ensure local needs and priorities are met. This includes active participation in review of results prior to publication or dissemination to ensure that information accurately reflects the contribution by the communities and individuals, and upholds the WorldFish Policy.

**We actively seek to enable farmer led research:** In many circumstances, WorldFish works with communities and individuals to identify and undertake their own research. In doing so, WorldFish and partners will support communities through capacity building, farmer information exchange, or other appropriate methods with the aim of ensuring quality research results for wider adoption.

**We manage risks and strive to protect:** WorldFish researchers will strive to protect the individual and collective rights and norms of participants, considering how research may impact upon men and women differently, and take actions to minimize any negative impacts of the research. This may include undertaking a risk analysis. WorldFish researchers will be sensitive to the special needs of children, disabled and minority groups.

**We value the sharing of traditional knowledge and technologies**: Local communities and indigenous people who exchange traditional knowledge and technologies with WorldFish shall be fully aware of the research plan that utilizes that knowledge and technologies, and any dissemination plans that include the knowledge and/or technologies. Acknowledgement, confidentiality and anonymity shall all be discussed and adopted as the situation requires to ensure that the WorldFish commitment to produce International Public

Goods is not impeded while respecting the ownership of the information or technology. This principle includes the recognition that indigenous people have prior proprietary rights and cultural responsibilities for their environment that they have traditionally inhabited or accessed and they may wish to keep some information confidential. The legal framework for the use of traditional knowledge associated with genetic resources is established in the Nagoya Protocols.

**We ensure prior informed consent in ways appropriate to the local context**: Before undertaking any research WorldFish personnel will ensure that consent is given as determined through local community governance structures or through a process that is inclusive and acceptable to the communities. This process establishes a relationship that is ongoing throughout the research cycle, and involves full disclosure of potential positive and negative outcomes (tangible and intangible). If the research continues over a substantial period of time, or changes with respect to its objectives or risks, consent will be renewed as often as appropriate.

**We prioritize people's safety and welfare:** If any group or faction challenges the research team's right to be in the community, attempts to prevent the research from being conducted, or threatens violence, we will withdraw from the location and seek the assistance of partner institutions with authority to resolve the dispute. However, we will make every effort to ensure that no adverse consequences occur from the research, and remedial options should be discussed with communities in order to avoid damaging conflict or other negative consequences. Communities or individuals at risk should be aware of whom to contact, and have their details, to discuss any issues that arise regarding the research.

**We are proactive in sharing WorldFish knowledge with our partners:** We understand that we have an obligation to ensure that our partners are fully informed through continual engagement regarding all aspects of the research. We will strive to ensure that as research progresses, all research findings are shared in a meaningful manner, including in local languages, and in culturally appropriate ways.

**We respect the rights of the people we capture images of:** The dignity, rights, safety and well-being of the person or persons being portrayed shall be respected. Images must comply with local conditions or restrictions on reproduction. Verbal or written consent will be gained where appropriate, and refusal will be respected. We will ensure that photographs do not misrepresent any situation, location and context within which the image is captured. Privacy will be respected in situations where there are cultural and/or political sensitivities or the potential for social stigma. We will be compassionate and take particular care when photographing and using images of children.

**We respect personal constraints:** When organizing local workshops, focus group meetings or household interviews, researchers will be aware of people's work schedules and other time commitments, including when people are engaged in informal sector activities and appear to be available. It is important to be mindful of peak labor times in the fishing/agricultural calendar and to ensure that people do not feel obliged to forgo their work in order to participate in the research.

**We refrain from raising unrealistic expectations:** Care will be taken not to create unrealistic expectations among people who participate in research, either in terms of immediate material or non-material benefits, or longer-term positive impacts. This is particularly the case when the interaction is framed as 'action research', which is a joint process of learning between an external agent (in this case WorldFish or partner) and a group of people that specifically aims to achieve a social transformation for that group.

**We respect the cultures and traditions of others:** Researchers will respect the culture and traditions of the communities they engage with. They should have a sound understanding of the local context prior to interaction with communities, and should comply with any customs, protocols and local laws. Researchers have a responsibility to not impose external values, standards or cultural norms onto the communities. We do engage in research that challenges certain norms, including gender inequities or patterns of decision-making and authority that reinforce poverty or social exclusion, but we do so in ways that are grounded in an understanding of the local context and that respond to goals and priorities that local groups deem legitimate.

ATTACHMENT 3. **RESOURCE FOR IDENTIFICATION OF LEGAL INSTRUMENTS AND GUIDELINES THAT MAY APPLY TO WORLDFISH RESEARCH INVOLVING PEOPLE**[2]

**International:**

- UNICEF Principles for Ethical Reporting on Children
- UN Convention on the Rights of the Child
- Universal Declaration of Human Rights
- International Treaty on Plant Genetic Resources for Food and Agriculture
- International Treaty on the Conservation of Biological Diversity
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization
- Declaration of Helsinki (statement of ethical principles for medical research involving human subjects)

**National:**

- National protocols for international institutions and researchers engaged in research amongst people in that country
- National protocols for national institutions and researchers engaged in research amongst people in that country

**CGIAR:**

- CGIAR Policy on the Management of Intellectual Assets
- CGIAR Principles on the Management of Intellectual Assets
- CGIAR Open Access and Data Management Implementation Guidelines
- CRP Guidelines concerning research ethics

**WorldFish:**

- Country or Regional Guidelines that may exist
- Child Protection Policy and Guidelines
- Policy for Intellectual Policy Rights and Management of Aquatic Genetic Resources
- Policy for the Engagement of WorldFish Center in Technology Transfer Activities
- Policy Statement on Gender Research
- Social Media Guidelines
- Photography and Video Handbook
- Animal care, welfare and ethics policy

[2] This is not an exhaustive list and current only at the date of policy approval. It serves as a resource to aid in implementation of the Policy, and may be updated by approval of the Director General.

ATTACHMENT 4. **COMMONLY USED ACRONYMS AND DEFINITIONS**

| **Commonly used Acronyms** | **Definition** |
|---|---|
| CGIAR | Consultative Group for International Agricultural Research |
| CRP | CGIAR Research Program |
| RERP | (WorldFish) Research Ethics Review Panel |
| UN | United Nations |
| UNICEF | United Nations Children's Fund |
| **Commonly used Definitions** | |
| Anonymous | Refers to data collected without any identifiable information and in no way can be linked to an individual. |
| Assent | An affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. |
| Confidentiality | Refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. |
| Informed Consent | A process to ensure that a research participant is aware of all the reasonably foreseeable risks and costs involved in participation in research and enable persons to voluntarily decide whether or not to participate as a research subject. |
| Privacy | Refers to a person's desire to control the access of others to information about themselves. |
| Research Support Hub | WorldFish unit supporting research implementation |
| Risks | The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in research. |

# Briefing on Human and Animal Ethics: WorldFish Research Ethics Panel

WorldFish

# Contents:

1. Introduction and Background
2. SOP Briefing, Documentation and Tools
3. Operationalization of the WorldFish Ethics Panel
4. Next Steps and Important Dates
5. AOB / Q & A

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# Introduction

**Why do we need the process?**

- Adhere to internal policies, CGIAR policies and universally acknowledged ethical standards of research
- Improving research quality - studies are held to the highest research quality standard
- Improving ethical review process (CGIAR/donors)
- Ensure research is conducted in a responsible and ethically accountable way

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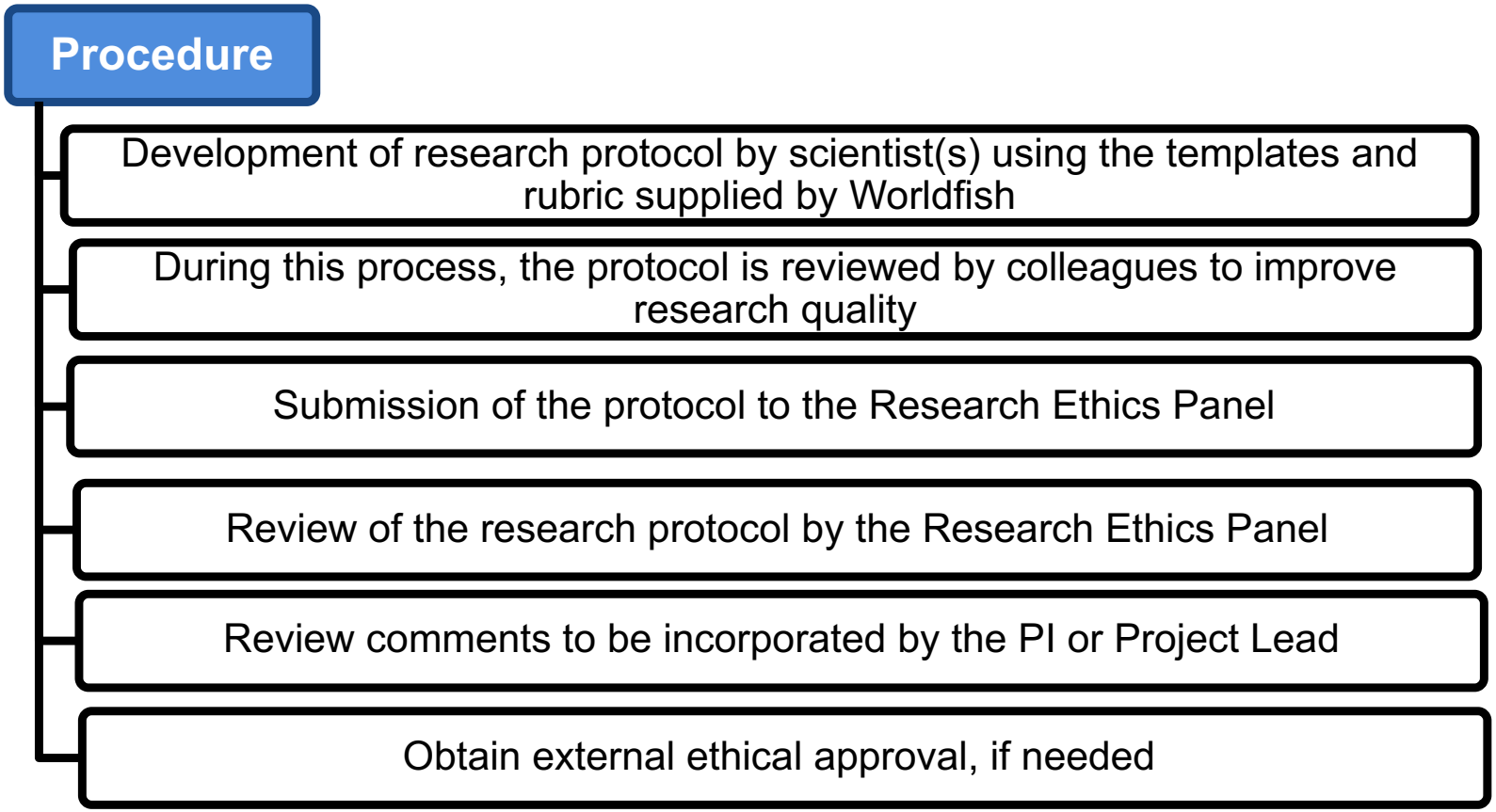
# Standard Operating Procedures (SOP) for Obtaining Ethical Approval of Research




Document links:

- SOP for Obtaining Ethical Approval of Research
- Protocol Listing
- Online Submission Form
- Feedback Form – Sample

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# Operationalization of the WorldFish Research Ethics Panel

## Composition (page 3)

- Chair (Research Director or senior/principal scientist)[a]
- One animal ethics specialist
- One human ethics specialist
- 2 other WorldFish scientists on a rotating roster[a, b]
- A member of the WorldFish Research Support Unit

## Roles and Responsibility

- To review the **protocols of all studies conducted by WorldFish that collect primary data** from human participants or animal subjects from an ethical perspective
- To determine if external human or animal ethics approval will be required for each research protocol

## Research Ethics Panel Meeting

- It is expected that scientists submit their research protocols on the fixed rates provided by the RSU
- Monthly meeting to be organized by RSU (on the final week of every month – panel members are determined, depending on submitted protocols)
- Approximately 2 weeks notice will be given for review prior to the panel meetings

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# AOB

- Q&A
- Questions on the process can be also be directed to : wf-ethics@cgiar.org

Supporting documentation (links also found throughout SOP):

- Instructions for Online Protocol Submission
- Resources for Animal Ethics (inc protocol template)
- Resources for Human Ethics (inc protocol template)
- Research Protocol Review Rubric

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# Thank You

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# Introduction to the Human and Animal Ethics Approval Process

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# Agenda

1. Introduction to Research Ethics
    - Policies
2. Research Protocols
3. Process for Human and Animal Ethics Approval
    - Ethical Approval Process Overview
    - Standard Operating Procedures (SOP) for Obtaining Ethical Approval of Research
    - Protocol Online Submission
4. Next Steps, Timeline and Important Dates
5. AOB / Q & A

WorldFish

# Introduction to Research Ethics

**Why do we need to strengthen our ethical review processes?**

- Adhere to internal policies, CGIAR policies and universally acknowledged ethical standards of research
- Improve research quality – ethics a clear part of research process, holding our research to the highest research quality standard
- Improve ethical review process to adhere do national and donor priorities
- Ensure research is conducted in a responsible and ethically accountable way

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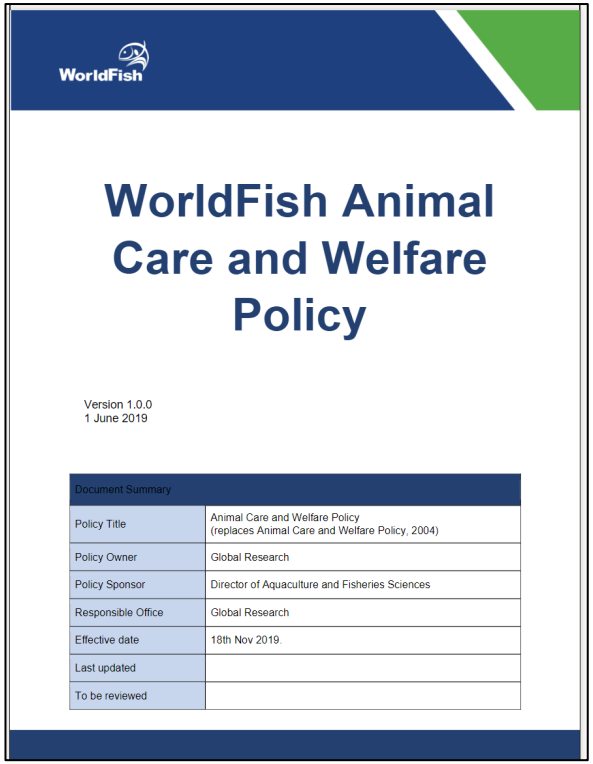
# Policies

Documents:

- WorldFish Animal Care and Welfare Policy
- WorldFish Policy on Ethics of Research Involving People



WorldFish

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Version 1.0.0
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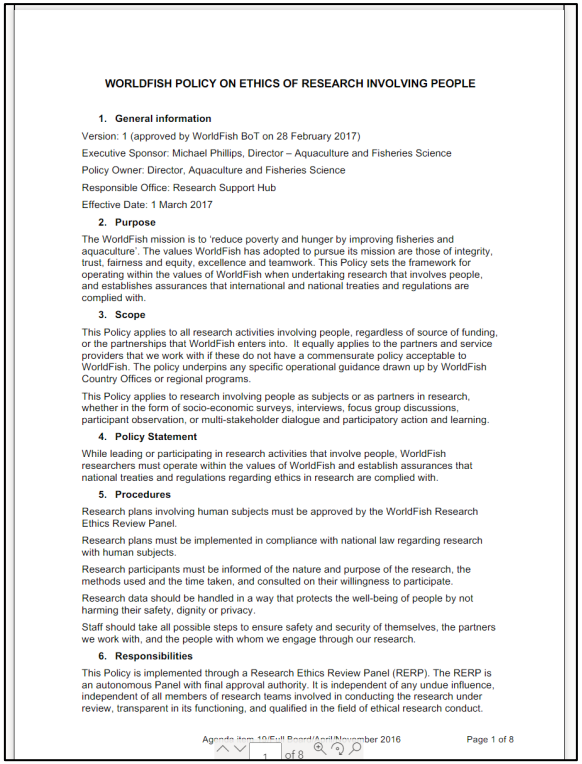

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**5. Procedures**

Research plans involving human subjects must be approved by the WorldFish Research Ethics Review Panel.

Research plans must be implemented in compliance with national law regarding research with human subjects.

Research participants must be informed of the nature and purpose of the research, the methods used and the time taken, and consulted on their willingness to participate.

Research data should be handled in a way that protects the well-being of people by not harming their safety, dignity or privacy.

Staff should take all possible steps to ensure safety and security of themselves, the partners we work with, and the people with whom we engage through our research.

**6. Responsibilities**

This Policy is implemented through a Research Ethics Review Panel (RERP). The RERP is an autonomous Panel with final approval authority. It is independent of any undue influence, independent of all members of research teams involved in conducting the research under review, transparent in its functioning, and qualified in the field of ethical research conduct.



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# Using Research Protocols to Improve Research Quality

**Definition**: A  detailed document outlining the details of the research to be conducted, with specific sections for rationale, research questions, methods, statistics, timelines, etc.

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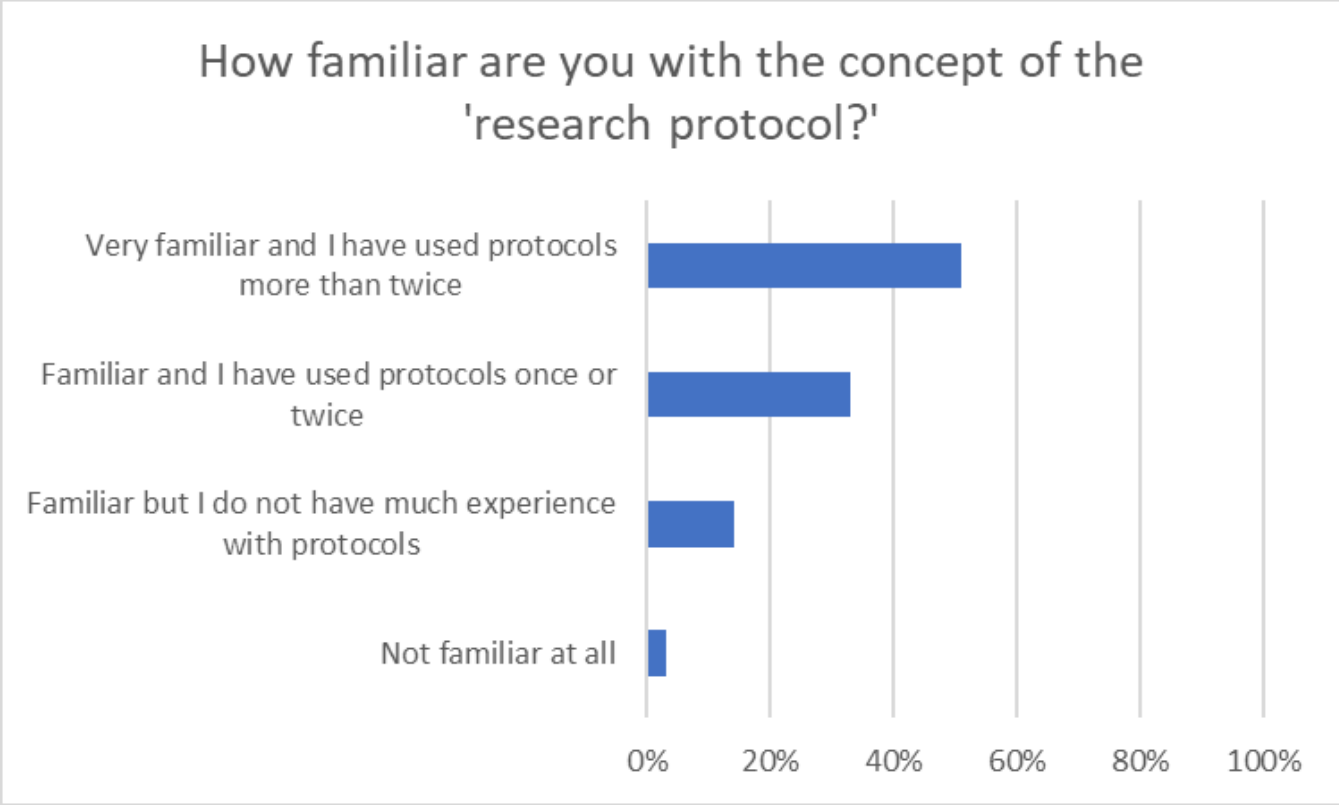
# Use of Protocols in Research

Findings from the baseline survey (conducted mid-2020 with WorldFish staff, n = 59)

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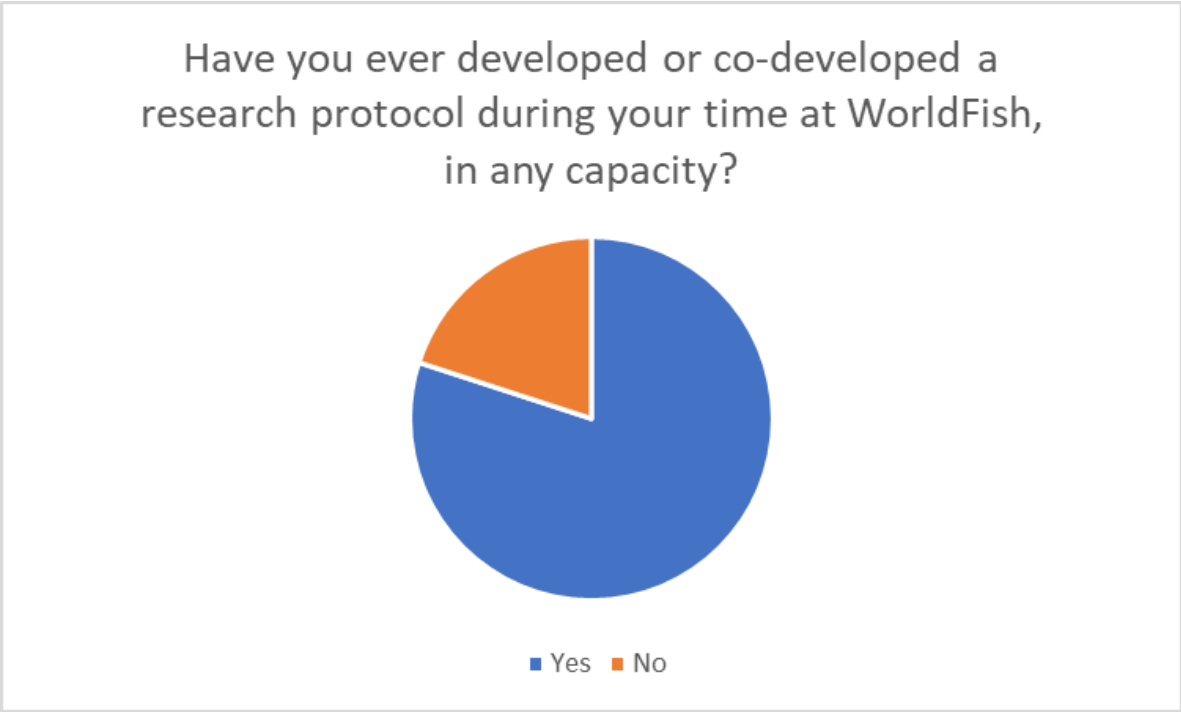
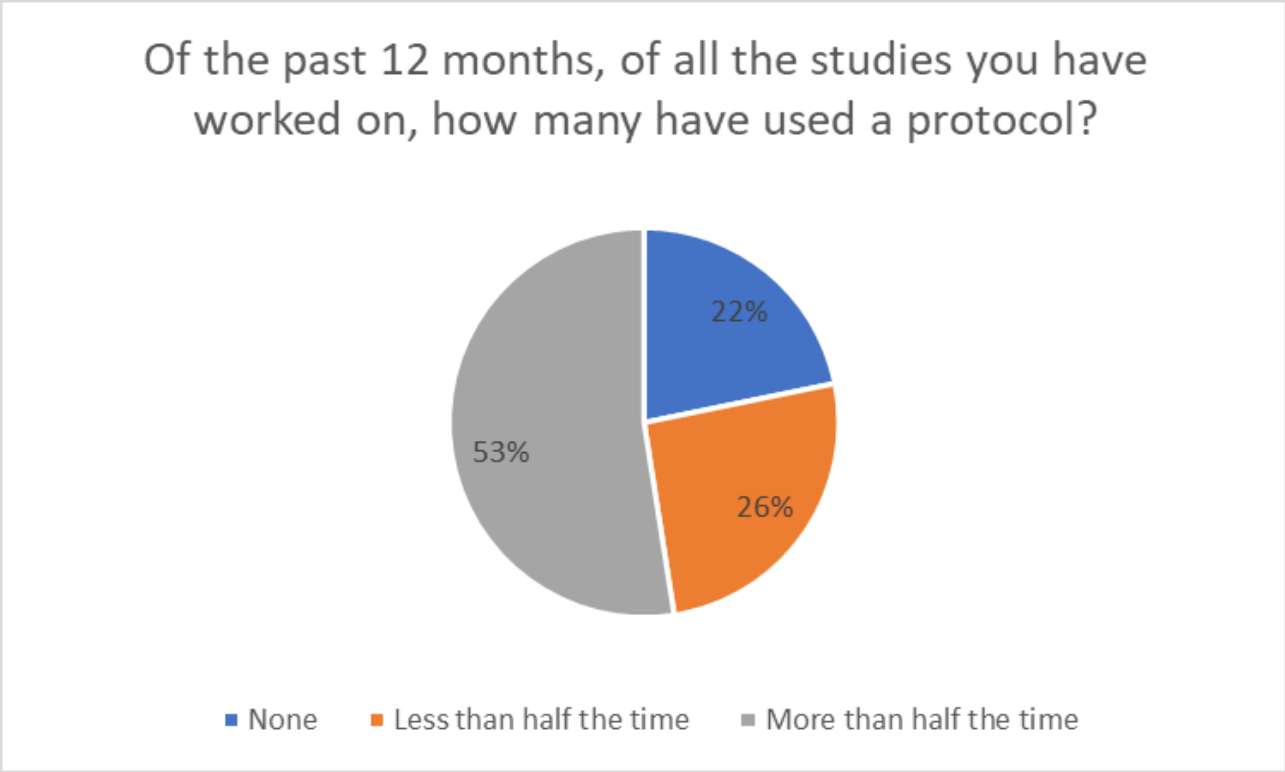
# Use of Protocols in Research

Findings from the baseline survey (conducted mid-2020 with WorldFish staff, n = 59)



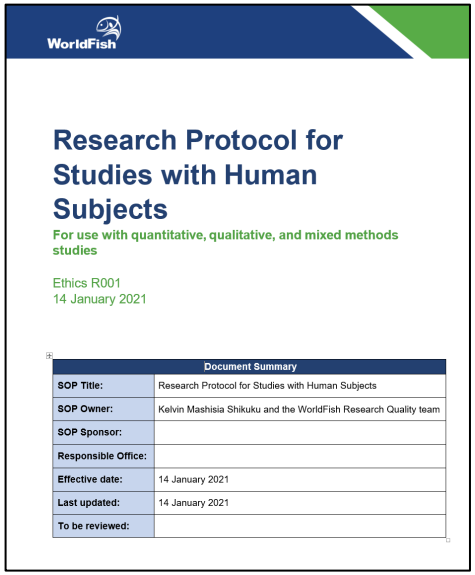
# Use of Protocols in Research

Findings from the baseline survey (conducted mid-2020 with WorldFish staff, n = 59)



# Use of Protocols in Research

## Protocol Development and Resources for Review



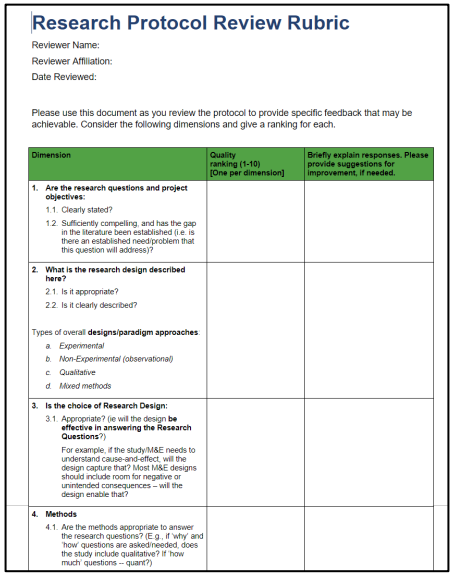
WorldFish

**Research Protocol for Studies with Human Subjects**

**For use with quantitative, qualitative, and mixed methods studies**

Ethics R001
14 January 2021

| Document Summary | |
|---|---|
| **SOP Title:** | Research Protocol for Studies with Human Subjects |
| **SOP Owner:** | Kelvin Mashisia Shikuku and the WorldFish Research Quality team |
| **SOP Sponsor:** | |
| **Responsible Office:** | |
| **Effective date:** | 14 January 2021 |
| **Last updated:** | 14 January 2021 |
| **To be reviewed:** | |

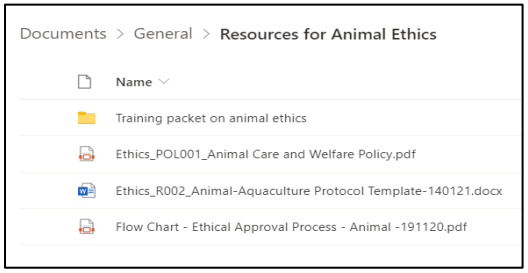


**Research Protocol Review Rubric**

Reviewer Name:
Reviewer Affiliation:
Date Reviewed:

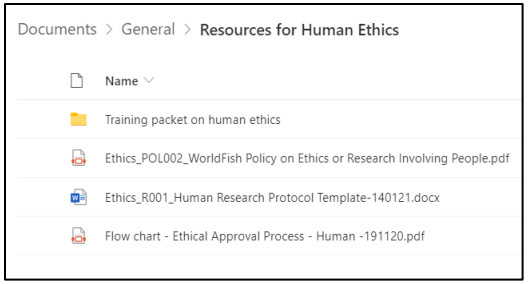
Please use this document as you review the protocol to provide specific feedback that may be achievable. Consider the following dimensions and give a ranking for each.

| Dimension | Quality ranking (1-10) [One per dimension] | Briefly explain responses. Please provide suggestions for improvement, if needed. |
|---|---|---|
| **1. Are the research questions and project objectives:**<br>1.1. Clearly stated?<br>1.2. Sufficiently compelling, and has the gap in the literature been established (i.e. is there an established need/problem that this question will address)? | | |
| **2. What is the research design described here?**<br>2.1. Is it appropriate?<br>2.2. Is it clearly described?<br><br>Types of overall **designs/paradigm approaches**:<br>a. *Experimental*<br>b. *Non-Experimental (observational)*<br>c. *Qualitative*<br>d. *Mixed methods* | | |
| **3. Is the choice of Research Design:**<br>3.1. Appropriate? (ie will the design **be effective in answering the Research Questions**?)<br>For example, if the study/M&E needs to understand cause-and-effect, will the design capture that? Most M&E designs should include room for negative or unintended consequences – will the design enable that? | | |
| **4. Methods**<br>4.1. Are the methods appropriate to answer the research questions? (E.g., if 'why' and 'how' questions are asked/needed, does the study include qualitative? If 'how much' questions – quant?) | | |



Documents > General > **Resources for Animal Ethics**

| Name |
|---|
| Training packet on animal ethics |
| Ethics_POL001_Animal Care and Welfare Policy.pdf |
| Ethics_R002_Animal-Aquaculture Protocol Template-140121.docx |
| Flow Chart - Ethical Approval Process - Animal -191120.pdf |



Documents > General > **Resources for Human Ethics**

| Name |
|---|
| Training packet on human ethics |
| Ethics_POL002_WorldFish Policy on Ethics or Research Involving People.pdf |
| Ethics_R001_Human Research Protocol Template-140121.docx |
| Flow chart - Ethical Approval Process - Human -191120.pdf |

List of resources:

- Research Protocol Review Rubrics
- Resources for Animal Ethics
- Resources for Human Ethics

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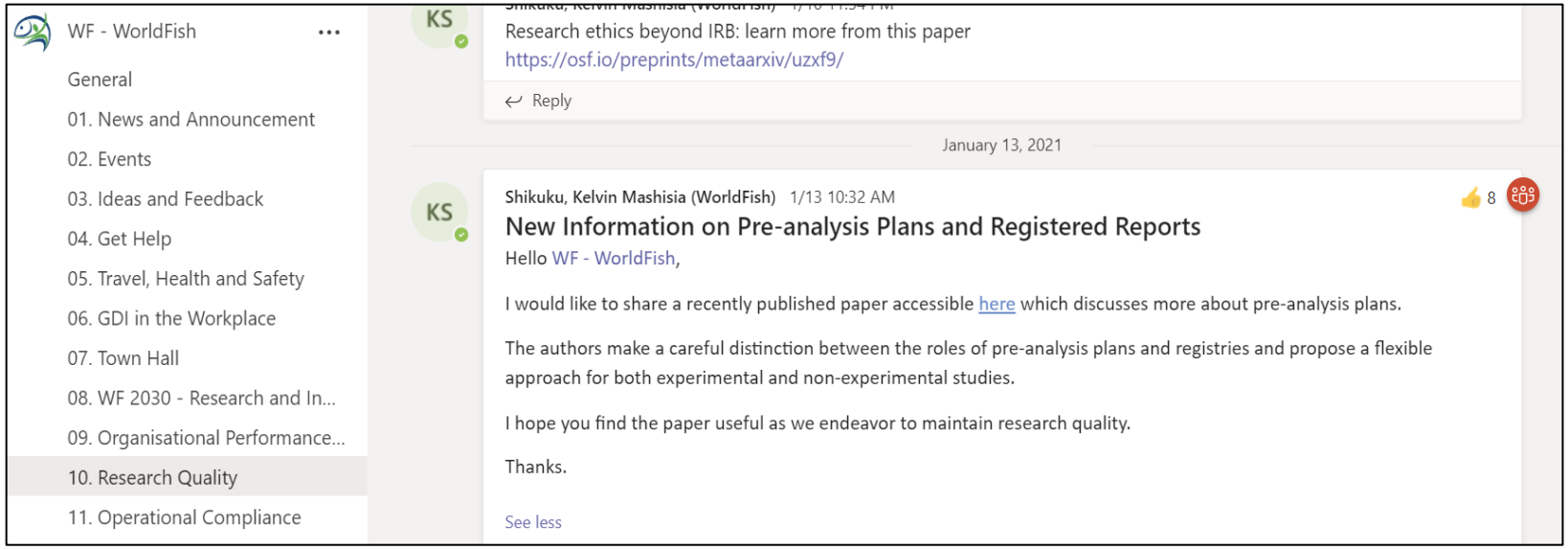
# Support for using protocols in research

- To connect researchers: watch for upcoming learning hours, ‘office hours’, etc for those who need support
- See ‘Research Quality’ channel



# Animal and Human Ethics Approval Processes

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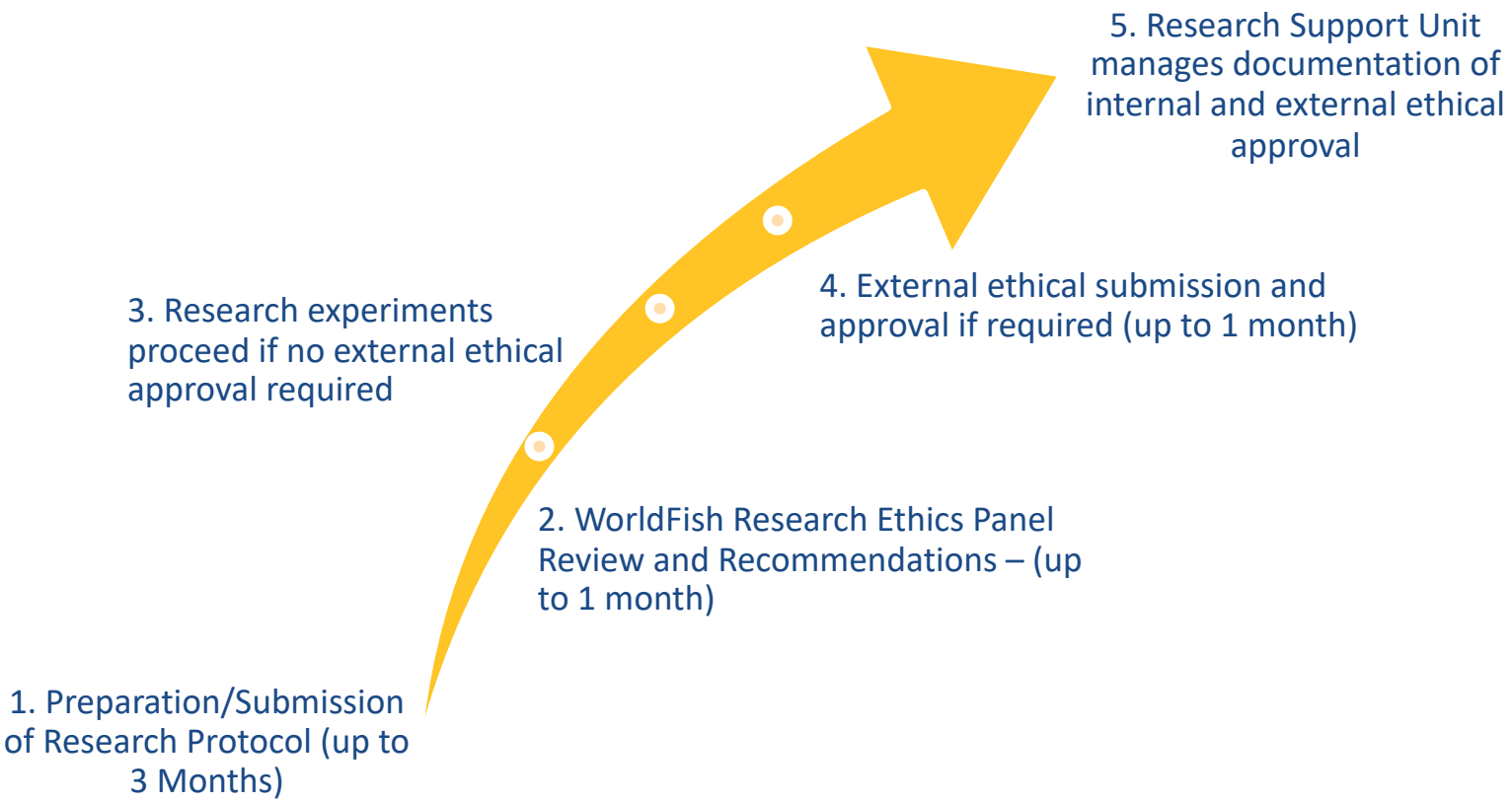
# Overview: Ethical Approval Process




Documents:

- Flow Chart – Ethical Approval Process, Animal Ethics
- Flow Chart – Ethical Approval Process. Human Ethics

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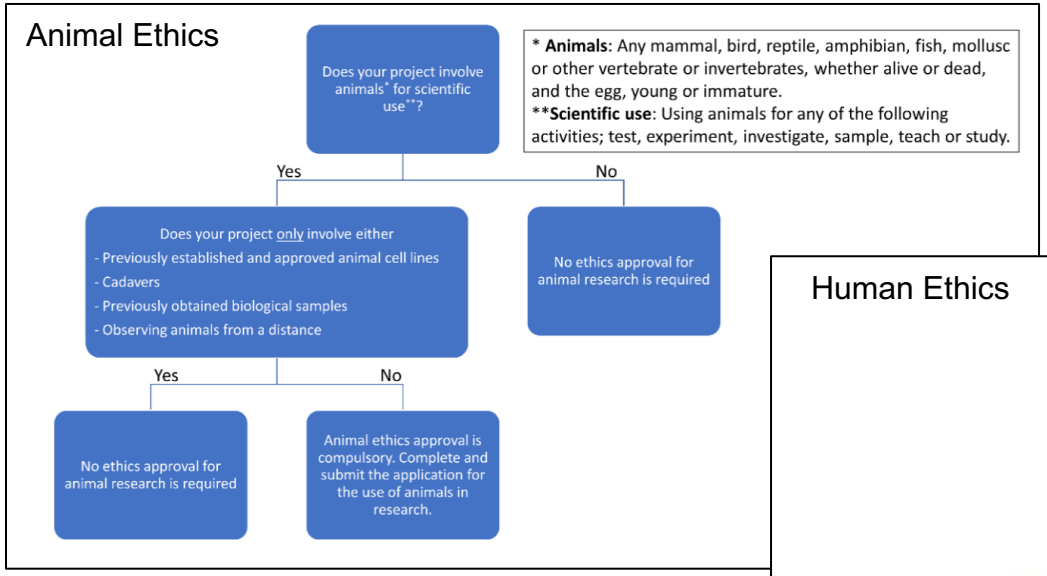
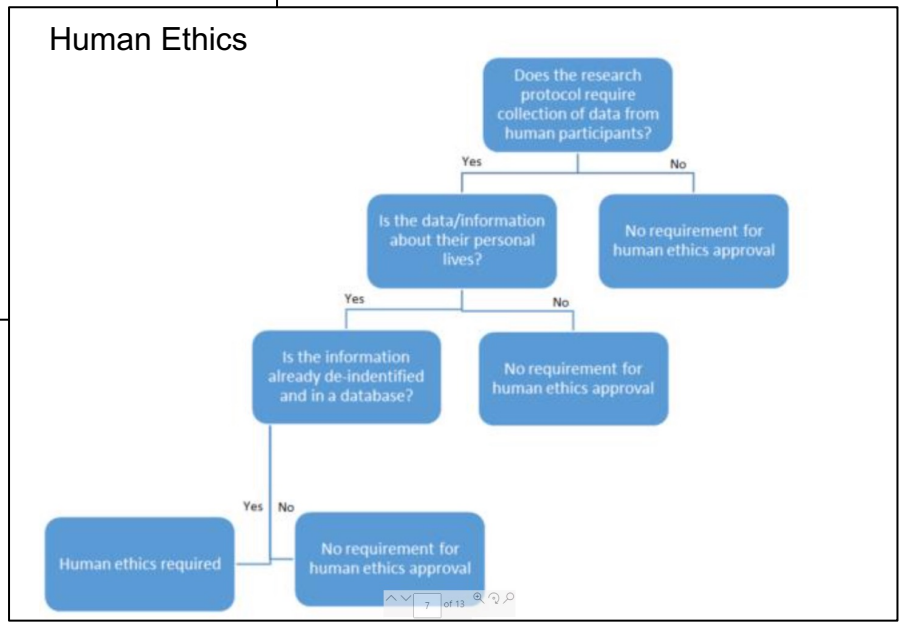
# Decision Tree: Animal and Human Ethics




* Kindly refer to the SOP for further description.

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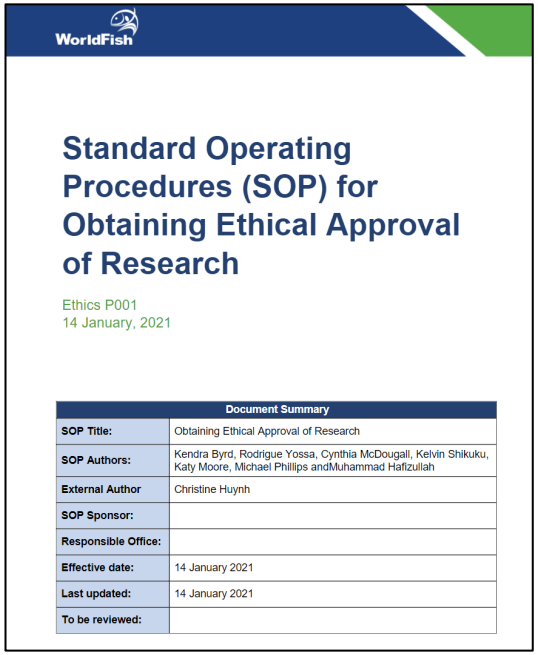
# Standard Operating Procedures (SOP) for Obtaining Ethical Approval of Research



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**Standard Operating Procedures (SOP) for Obtaining Ethical Approval of Research**

Ethics P001
14 January, 2021

| Document Summary | |
|---|---|
| **SOP Title:** | Obtaining Ethical Approval of Research |
| **SOP Authors:** | Kendra Byrd, Rodrigue Yossa, Cynthia McDougall, Kelvin Shikuku, Katy Moore, Michael Phillips andMuhammad Hafizullah |
| **External Author** | Christine Huynh |
| **SOP Sponsor:** | |
| **Responsible Office:** | |
| **Effective date:** | 14 January 2021 |
| **Last updated:** | 14 January 2021 |
| **To be reviewed:** | |

Document links:
SOP for Obtaining Ethical Approval of Research

Roles and Responsibilities

- Scientists and post-doctoral scholars
  - Development of high-quality protocols
  - Submission of applications to ethical review boards where necessary
- Principal Investigators and Project leads
  - Oversee projects and collection of primary data
  - Confirm that scientists have the adequate training to perform the tasks
  - Confirm that scientists have the adequate training for human and animal ethics
- Country Directors
  - Ensure that all projects that collect primary data (whether from animals or humans) have been vetted by the Research Ethics Panel and have obtained official ethical approval as needed
- Research Director (or designate)
  - Appoint scientists to the Research Panel
  - Settle disputes that arise from the "Obtaining Ethical Approval of Research" process
- Research support unit
  - Coordinate the research panel
  - Applies for all animal ethics approvals through approved IACUCs
  - Administrative service

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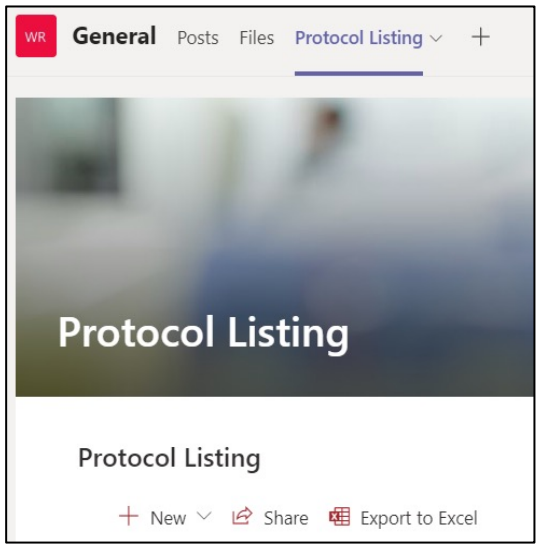
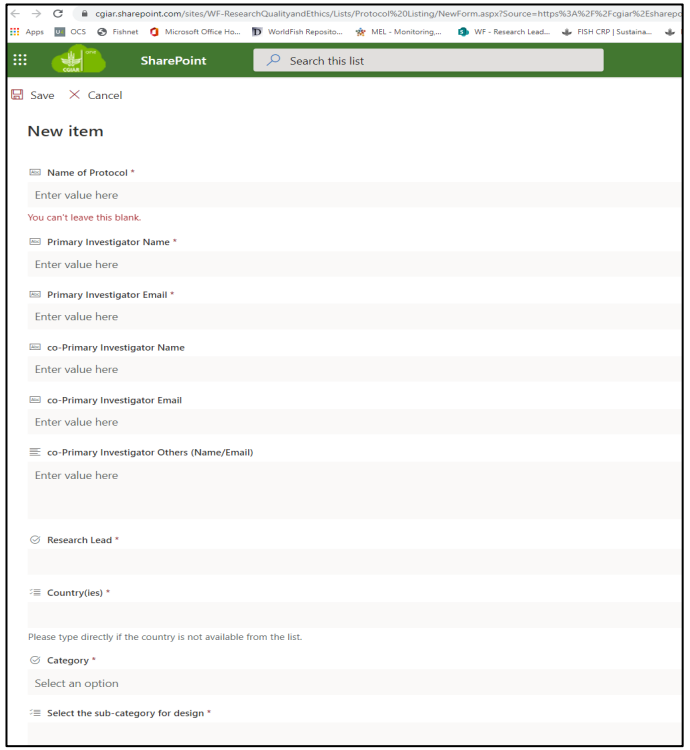
# Online Submission for Ethical Approval

Link: Protocol Listing
Document: Instruction for Submission of Protocol Online Procedure / Feedback Form – Sample

## 1. MS Teams


## 2. Fill in Online Submission Form




*Submitted protocol list will be available on same page.

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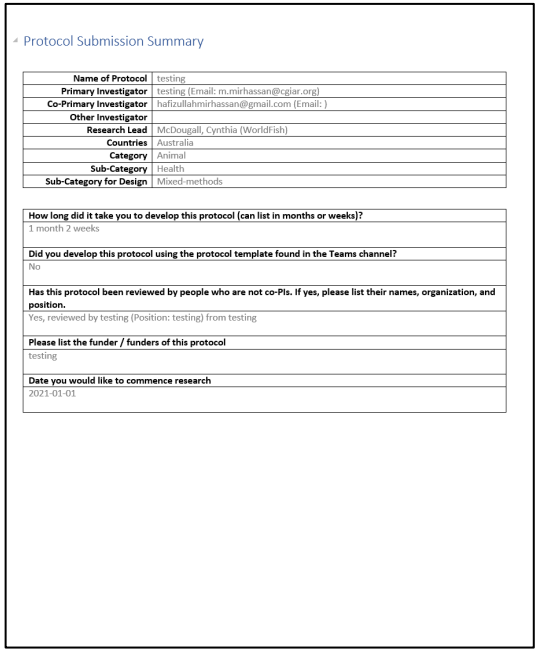
# Protocol Review by WorldFish Research Ethics Panel

## 3. Monthly meeting of the WorldFish Research Ethics Panel will review protocols and provide feedback and recommendations- decision

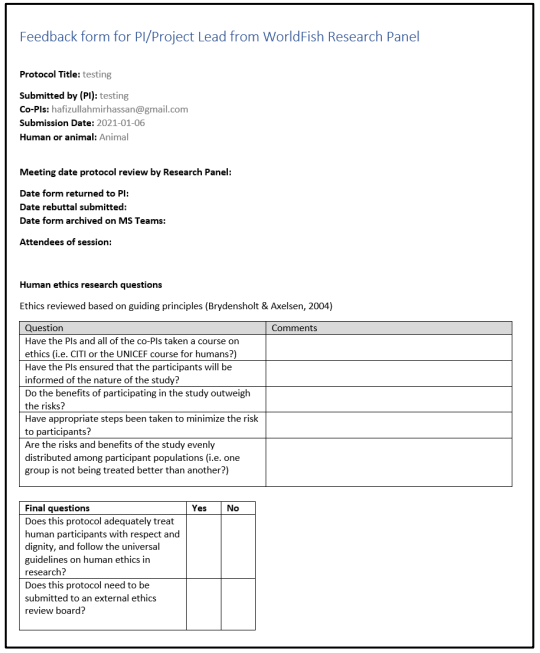
## 4. Management of the Process and Communication provided by the WorldFish Research Support Unit



Protocol Submission Summary

| | |
|---|---|
| **Name of Protocol** | testing |
| **Primary Investigator** | testing (Email: m.mirhassan@cgiar.org) |
| **Co-Primary Investigator** | hafizullahmirhassan@gmail.com (Email: ) |
| **Other Investigator** | |
| **Research Lead** | McDougall, Cynthia (WorldFish) |
| **Countries** | Australia |
| **Category** | Animal |
| **Sub-Category** | Health |
| **Sub-Category for Design** | Mixed-methods |

| |
|---|
| **How long did it take you to develop this protocol (can list in months or weeks)?** |
| 1 month 2 weeks |
| **Did you develop this protocol using the protocol template found in the Teams channel?** |
| No |
| **Has this protocol been reviewed by people who are not co-PIs. If yes, please list their names, organization, and position.** |
| Yes, reviewed by testing (Position: testing) from testing |
| **Please list the funder / funders of this protocol** |
| testing |
| **Date you would like to commence research** |
| 2021-01-01 |



Feedback form for PI/Project Lead from WorldFish Research Panel

**Protocol Title:** testing

**Submitted by (PI):** testing
**Co-PIs:** hafizullahmirhassan@gmail.com
**Submission Date:** 2021-01-06
**Human or animal:** Animal

**Meeting date protocol review by Research Panel:**

**Date form returned to PI:**
**Date rebuttal submitted:**
**Date form archived on MS Teams:**

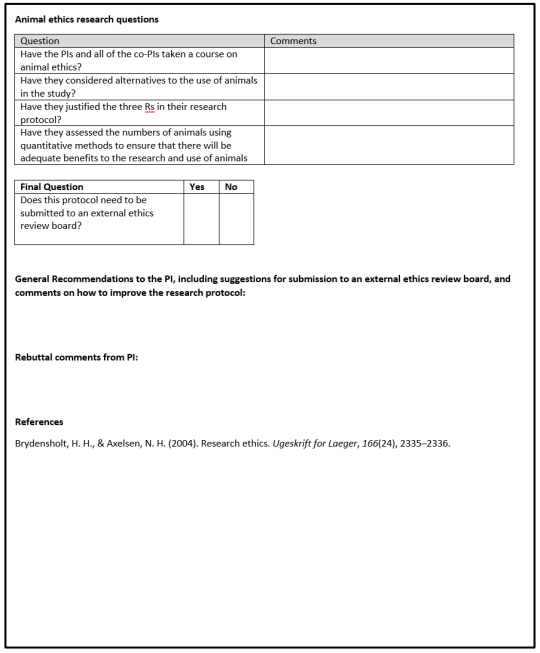
**Attendees of session:**

**Human ethics research questions**

Ethics reviewed based on guiding principles (Brydensholt & Axelsen, 2004)

| Question | Comments |
|---|---|
| Have the PIs and all of the co-PIs taken a course on ethics (i.e. CITI or the UNICEF course for humans?) | |
| Have the PIs ensured that the participants will be informed of the nature of the study? | |
| Do the benefits of participating in the study outweigh the risks? | |
| Have appropriate steps been taken to minimize the risk to participants? | |
| Are the risks and benefits of the study evenly distributed among participant populations (i.e. one group is not being treated better than another?) | |

| Final questions | Yes | No |
|---|---|---|
| Does this protocol adequately treat human participants with respect and dignity, and follow the universal guidelines on human ethics in research? | | |
| Does this protocol need to be submitted to an external ethics review board? | | |



**Animal ethics research questions**

| Question | Comments |
|---|---|
| Have the PIs and all of the co-PIs taken a course on animal ethics? | |
| Have they considered alternatives to the use of animals in the study? | |
| Have they justified the three Rs in their research protocol? | |
| Have they assessed the numbers of animals using quantitative methods to ensure that there will be adequate benefits to the research and use of animals | |

| Final Question | Yes | No |
|---|---|---|
| Does this protocol need to be submitted to an external ethics review board? | | |

**General Recommendations to the PI, including suggestions for submission to an external ethics review board, and comments on how to improve the research protocol:**

**Rebuttal comments from PI:**

**References**

Brydensholt, H. H., & Axelsen, N. H. (2004). Research ethics. *Ugeskrift for Laeger*, *166*(24), 2335–2336.

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# Operationalization of the WorldFish Research Ethics Panel

## Composition

- Chair (Research Director or senior/principal scientist)[a]
- One animal ethics specialist
- One human ethics specialist
- 2 other WorldFish scientists on a rotating roster[a, b]
- A member of the WorldFish Research Support Unit

## Roles and Responsibility

- To review the **protocols of all studies conducted by WorldFish that collect primary data** from human participants or animal subjects from an ethical perspective
- To determine if external human or animal ethics approval will be required for each research protocol

## Research Ethics Panel Meeting

- It is expected that scientists submit their research protocols on the fixed dates provided by the RSU
- Monthly meeting to be organized by RSU (on the final week of every month – panel members are determined, depending on submitted protocols)
- Approximately 2 weeks notice will be given for review prior to the panel meetings

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# AOB

- Q&A
- Questions on the process can be also be directed to : wf-ethics@cgiar.org

Supporting documentation (links also found throughout SOP):

- Instructions for Online Protocol Submission
- Resources for Animal Ethics (inc protocol template)
- Resources for Human Ethics (inc protocol template)
- Research Protocol Review Rubric

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# Thank You

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# The care and use of animals for scientific purposes: How to obtain ethics approval for research

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# The Code

Malaysian code of practice for the care and use of animals for scientific purposes

Purpose of  the code -> ensure the ethical and humane care and use of animals for scientific purposes.

Enforces our responsibility to

- Ensure the use of animals is justified
- Ensure the welfare of animals is always considered
- Promote the development and use of techniques that replace the use of animals
- Minimize the number of animals used
- Refine protocols to avoid pain and distress of animals used in science

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# What is animal welfare?

Animal welfare means the physical and mental state of an animal in relation to the conditions where it lives and dies.

Welfare reflects how well an animal is coping within the production system and throughout the scientific project.

Good welfare means the animal is healthy, well-nourished, comfortable, able to express many of its natural behaviours and is not suffering from pain or distress.

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# The Five Freedoms

An internationally recognised backbone for aquatic animal welfare.

Good welfare is largely driven by good husbandry practices and maintenance of a well-designed production system.

Investigators must take all possible steps to uphold these standards of care.


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# Which animals do I need approval for?

You will need animal ethics approval for studies involving any of the following:

- Mammals (other than humans)
- Birds
- Reptiles
- Amphibians
- Fish
- Molluscs
- Arthropods
- Other vertebrates or invertebrates, whether alive or dead, eggs, young or immature form

Fish are sentient animals. Sentience is the capacity to feel, perceive or experience subjectively.

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# Welfare is balanced with a justification of use

Animals are only used when it is essential

- to establish significant information relevant to the understanding of humans and/or animals
- for the maintenance and improvement of human and/or animal health and welfare
- for the improvement of animal management or production
- to establish significant information relevant to the understanding, maintenance or improvement of the natural environment
- for the achievement of educational objectives

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# Institutional Animal Care and Use Committees (IACUC)

- IACUC weighs up the predicted scientific value of the project against the potential effects on the welfare of the animals to grant or decline permission to undertake the project
- IACUC may also oversee and inspect your housing and trial facility

Who makes up IACUC? Minimum of 4 people

1. A person with qualifications in veterinary science
2. A researcher that has experience in the use of animals in science or teaching
3. Animal welfare expert
4. A person who is independent from the institution and the categories above

# Your responsibilities

- Obligation to treat the animals with respect and to consider their welfare as an essential factor when planning or conducting projects.
- All animals used must conform to the standards of The Code and with relevant Federal and State legislation.
- Scientific and teaching activities must not commence until written approval has been obtained from the IACUC.
- The responsibility to conform to the code ultimately lies with the main investigator as identified on the application.

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# 3R

## Replace

Replace animal studies with other methods

## Reduce

As many trials as required, as few as possible

## Refine

Minimize stress of study animals

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# Replacement

Techniques that completely or partially replace the use of animals for scientific purposes must be sought and used wherever possible.

Examples:

- *In vitro* cell lines
- Archived samples
- Can a lower order of life be used as an appropriate experimental model?

  e.g. bacteria, fungi, protozoa and non-sentient invertebrates should have preference over sentient animals like vertebrates

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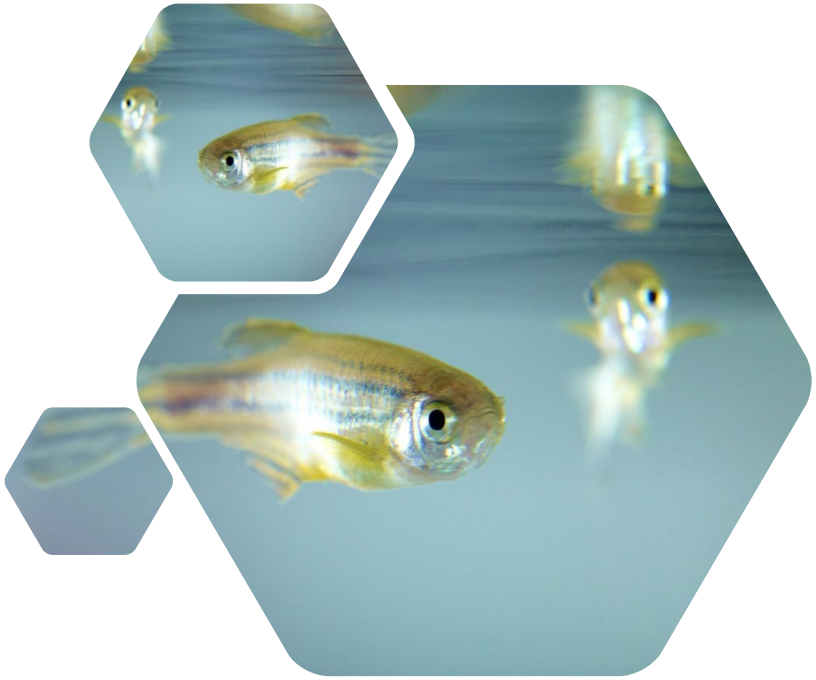
# Reduction

- Use no more than the minimum number of animals necessary to ensure scientific and statistical validity.
- Teaching activities must involve no more than the minimum number of animals required to reach the educational objectives.
- Overproduction of animals bred for scientific purposes should be avoided so that the need to kill healthy animals is minimised.



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# Refinement

- Animals must be suitable for the scientific purpose.
- Animals should be transported, housed, fed, handled and used under conditions that meet species-specific needs.
- Use the best available scientific and educational techniques and be competent in the procedures.
- Projects should be designed to avoid both pain and distress in animals. If this is not possible, pain or distress must be minimised.
- An animal with signs of pain or distress not predicted in the proposal, must have the pain or distress alleviated by treatment or humane euthanasia.
- ‘Death as an end-point’ must be avoided wherever possible.

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# Preparing your proposals

- Detail the project aims and design using simple language. Avoid scientific language where possible to cater for the diversity of people on the committee.
- You must satisfy the IACUC that the proposed use of animals is justified by weighing the predicted scientific value of the proposal against the potential impact on the welfare of the animals.
- You must explain how the impact on animal welfare has been minimised.
- Important to address 3 Rs
- How are you monitoring the welfare of the animals?
- Highlight people are trained and/or experienced
- Declaration
- You can use Standard Operating Procedures (SOPs) that have been previously approved by the internal research panel in the last three years to help support the proposal

# How to address the 3R in your proposal

**Replacement**

Explain why animals are needed for the project, including:

- a list of any potential alternatives to animal use
- whether any of these alternatives would be used, and if not
- why alternatives are unsuitable

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# How to address the 3R in your proposal

**Reduction**

A clear description of:

- the number, species and strain of animals required, by treatment groups, where appropriate
- the reasons why this number is necessary, including whether the proposal is for a repeat of an earlier project and if so, why repetition is necessary
- whether there is an opportunity for the sharing of tissues or animals

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# How to address the 3R in your proposal

## Refinement

- Identify and justify the impact of all aspects of the project on the animal's wellbeing, from the time animals are obtained until the project is completed
- Detail how these impacts will be minimised

transportation
acclimation
experimental procedures
surgical procedures

sequence and timing of events
method of humane killing
routine animal husbandry and handling practices
monitoring plan of animals

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# After approval

You must have written approval before you start. Once approved

- Complete the project as detailed in the approved application
- Notify the IACUC of planned amendments
- Monitor the animals and keep records to show IACUC
- Report adverse events
- You may be inspected by a member of the IACUC, particularly for projects that are likely to cause pain or distress
- Progress report is mandatory if project is to be extended – the project may continue, be suspended and require modification or be discontinue

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# Monitoring

Welfare indicators for fish:

- water quality (dissolved oxygen, temperature, pH, salinity, ammonia, nitrite, nitrate)
- feed rate, feed conversion ratio, growth rate
- mortality rate
- health checks (scale loss, skin condition, eye status, mouth wounds, vertebral deformities, opercular damage, fin damage, condition factor and faeces in the hind gut)
- behavioural indicators
- mortality rate

ALL MONITORING RECORDS SHOULD BE DIGITISED AND KEPT AVAILABLE FOR AUDITING.

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# Completion Report

Completed or discontinued reports should be submitted to IACUC, including

- whether the stated aims were achieved
- whether the number of animals used varied from the number approved and if so, why
- whether the wellbeing of the animals was consistent with that anticipated in the proposal
- detail how procedures in future projects could be modified to reduce an impact on animal welfare
- details of publications and presentations that have resulted from the project

# Always refer to The Code for projects involving:

- Anaesthesia and analgesia
- Humane Killing and Euthanasia
- Death as an end-point
- Repeated use of Animals for Scientific Purpose
- Handling, restraint and confinement of animal
- Withholding of food and water
- Modifying animal behaviour
- Neuromuscular paralysis
- Implanted devices
- Genetic modification
- Induction of Tumours
- Surgery and Post-operative Care
- Blood sampling and tissue harvesting from laboratory animals
- Toxicology studies
- Experiments involving hazards to humans and animals
- AND MORE

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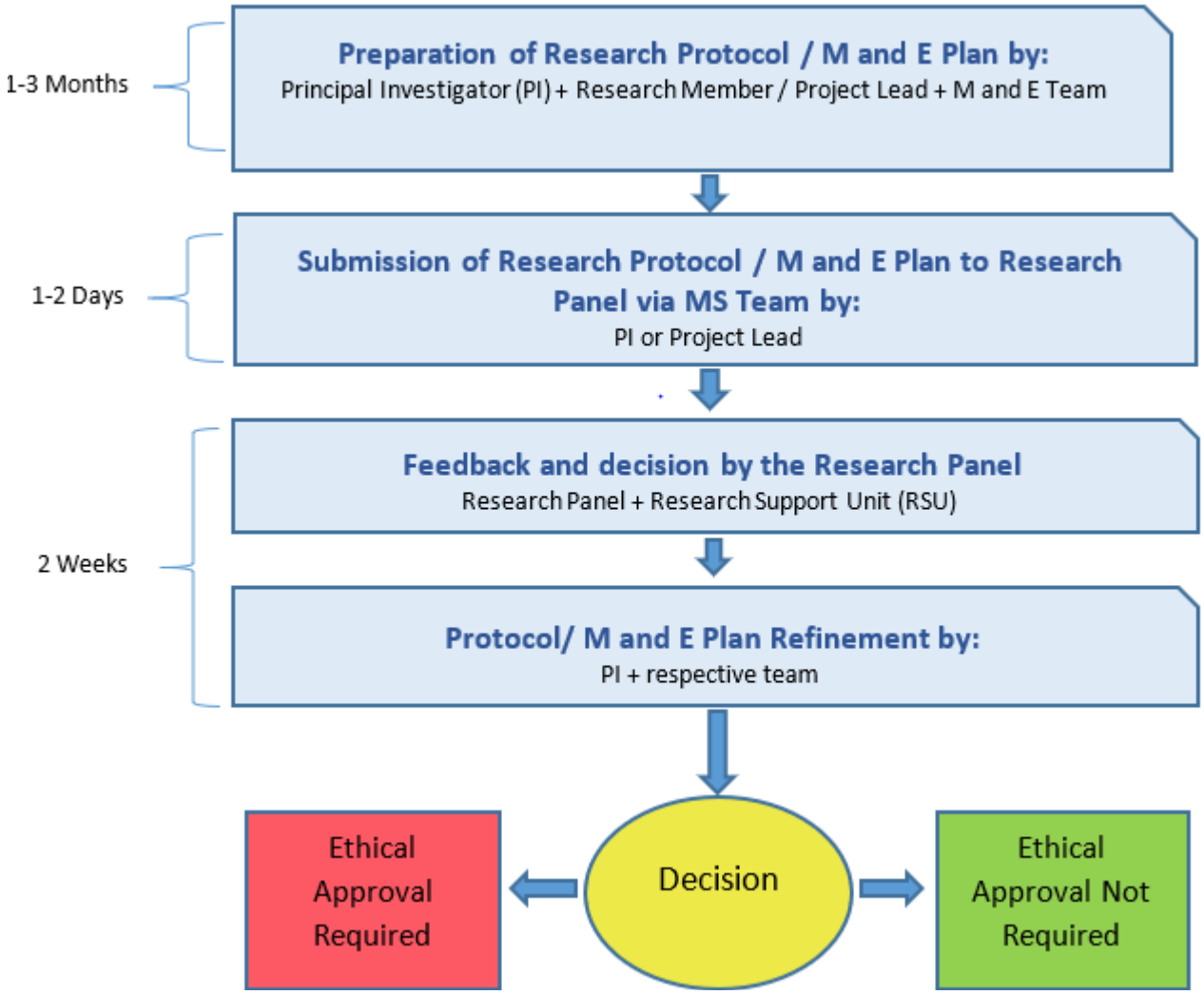
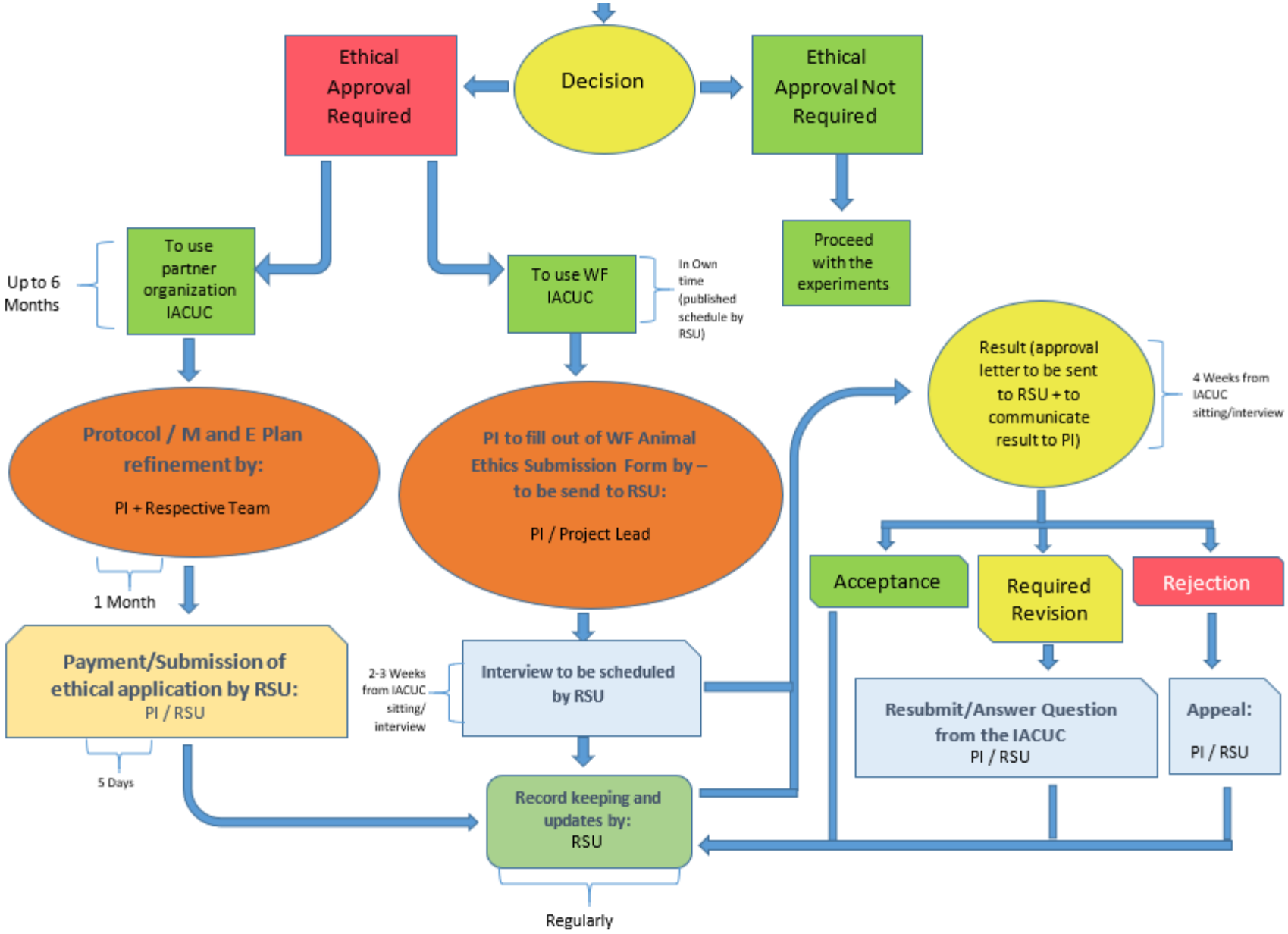
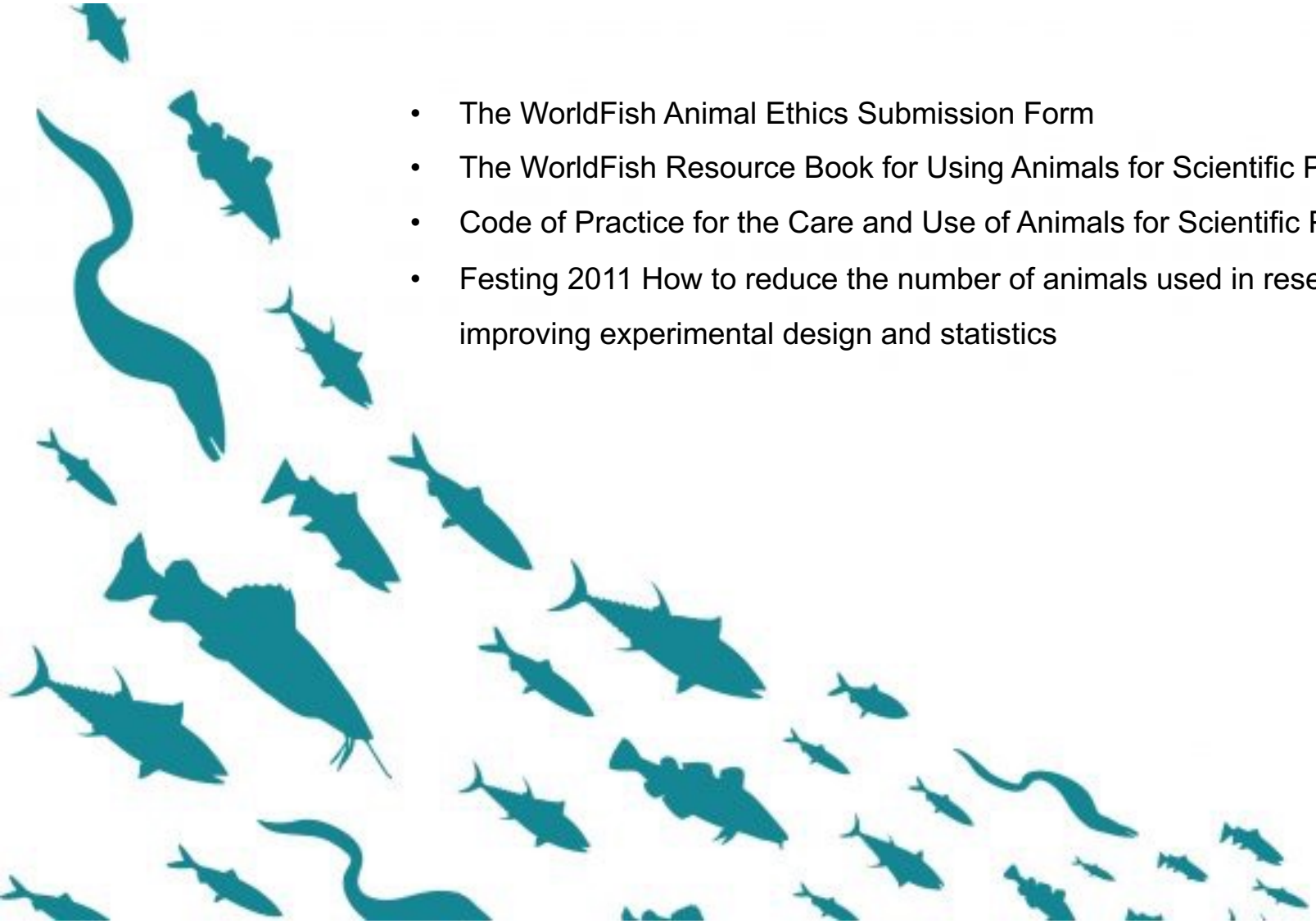
# Ethical Approval Process



# Ethical Approval Process…continued



# Forms and resources



- The WorldFish Animal Ethics Submission Form
- The WorldFish Resource Book for Using Animals for Scientific Purposes
- Code of Practice for the Care and Use of Animals for Scientific Purposes
- Festing 2011 How to reduce the number of animals used in research by improving experimental design and statistics

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# Thank You

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# Ethics in Human Research at WorldFish: An Update and Refresher

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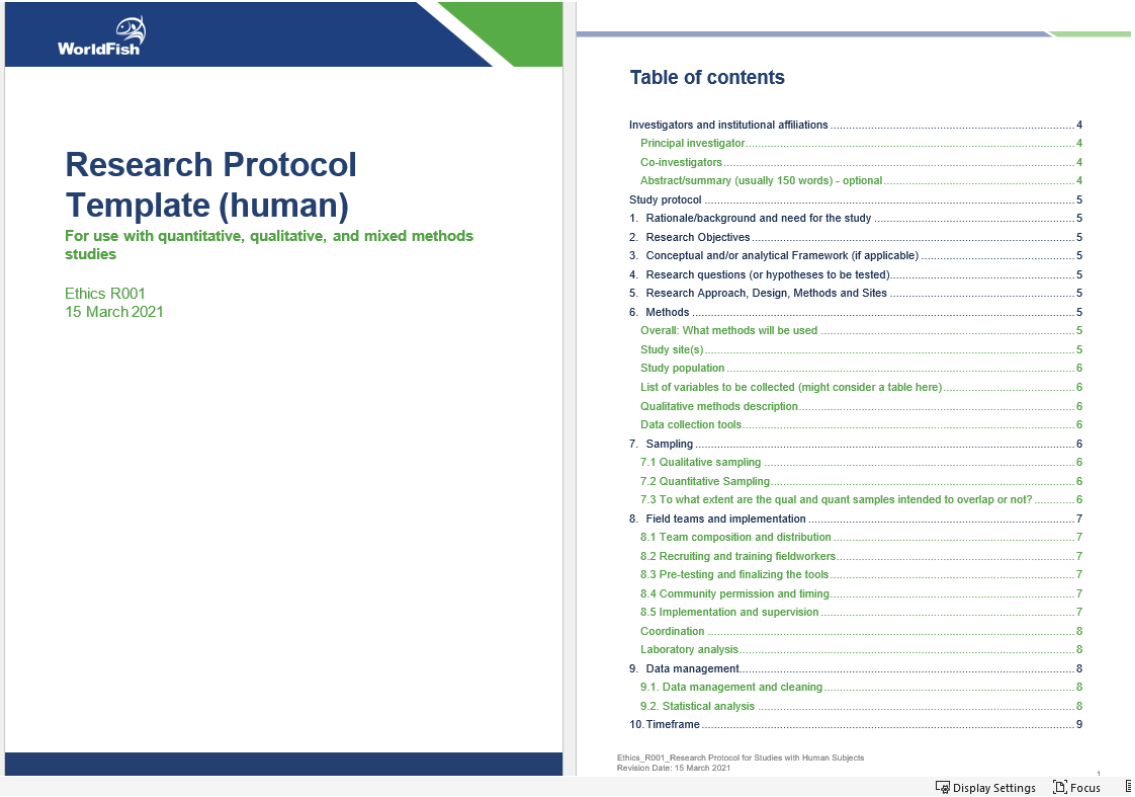
# Improving Research Quality: The Protocols Pilot

- Project designed to get more research at WorldFish to develop research protocols
- Driven by a need to more systematically document research projects (both human and animal)
    - Bring all research up to the same level of quality
    - Learn from each other
    - Produce more high-quality, open-access datasets
    - Bridge the gap between the proposal writing process and the manuscript writing process
- Pilot involved several human and animal scientists at WorldFish: Cynthia McDougall, Kelvin Shikuku, Lauren Pincus, myself, and Rodrigue Yossa. The project was led by Katy Moore

WorldFish

# Developed templates to guide protocol development



WorldFish

Research Protocol Template (human)

For use with quantitative, qualitative, and mixed methods studies

Ethics R001
15 March 2021

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Display Settings  Focus

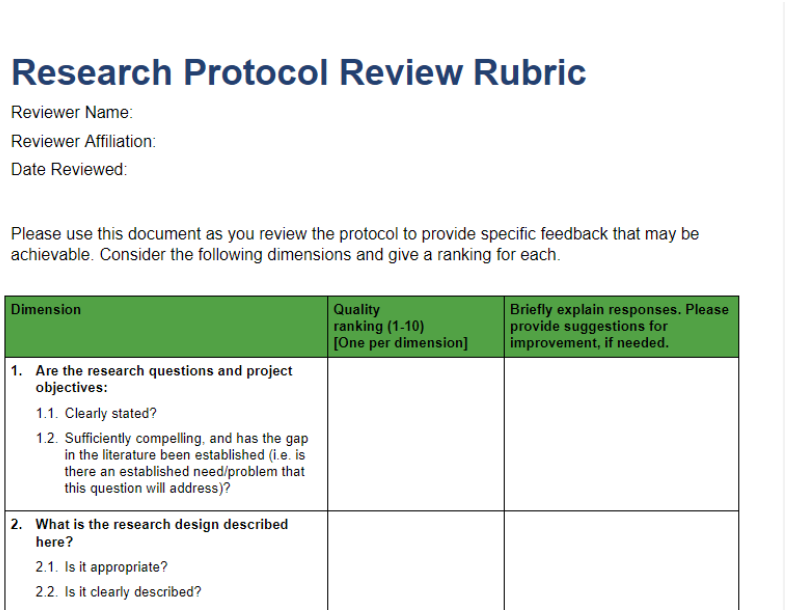
Template can be found on Teams **Research Quality and Ethics Channel** or by clicking here

Can be used with both quantitative, qualitative, and mixed-methods

WorldFish

# Idea was to get protocols adequately reviewed by co-authors and partners

- We developed a rubric for assessing quality of protocols
- Rubric can be found on Teams **Research Quality and Ethics Channel** or by clicking here
- Also designed for use in both qualitative and quantitative research



## Research Protocol Review Rubric

Reviewer Name:

Reviewer Affiliation:

Date Reviewed:

Please use this document as you review the protocol to provide specific feedback that may be achievable. Consider the following dimensions and give a ranking for each.

| Dimension | Quality ranking (1-10) [One per dimension] | Briefly explain responses. Please provide suggestions for improvement, if needed. |
|---|---|---|
| **1. Are the research questions and project objectives:**<br>1.1. Clearly stated?<br>1.2. Sufficiently compelling, and has the gap in the literature been established (i.e. is there an established need/problem that this question will address)? | | |
| **2. What is the research design described here?**<br>2.1. Is it appropriate?<br>2.2. Is it clearly described? | | |

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# Protocols allow for increased opportunity for publications!

Can publish study protocols, statistical analysis plans, or data

Data in Brief
Volume 30, June 2020, 105540

Data Article

## Experimental and survey-based data on willingness to pay for seafood safety and environmental sustainability certification in Nigeria

Kelvin Mashisia Shikuku [a], Nhuong Tran [b], Lauren Pincus [a], Vivian Hoffmann [c], Carl Johan Lagerkvist [d], Shehu Latunji Akintola [e], Kafayat Adetoun Fakoya [e], Jacquieline Muliro [a]

Comment on this paper

## A randomised controlled trial to test the effects of fish aggregating devices and SBC activities promoting fish consumption in Timor-Leste: A study protocol

Alexander Tilley, Kendra A Byrd, Lauren Pincus, Katherine Klumpyan, Katherine Dobson, Joctan do Reis Lopes, Kelvin Mashisia Shikuku

**doi:** https://doi.org/10.1101/2021.08.10.21261568

**This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice.**

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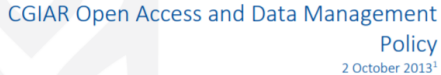
# Ethics in Human Research at WorldFish

- Led by Mike Phillips
- Guided by the CGIAR Research Ethics Code
  - Most specifically using section 4.1: Research involving human participants
- And the CGIAR Open Access Data Management Policy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# Developed an SOP to guide scientists through obtaining ethical approval of their research

WorldFish

Standard Operating Procedures (SOP) for Obtaining Ethical Approval of Research

Ethics P001
26 February 2021

| Document Summary | |
|---|---|
| SOP Title: | Obtaining Ethical Approval of Research |
| SOP Authors: | Kendra Byrd, Rodrigue Yossa, Cynthia McDougall, Kelvin Shikuku, Katy Moore, Michael Phillips and Muhammad Hafizullah |
| External Author | Christine Huynh |
| SOP Sponsor: | |
| Responsible Office: | |
| Effective date: | 14 January 2021 |
| Last updated: | 7 April 2021 |
| To be reviewed: | |

Document can be found on Teams **Research Quality and Ethics Channel** or by clicking here

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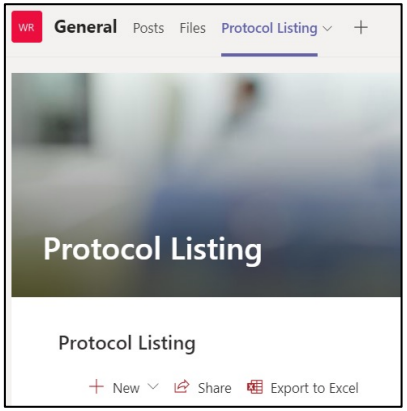
# Established WorldFish Research Ethics Panel

- One panel for human and animal research
- Standardized WF approach to human and animal ethics
- Sharpens research skills of WF scientific staff by rotating participation in panels
- For animal application, panel submits application to a university in Malaysia
- For human research applications:
  - Panel cannot provide permission to conduct your research (that comes from the country where the research is taking place)
  - Provides support for ethics application to host country

# Composition of the WorldFish Research Ethics Panel

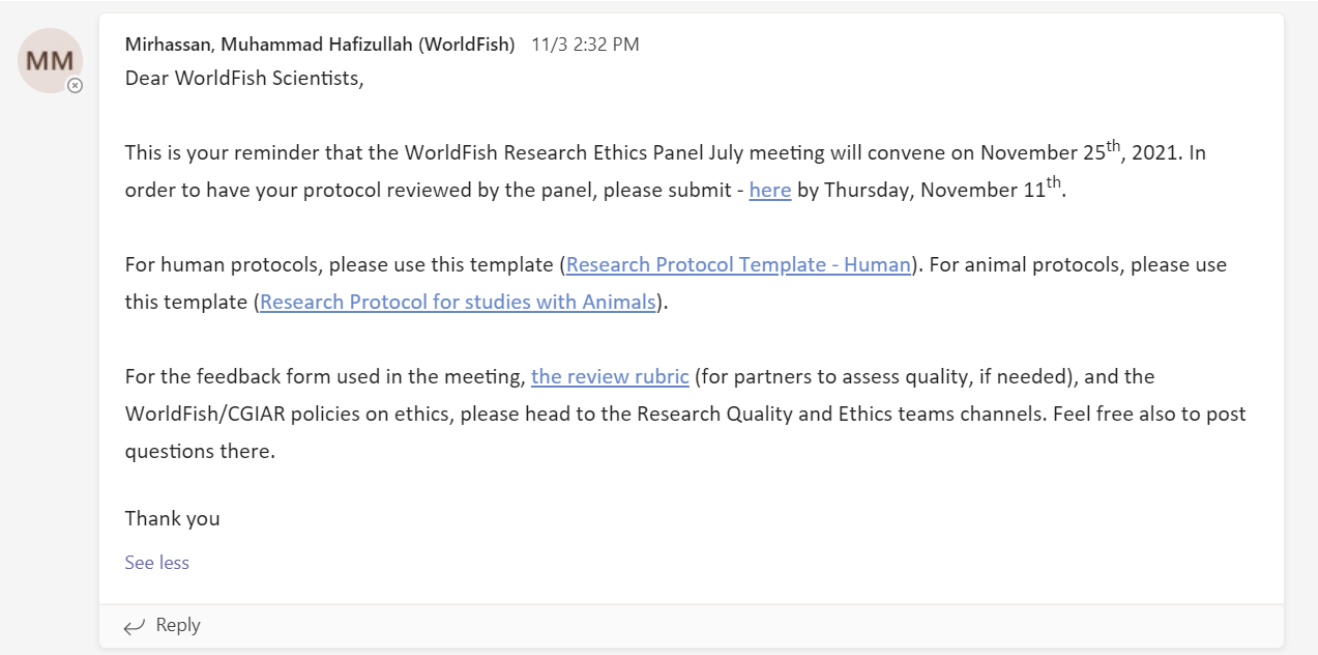
# Submission of developed protocol to WF Research Ethics Panel

- Scientists develop a high-quality protocol with co-authors
- Submit protocol to the WorldFish Research Ethics Panel for review via Teams Channel

# WF Research Ethics Panel meets to review protocols once per month

- Reminders sent out via email and put on the Teams channel



MM

**Mirhassan, Muhammad Hafizullah (WorldFish)** 11/3 2:32 PM

Dear WorldFish Scientists,

This is your reminder that the WorldFish Research Ethics Panel July meeting will convene on November 25th, 2021. In order to have your protocol reviewed by the panel, please submit - here by Thursday, November 11th.

For human protocols, please use this template (Research Protocol Template - Human). For animal protocols, please use this template (Research Protocol for studies with Animals).

For the feedback form used in the meeting, the review rubric (for partners to assess quality, if needed), and the WorldFish/CGIAR policies on ethics, please head to the Research Quality and Ethics teams channels. Feel free also to post questions there.

Thank you

See less

Reply

WorldFish

# Panel timeline

- Allow one month for the panel to review submission/provide feedback
    - In rare cases, emergency meetings may be called (i.e., the donor would like to see ASAP that the research panel has reviewed the protocol)
- Protocols need to be developed and reviewed by co-authors (and potentially other partners) 2-3 months prior to submission to WF Research Panel

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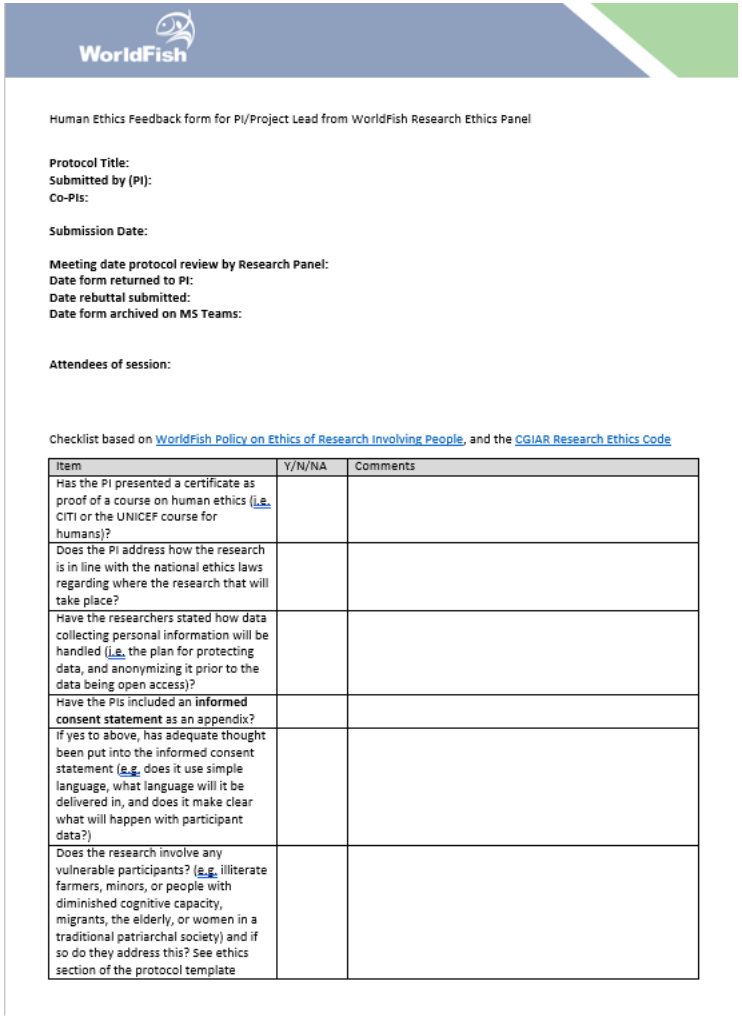
# Feedback from panel

- Feedback will come using a standardized feedback form discussed as a panel (also found on Teams)
- Teams can respond and/or provide a rebuttal to the panel's comments



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Human Ethics Feedback form for PI/Project Lead from WorldFish Research Ethics Panel

**Protocol Title:**
**Submitted by (PI):**
**Co-PIs:**

**Submission Date:**

**Meeting date protocol review by Research Panel:**
**Date form returned to PI:**
**Date rebuttal submitted:**
**Date form archived on MS Teams:**

**Attendees of session:**

Checklist based on WorldFish Policy on Ethics of Research Involving People, and the CGIAR Research Ethics Code

| Item | Y/N/NA | Comments |
|---|---|---|
| Has the PI presented a certificate as proof of a course on human ethics (i.e. CITI or the UNICEF course for humans)? | | |
| Does the PI address how the research is in line with the national ethics laws regarding where the research that will take place? | | |
| Have the researchers stated how data collecting personal information will be handled (i.e. the plan for protecting data, and anonymizing it prior to the data being open access)? | | |
| Have the PIs included an **informed consent statement** as an appendix? | | |
| If yes to above, has adequate thought been put into the informed consent statement (e.g. does it use simple language, what language will it be delivered in, and does it make clear what will happen with participant data?) | | |
| Does the research involve any vulnerable participants? (e.g. illiterate farmers, minors, or people with diminished cognitive capacity, migrants, the elderly, or women in a traditional patriarchal society) and if so do they address this? See ethics section of the protocol template | | |

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# Submission to host country review board

- Scientists need ethical permission from the country where the research is taking place
    - University partner in host country
    - Ministry of Health/other Ministry
    - Other official body in country that approves research
- Panel can provide support and guidance, potentially support can come from the Country Director also/others in country
- Panel is starting to gather and collate information on these institutions in all our focal countries
- Time for in-country approval varies by country – need to allow for as much time as possible
    - Sometimes a presentation of research is required (e.g., in Timor-Leste)

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# Progress of WF Research Ethics Panel so far

- Held 7 regularly scheduled panels meetings (we don't get submissions every month)
  - Held one emergency meeting
- 27 protocols reviewed and feedback provided
- Have a record of research protocols accessible to all WF scientific staff
- Have a better understanding of where to submit human ethics applications
  - Projects can guide each other (e.g., in Timor-Leste and Nigeria)
- More scientists have research ethics certifications
- Proposals are improving with each submission!

WorldFish

# Common areas where we see need for improvement

- Informed consent statements
  - Sometimes it's just copied and pasted
- Delination of how personal data will be handled
  - Sometimes this is not addressed in the protocol
- Protection of vulnerable participants
  - i.e., low-literacy populations, women in a male-dominated society, minors

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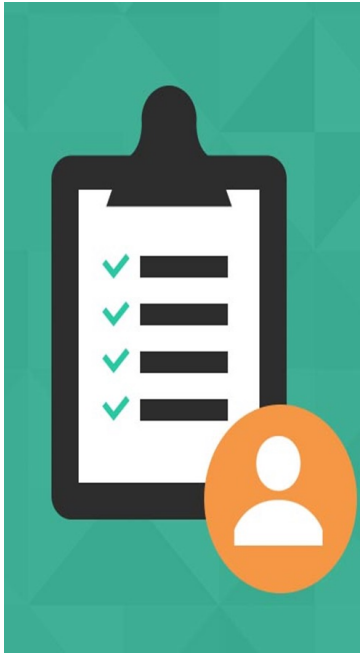
# Potential future projects

- Streamline documents and make accessing them less confusing
- Hold “office hours” for protocol development or statistics
- Incorporate training on research ethics procedures into HR onboarding



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# Key documents and resources

- CGIAR Research Ethics Code and CGIAR Open Access Data Management Policy
- Template for developing human research protocol
- Review rubric for reviewing protocol for quality
- SOP for submitting protocol to WF Research Ethics Panel
- Feedback form for human research used by WF Research Ethics Panel

AND link for submission of research protocol to WF Research Ethics Panel

Other resources for developing high-quality protocols and statistical analysis plans can be found in this folder

WorldFish

# Thank You

WorldFish

# CGIAR Open Access and Data Management Policy

2 October 2013[1]

[1] This Open Access and Data Management Policy is effective as of 2 October, 2013. It was endorsed by the System Management Board on 13 July 2016 (SMB/M1/DP7). It was first approved by the Consortium Board on 2 October, 2013 and endorsed by all Centers on 20 November 2013, prior to the transition to the revised CGIAR System that took effect on 1 July 2016. While nomenclature has been amended to reflect these governance changes, the historical context of the document has not been updated.

## 1. Preamble

CGIAR regards the results of its research and development activities as international public goods and is committed to their widespread dissemination and use to achieve the maximum impact to advantage the poor, especially smallholder farmers in developing countries. CGIAR considers Open Access (defined below) to be an important practical application of this commitment as it enhances the visibility, accessibility and impact of its research and development activities. Open Access improves the speed, efficiency and efficacy of research; it enables interdisciplinary research; assists novel computation of the research literature; and allows the global public to benefit from CGIAR research. Furthermore, CGIAR recognizes the benefits that accrue to individual researchers and to the research enterprise from wide dissemination, including greater recognition, more thorough review, consideration and critique, and a general increase in scientific, scholarly and critical knowledge. CGIAR further recognizes that, in implementing this Policy, it can more easily and collectively build the infrastructure necessary to be at the forefront of the open access and open data for agriculture movement.

This Policy stems from – and complies with – the *CGIAR Principles on the Management of Intellectual Assets* ("**CGIAR IA Principles**")[1], which is the umbrella document for this Policy. In particular, this Policy expands on Article 6.1 of the CGIAR IA Principles which provides that "*The [CGIAR] System Organization and the Centers shall promptly and broadly disseminate their research results, subject to confidentiality as may be associated with [certain] permitted restrictions, or subject to limited delays to seek IP Rights [(patents, etc.)]*".

## 2. Scope and implementation

This Policy was approved by the CGIAR System Organization[2] on October 2, 2013 and is effective as of this date (the "**effective date**"). Implementation of and compliance with this Policy by CGIAR System Organization, CGIAR Centers and their implementing partners within the scope of the Strategy and Results Framework ("**SRF**") and the CGIAR Research Programs ("**CRPs**") will be phased over a transition period. The transition period runs from the effective date of the Policy for an initial period of 5 years, with comprehensive implementation by the end of 2018. This Policy should be read in conjunction with the CGIAR Open Access and Data Management Implementation Guidelines[3], which may be updated from time to time to reflect current recommended practices.

[1] The CGIAR IA Principles are available at https://library.cgiar.org/bitstream/handle/10947/4486/CGIAR%20IA%20Principles.pdf?sequence=1

[2] This Policy was approved by the CGIAR System Organization when it was called the Consortium of International Agricultural Research Centers and operated under the name "CGIAR Consortium"

[3] Available at http://library.cgiar.org/bitstream/handle/10947/4489/Open%20Access%20Data%20Management%20Implementation%20Guidelines.pdf

## 3. Information products

This Policy sets common expectations with respect to Open Access to the following indicative types of information products ("**information products**"): peer-reviewed journal articles; reports and other papers; books and book chapters; data and databases; data collection and analysis tools (e.g. models and survey tools); video, audio and images; computer software; web services (e.g. data portals, modeling on-line platforms); and metadata associated with the information products above.

## 4. Policy statement

### 4.1 General

4.1.1 Openness. Best efforts shall be used to make all information products Open Access, subject always to the legal rights and legitimate interests of stakeholders and third parties, including intellectual property rights, confidentiality, sensitivity (including price and politically sensitive information), farmers' rights and privacy.

Information products may not always be of value to others, for example because those outputs are draft, poor quality or incomplete. Open Access arrangements should consider the characteristics of the information product, their potential impact, the level of data processing required, and whether the information products generated are within the scope of this Policy. Some judgment therefore needs to be made over the information products that will be made Open Access.

4.1.2 Suitable Repositories. Stable, permanent, Open Access repositories shall be utilized, to enable users and other sites and search engines to access or locate information products, including application programming interfaces (APIs) or other mechanisms enabling those information products to be available from the CGIAR website and associated web-based products. Preference should be given to existing repositories to minimize the number of repositories in use (and the interoperability challenges presented by multiple incidences of repositories).

4.1.3 Interoperability. Syntactic and semantic interoperability is a key consideration in enabling and promoting international and interdisciplinary access to and use of information products. Information products must therefore be described with standardized metadata, and stored and delivered using appropriate protocols and formats to ensure that their content can be discovered, shared and incorporated across different technological platforms.

4.1.4 Data storage and preservation for future use. Information products must be stored where users can find them and where they will be preserved for future use. As time goes by, they will need to be managed, maintained and curated.

4.1.5 Copyright and Open Licenses. Suitable open licenses shall be used that recognize the legal rights to information products and encourage their use and adaptation.

4.1.6 Incentives and professional expertise. Incentives and the development of professional expertise in all areas of Open Access and data management shall be devised, adopted and promoted.

4.1.7 Translation. Translations of key documents and other media into pertinent languages are encouraged. All versions should be deposited in suitable repositories and made Open Access.

4.1.8 Limited internet connectivity. To assist those with limited internet connectivity, designing easily accessible information products (e.g. websites, PDFs) or making available alternative versions that require minimal data download to see and use is encouraged.

4.1.9 Open Access and Data Management Plans. Open Access and Data Management Plans should be prepared in order to ensure implementation of this Policy. Such Plans shall, in particular, outline a strategy for maximizing opportunities to make information products Open Access.

**4.2 Open Access for indicative types of information products**

4.2.1 Peer-reviewed journal articles. Peer-reviewed versions of scholarly articles reporting research should be deposited in a suitable repository and made Open Access as soon as possible, ideally at the time of publication, and no later than 6 months from the date of publication. Authors are free to choose the journal that is most appropriate to their needs. Where an author publishes in a closed access journal, he/she shall self-archive in an Open Access repository a digital version of the final accepted manuscript (the "postprint" version).

4.2.2 Reports and other papers. Information products that are not intended for peer-review journals, such as reports, conference papers, policy briefs and working papers, shall be deposited in suitable repositories and made Open Access as soon as possible and in any event within 3 months of their completion.

4.2.3 Books and book chapters. The full digital version of books and book chapters shall be made Open Access as soon as possible after publication and in any event within 6 months either through self-archiving or other suitable publication arrangements.

4.2.4 Data and databases. Data (and any relevant data collection and analysis tools) shall, subject to any additional donor requirements, be deposited in a suitable repository

and made Open Access as soon as possible and in any event within 12 months of completion of the data collection or appropriate project milestone, or within 6 months of publication of the information products underpinned by that data, whichever is sooner. Data deposited shall be prepared in a manner consistent with the aims of this Policy. Existing and future databases shall be made Open Access.

4.2.5 Video, audio and images. Complete final digital versions of video and audio outputs, and image collections must be stored appropriately and made Open Access within 3 months of their completion.

4.2.6 Computer software. Where an information product is software developed internally, the associated source code must be deposited in a free/open software archive upon completion of the software development. Access to such information products may be granted subject to appropriate licences (e.g. Copyleft).

4.2.7 Metadata. The metadata of an information product must be deposited in a suitable repository before or on publication of the information product. Where an information product is not deposited in a suitable repository, the deposited metadata must include a link to the information product.

## 5. Review

The System Management Office will carry out an evidence-based review of the implementation of this Policy on an annual basis. The reviews will be used to devise appropriate institutional tools and guidelines for the implementation of this Policy.

The System Management Office (in consultation with the Centers) will review this Policy in 2015 and every two years thereafter in light of experiences gained. This Policy may be amended at any time by agreement of the System Organization, in consultation with the Centers.

## 6. Definitions

For the purposes of this Policy:

**Data** means the digital recorded factual material commonly accepted in the scientific community as necessary to validate research findings, including data sets used to support publications and/or that have been prepared and validated but that do not support publications. This does not include laboratory notebooks, preliminary analyses, drafts of

scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as laboratory specimens.[4]

**Database** means a collection of independent works, data or other materials, which are arranged in a systematic or methodical way and which are individually accessible by electronic or other means.[5]

**Open Access** means the immediate, irrevocable, unrestricted and free online access by any user worldwide to information products, and unrestricted re-use of content (which could be restricted to non-commercial use and/or granted subject to appropriate licences in line with the CGIAR IA Principles), subject to proper attribution.

[4] Adapted from the Office of Science and Technology Policy Guidelines.
[5] From Directive 96/9/EC of the European Parliament of 11 March 1996 on the legal protection of databases.

# CGIAR RESEARCH ETHICS CODE

Approved by the CGIAR System Board as a CGIAR Policy with effect from 3 November 2020
(Decision Reference SB/M17/EDP12)

# CGIAR's Core Ethical Values

Integrity | Dignity and Respect | Sustainability |Excellence and Innovation | Partnership[1]

## Integrity

We are honest, tell the truth, keep promises, pursue objective scientific research, admit mistakes, earn trust, and always act professionally by being accountable and transparent

## Dignity and Respect

We value and embrace diversity and inclusion, treat all stakeholders with respect and dignity, promote equity, avoid all forms of discrimination, and promote human rights

## Sustainability

We plan responsibly for the long term, and are committed to environmental, social and economic food security, safety and global prosperity

## Excellence and Innovation

We strive for excellence by maintaining high standards of scientific rigor, actively encouraging innovation and creativity, and pursuing our passion for learning and discovery

## Partnership

We value the diverse voices of our internal and external stakeholders, and seek all forms of engagement, collaboration and teamwork

[1] These Core Ethical Values are extracted from the CGIAR Ethics Framework endorsed by the System Management Board on 3 October 2019.

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# 1. Purpose

1.1 CGIAR entities have a shared mission: *Ending hunger by 2030 – through science to transform food, land and water systems in a climate crisis*. To deliver on this common mission, CGIAR has adopted a unified system of governance for all CGIAR legal entities, to provide forward-looking and aligned strategic direction and oversight for bold cross-disciplinary research.

1.2 CGIAR strives to conduct its operations according to the highest ethical standards and create an environment that promotes CGIAR's Core Ethical Values of integrity, dignity and respect, sustainability, excellence and innovation, and partnership.[2]

1.3 Those involved in CGIAR research activities have a significant obligation and responsibility to embody CGIAR's Core Ethical Values. Their adherence to working in accordance with best practice ethical standards is fundamental to ensuring broad public trust and confidence in CGIAR operations.

1.4 The purpose of this Research Ethics Code ("this Code") is to ensure that clear, achievable and relevant standards of ethical conduct apply to all CGIAR Research. [2]

1.5 This Code may be complemented by additional policies where appropriate, provided that these are consistent with this Code.

# 2 Scope

This Code applies to the following persons (collectively referred to as "Researchers"):

i) all individuals employed or otherwise contracted by a CGIAR entity (for example, staff, consultants, secondees, students, visiting fellows and scholars) who are involved in research activities of any kind; as well as

ii) individuals employed or contracted by CGIAR partners who are involved in CGIAR research programs or projects or whose research is otherwise funded by a CGIAR entity.

# 3 General standards

## 3.1 Scientific quality and integrity

3.1.1 Researchers must strive to conduct high-quality research that has clear developmental and practical value in relation to the CGIAR mission. They must develop studies and research programs that are built on adequate prior knowledge and are scientifically sound, undertaking scientific activities only within the boundaries of their

[2] As defined by the CGIAR System Framework and the Charter of the CGIAR System Organization, as amended from time to time. On the date of approval of this Code, "CGIAR Research" is defined as "*the research carried out by the Centers and the CGIAR System Partners in support of the CGIAR Strategy and Results Framework*".

competence, based on their education, training or work experience. Researchers must adhere to the highest possible technical standards that apply to their field of work.

3.1.2 Researchers must strive for the highest reliability in the quality of research, including the design, methodology, analysis and use of resources. They must do their utmost to ensure factual accuracy of data and research results and must not engage in research misconduct (falsification, fabrication, plagiarism, suppression or purposeful misinterpretation of data or research results). They shall keep good records of scientific activities, such as data collection, research design and correspondence with collaborators or journals and shall adhere to the CGIAR Open Access and Data Management Policy in the management of data.

3.1.3 Researchers shall promote the open exchange of ideas, research methods, data and results, and their discussion, scrutiny and debate, subject to any considerations of confidentiality and third-party rights. They shall ensure that their methodologies and findings are open for discussion and peer review. Researchers are independent and impartial in their communication with other Researchers and open and honest to the public.

3.1.4 Research managers must ensure that Researchers under their supervision have the necessary resources to conduct scientific activities in line with required standards and ensure that the right capabilities and competences are assigned to research activities. Researchers must ensure that they have the necessary skills and resources to carry out research themselves or through collaboration with specialists in relevant fields. They recognize the need for ongoing education in order to remain competent and they utilize the appropriate scientific, professional, technical and managerial resources needed to ensure competence in their work-related activities.

### 3.2 Reporting and dissemination of research results

3.2.1 In accordance with the CGIAR Principles on the Management of Intellectual Assets, CGIAR regards the results of its research and development activities as international public goods. CGIAR is committed to the widespread diffusion and use of research results to achieve the maximum possible access, scale, scope of impact and sharing of benefits to advantage the poor, and particularly farmers, in developing countries. To facilitate this, Researchers must ensure the prompt publication and dissemination of research results by the most appropriate means, subject to intellectual property, privacy, confidentiality and contractual considerations. The management of research data must be done in accordance with the CGIAR Open Access and Data Management Policy, the CGIAR Open Access and Data Management Implementation Guidelines and the CGIAR Principles on the Management of Intellectual Assets.

### 3.2.2 **Responsibility for research findings**

a) Researchers must ensure that reporting results serve, and do not compromise, the initial goals and purpose of their research. Researchers must take particular care to state all relevant qualifications on the findings and interpretation of their research. Researchers must also disclose underlying assumptions, theories, methods, measures, and research designs that might bear upon findings and interpretations of their work. In presenting their work, Researchers must report their findings fully and not omit relevant data.

b) Consistent with the spirit of full disclosure of methods and analyses, once findings are publicly shared, Researchers shall permit their open assessment and verification by other responsible Researchers with appropriate safeguards, and where applicable, protect the anonymity of research participants.

c) If Researchers discover significant errors in their publication or presentation of data, they must take reasonable steps to correct such errors in a correction, a retraction, published errata or other public fora as appropriate.

### 3.2.3 **Authorship credit**

a) Researchers must take responsibility and credit, including authorship credit, only for work they have actually performed or to which they have contributed. They must ensure that principal authorship and other publication credits are based on the proportional scientific or professional contributions of the individuals involved, regardless of their status. Decisions on publication and authorship must be agreed jointly and communicated to all members of the research team.

b) Researchers must fully credit the contributions of research partners, including non-professional partners such as farmers. Credits include co-authorship, which is strongly encouraged, and being named in acknowledgements. Authorship will not be allocated to honorary or guest authors (and those that do not fulfil criteria of authorship).

### 3.2.4 **Respect for intellectual property and confidentiality**[3]

a) Researchers must honor patents, copyrights and all other forms of intellectual property. Researchers must follow the terms of specific applicable licenses to the intellectual property accessed and used. Researchers must not use unpublished data, methods or results without permission from the intellectual property owner.

b) Researchers must clearly acknowledge all sources used in their research and obtain permission from any individuals if a significant amount of their work has been used in a publication. In their publications, presentations, training, practice and service, all

[3] For further guidance on the management of intellectual assets and intellectual property rights please refer to the CGIAR Principles on the Management of Intellectual Assets and the Implementation Guidelines for the CGIAR Intellectual Assets Principles on the Management of Intellectual Assets.

Researchers must provide acknowledgment of, and reference to, the use of the work of others, even if the work is not quoted verbatim or paraphrased.

c) Researchers must provide fair, prompt and rigorous evaluations and respect confidentiality when reviewing the work of others. In all circumstances, Researchers must not use or otherwise seek to gain from information or material received in a confidential context (such as knowledge obtained from reviewing a manuscript, serving on a proposal review panel or reviewing budgetary information), unless they have authorization to do so, or until that information is otherwise made publicly available.

#### 3.2.5 Funder acknowledgement

All funders and sponsors of research must be acknowledged in accordance with the CGIAR Funder Acknowledgement Guidelines as well as any applicable instructions or terms provided by such funders and/or sponsors.

#### 3.2.6 Accountability and transparency

a) Researchers must ensure that any research undertaken complies with the agreements, terms and conditions relating to their project and facilitate systematic and transparent tracking of outputs and impacts as per established procedures for performance management.

b) Research managers and supporting operational units (such as finance, procurement and partnerships units) must adhere to appropriate, accountable and transparent use of funding for research by ensuring compliance with the procedures that are in effect for the planning, monitoring, reporting, evaluation and impact assessment of CGIAR projects (including projects conducted by CGIAR alone and with partners).

### 3.3 Conflict of interest

#### 3.3.1 Conflict of interest: concept

a) A conflict of interest arises in a situation where there are reasonable grounds to believe that a Researcher's:

   i. direct or indirect personal interest, including that of a closely associated third party such as a family member, in a matter; or

   ii. duty owing to another organization outside the CGIAR System

present a risk that a Researcher's professional judgment will, may or may be perceived to be unduly influenced.

b) A conflict of interest may be actual (it exists), potential (it might develop into one) or perceived (it may be considered to exist by others).

c) Conflicts of interest may arise as a result of a Researcher's association with an organization external to the CGIAR System, or closely associated third parties (such as family members and/or professional associates) whose interests may conceivably conflict with those of one or more of the CGIAR entities on a given issue.

d) In many situations, conflicts of interest will relate to financial interests, or the potential for personal or professional advantage, but they may also arise by virtue of the potential a given situation or relationship presents for the undue exercise of influence.

e) In situations where Researchers are required to address a conflict of objectives, they must be particularly vigilant when taking decisions, ensuring they are made with full objectivity and transparency. In taking such decisions, Researchers must take into account a range of factors and potential outcomes in determining the appropriate course of action to take, mindful of trade-offs that may need to be made in the process.

3.3.2 **Declaring conflicts of interest**

a) The onus is on each Researcher to self-identify actual, potential or perceived conflicts of interest, since only he/she has the detailed knowledge to do so.

b) Researchers must identify and declare conflicts of interest as and when they arise, in accordance with established operating procedures.

c) Researchers should actively seek advice from others to assist them in determining whether an actual, potential or perceived conflict of interest might exist. Advice channels may include the CGIAR Chief Ethics Counsel, fellow Researchers, ethics focal points, legal counsel or focal points of a CGIAR entity. Researchers should remain open to indications of potential conflicts of interest from other individuals.

3.3.3 **Managing conflicts of interest**

a) Once identified, a conflict of interest must be managed appropriately, in accordance with established operating procedures.

b) In determining the course of action to follow, the materiality of the interest and the likelihood that it will impair the objective and impartial exercise of judgment required of Researchers must be duly assessed.

### 3.4 Working with research and development partners

3.4.1 In delivering scientific innovations to achieve its mission, CGIAR Researchers collaborate with development partners, national agricultural research and extension services and the private sector to achieve impact at scale. CGIAR's Core Ethical Values reflect the importance of these partnerships by highlighting the value of the diverse voices of stakeholders and commitment to all forms of engagement, collaboration and teamwork. There is therefore an ethical obligation on the part of Researchers to treat their partners with respect, as equals in the joint activity and with sensitivity to the cultural norms and values of partner countries.

3.4.2 CGIAR's Core Ethical Values must be clearly articulated to research and development partners, emphasizing CGIAR's commitment to valuing and embracing diversity and inclusion, treating all stakeholders with respect and dignity, promoting equity, avoiding all forms of discrimination and promoting human rights. Where Researchers encounter apparent discrepancies between the expectations of partners and the CGIAR mission and the Core Ethical Values, they are encouraged to engage in dialogue with partners with the view to overcome any discrepancies and to seek external expert advice when necessary.

3.4.3 Researchers must ensure transparency with regard to the objectives of the partnership, expectations related to the outputs and outcomes, and communication about research progress and uptake of research during the partnership. Researchers must engage in open dialogue with partners regarding their aspirations for collaboration and strive to ensure that CGIAR research delivers on the goals agreed with partners.

3.4.4 In relation to the outputs of partnerships, CGIAR Researchers must ensure that all participants of any collaboration, including local and external scientists and non-research specialists, have access to research results (for example, in the form of data and publications) and are appropriately credited, either through authorship, contribution or formal acknowledgement, as per the provisions in section 3.2.3.

# 4 Specific standards

## 4.1 Research involving human subjects

4.1.1 The provisions in this section apply to research involving people as subjects in research, whether in the form of surveys, interviews, focus group discussions, participant observations, multi-stakeholder dialogues or participatory action and learning. For a full definition and examples, please refer to Annex III. The procedures for approval of research involving human subjects shall be established as part of System-wide policies and services within the CGIAR Research Ethics Code.

4.1.2 Researchers must ensure that all their research complies with international standards of ethical treatment and protection of human subjects, including the three core principles of respect for persons, beneficence and justice, as stated and explained in the Belmont Report. All research plans must be implemented in compliance with national laws regarding research involving human subjects, including laws and regulations on personal data or personally identifiable information ("PII") (see section 4.1.8 below), and in accordance with relevant policies on personal data protection. [4]

4.1.3 In all its research activities, CGIAR must treat human participants with dignity and respect and have procedures in place to (i) obtain prior informed consent to ascertain that research is voluntary; (ii) protect the privacy of the individual or household, as

[4] Such policies are under development.

applicable; and (iii) protect participants from any risk to which they may be exposed while participating in CGIAR research.

4.1.4 Researchers must make a non-arbitrary, systematic and fair assessment of the possible harms and benefits of their research. This must include physical, psychological, legal, social and economic harm and benefits accruing to individuals, families and communities.

4.1.5 **Selection of research participants**

a) The selection of participants shall be made on the basis of the objectives of the study, rather than on non-research interests. When the experimental design of research involving human subjects includes various groups, adequate selection methods and other specific technical standards relevant to the study must be used to obtain an impartial allocation of the participants in each group. Special attention must be paid to ensuring diverse representation from subject groups, including participation from women, men and minority groups where possible and consistent with the objectives of the study.

b) Research may require the involvement of marginalized or vulnerable people. Researchers shall not exclude vulnerable groups from studies based on the complications involved, but rather take measures to protect vulnerable individuals and groups adequately. For this, Researchers must ensure that research plans minimize the possibility of coercion, undue influence or manipulation, and maximize the likelihood of valid informed consent.

4.1.6 Researchers must not offer excessive or inappropriate financial or other inducements to obtain the participation of research participants, particularly when it might coerce participation. Researchers may provide compensation to the extent that resources are available and appropriate.

4.1.7 **Prior informed consent**

a) Voluntary participation is a precondition for involving human subjects in research. Researchers must therefore obtain informed consent from participants by obtaining permission before data collection and/or an intervention (refer to Annex III).

b) Researchers must uphold the right of research participants to consent to, withdraw from, or refuse to take part in research. Participants must be made aware that their participation is voluntary and that they can withdraw at any time. No coercion or undue inducements shall be given by Researchers or by those in authority acting for Researchers. In undertaking research with vulnerable people, [5] Researchers must take care to ensure that the voluntary nature of the research is understood, and that consent is not coerced.

[5] For example, illiterate farmers, children or youth, migrant populations or displaced persons. For a full definition, please refer to Annex I.

c) The standard informed consent process includes provision of information about the research project and receipt, from each subject, of consent (written or verbal) to participate in a research project. Before undertaking research activities, Researchers must ensure that research participants are fully informed about the nature, purpose, methods and intended possible uses of the research; [6] what their participation in the research entails; and any benefits, harm or risks to them and others induced by the research. Please refer to Annex III for more details on the process of obtaining prior informed consent.

d) Researchers must also obtain informed consent from any person involved prior to recording audio, video or taking photographs and obtain permission to use the recorded materials (please refer to Annex III for a template), unless these activities involve naturalistic observations in public places and it is not reasonably anticipated that the recording will be used in a manner that could cause personal identification or harm.

#### 4.1.8 **Confidentiality and personal data protection**

a) Research data must be handled in a way that protects the wellbeing of people by not harming their safety, dignity or privacy. As far as research data involves PII, Researchers must comply with relevant policies on personal data protection. [7]

b) CGIAR must protect the privacy of individuals and maintain the confidentiality of PII which, alone or collected together, can lead to the identification of a particular person or household, such as:

- a name and surname
- a home address
- an email address
- phone or mobile number and the advertising identifier of a phone
- an identification card number, social security number or similar ID
- location data including the location data function on a mobile phone
- geospatial coordinates of personal or household assets, including homesteads and fields owned and/or managed or used by subjects
- an Internet Protocol ("IP") address or a cookie ID
- any other identifier that allows for the identification of a person or a small group of persons, including people's images or voices
- nationality, religious beliefs or any other personal identifier, when collected together with any of the above.

[6] In some behavioral experiments it may be necessary for the true nature of the experiment to not be disclosed to participants. In such cases, after data collection is completed, the Researchers are required to provide the true objectives and details of the study and must request permission from the human subjects to use the data for research.

[7] Such policies are under development.

c) PII must not be released or made public in any manner as it is regarded as confidential by laws and regulations of most countries. All data must be adequately protected during storage to prevent losses and to ensure that the identity of participants cannot be traced to the source by Researchers analyzing the data. All PII (including records of interviews and informed consent forms) must be kept in a secure archive.

d) When research requires maintaining PII in databases or record systems, Researchers must delete any variables that identify a particular person or household before the information is made publicly available. If PII is entered into databases or records systems available to persons without the prior consent of the relevant parties, Researchers must protect anonymity by not including personal identifiers or by employing other techniques that mask or control the disclosure of individual identities.[8] PII data collected by CGIAR must not be shared with third parties without explicit permission from participants.

e) Researchers must comply with the standards for managing, storing and sharing research data outlined in the CGIAR Open Access and Data Management Policy and the CGIAR Open Access and Data Management Implementation Guidelines. All non-confidential research data collected by researchers shall be made open according to the CGIAR Open Access and Data Management Policy.

4.1.9 **Protection from risks**

a) Researchers working with local communities or other stakeholders must be vigilant of the potential risks posed by research undertaken and any potential negative responses or unintended effects. CGIAR Researchers shall collaborate with local organizations with extensive experience and sound records in identifying and mitigating possible risks in a way that is culturally appropriate in a given context. Efforts are made to consult and collaborate with local women's and minority groups to assist in identifying potential gender and diversity considerations in managing risks.

b) Researchers must take all possible steps to ensure the safety and security of themselves, partners, research participants and other persons affected by their research. When conducting research, Researchers must not encourage activities or behave in ways that are unhealthy or life-threatening to research participants or others. Similarly, they must avoid activities that may affect the reputation of those involved in research. Researchers must suspend research immediately if they perceive that its continuation could be damaging to anyone involved.

c) If any group affected by research activities challenges the research team's right to be in the community, attempts to prevent the research from being conducted, or threatens violence, Researchers shall withdraw from the location and seek the assistance of partner institutions with the authority to resolve the dispute and discuss remedial options with communities. Communities or individuals at risk must be aware

[8] For tools and procedures for managing confidential research data see, for example, the International Livestock Research Institute (ILRI) Policy Procedure on Disclosure of Confidential Research Data.

of whom to contact, and have their details, to discuss any issues that arise regarding their research.

### 4.2 Research involving animals

4.2.1 Respect for animals must form the foundation for all decisions regarding animal care and use for scientific purposes for CGIAR and its Researchers. CGIAR must aim to engender this same culture in collaboration with partners.

4.2.2 Animal ethics must serve as a moral and legal framework that is applied to evaluate whether proposed actions involving the use of animals should be performed. The consideration of animal ethics is required for any scientific procedure involving animals, observational studies where an animal's behavior or habitat may be affected or any other interactions with animals. It is unethical for Researchers to conduct unnecessary or poorly designed animal experiments, even if the impact on animals is low.

4.2.3 Any new or ongoing research or teaching activity using animals must receive animal ethics approval. This applies to all vertebrate and some invertebrate species, including cephalopods and decapod crustaceans, and any bird, reptile or mammal past the mid-point of gestation/incubation. Routine veterinary or agricultural practices do not need ethics approval. When evaluating environmental impacts (see section 4.4) this list of species should be broadened further to include all invertebrate species that are of importance, such as pollinators or any locally endangered species.

4.2.4 **The 3Rs: Replace, reduce and refine the use of animals in research**

a) The fundamental principle guiding research and training involving animals is that animals can, and should, be used in research or teaching which may benefit humans, animals or the environment, provided there is no acceptable non-animal alternative. This must apply to animals in laboratory, farm and field settings where evaluation of the necessity of the activity and the appropriateness of the design is carried out prior to and during the use of animals in experiments or teaching. This may involve some evaluations being conducted after previous approvals have been granted.

b) When animals are used for scientific purposes, the internationally established principles of replacement, reduction and refinement (the three Rs) [9] should be taken into account:

- **Replacement** requires that wherever possible, techniques that totally or partially replace the use of animals for scientific purposes must be sought.
- **Reduction** refers to the use of methods that enable Researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals.
- **Refinement** refers to the use of methods that prevent, alleviate or minimize pain, suffering, distress or lasting harm and/or enhance welfare for the animals used.

[9] Russell and Burch (1959).

Refinement includes the appropriate selection of relevant species with a lesser degree of structural and functional complexity in their nervous systems and a lesser apparent capacity for experiences that derive from this complexity.

c) When considering the 3Rs, and the ethical use of animals in research and training activities, CGIAR recognizes that this includes animal acquisition, transport, husbandry, enrichment, preventative care (including pain relief) and end-of-study plans. End-of-study plans can range from re-homing to reuse or euthanasia and the consideration of the humane end point – the clear, predictable and irreversible criteria that allow for early termination of a procedure before an animal experiences harm that is not authorized or scientifically justified. An example of this is euthanasia as soon as an animal has been determined to be infected in a disease infection study, rather than waiting for the disease to cause suffering or mortality in the animal.

d) Acclimation of animals to research settings is a critical part of **refinement** and involves a consideration of the dietary, behavioral, social and environmental needs of a species.

e) Coordination between projects is encouraged as part of **reduction** processes. For example, saving tissue from animals at the end of a trial for another experiment will save further animals from being used.

f) An assessment of the welfare impacts of, and cumulative effects on, an animal's lifetime experience must be conducted when designing experiments. Frequent mild procedures will create a cumulative burden on animals. Experimental designs that increase the welfare impact on fewer individual animals is not appropriate when aiming to **reduce** animal numbers (for example, doubling the number of surgical procedures one animal undergoes so that another does not need to be used fails to consider the impact of the cumulative burden).

g) Good animal welfare and effective application of the 3Rs is contingent on technical ability and expertise. Therefore, only qualified personnel are authorized to handle and supervise the handling of animals in experiments or teaching. These ethical concepts apply to domesticated and wild animals.

### 4.2.5 **Animal welfare and care**

a) As well as the ethical considerations of research, the welfare of animals must be considered. While related, these are two different concepts. Animal welfare is *the physical and mental state of an animal in relation to the conditions in which it lives and dies.* [10] Animal welfare is based on the principle that an animal should be treated in a way that meets its biological, behavioral and affective state needs, all which contribute to a good quality of life for the animal. With regard to research quality, compromised welfare can also result in greater variability of data; inappropriate or 'wrong' biological/clinical responses; data that cannot be reproduced/is incomplete; increased financial costs; and data that cannot be applied to other situations.

[10] World Organization for Animal Health (OIE), *Terrestrial Animal Health Code*, 2015.

b) It is recommended that the Five Domains framework be used when assessing an animal's needs and welfare. [11] The Five Domains framework comprehensively describes the essential components of an animal's quality of life: nutrition, environment, health, behavior and mental state. It builds on the important aspects of the well-known Five Freedoms, [12] while addressing some of their limitations. For example, while the Five Freedoms describe an absence of negative experiences, they do not describe the positive experiences that are needed for an animal to have a life worth living.

c) For the welfare of animals, including fish, under the care of any CGIAR research team it is required that:

- animals are sourced, bred, transported, used and disposed of with procedures that are in line with international and national regulations, policies and best practice
- temperature, humidity and ventilation be controlled at the appropriate levels and monitored regularly
- lighting be appropriate to support normal physiological function and a system for monitoring noise and vibration be put in place
- housing and space allow for the normal physiological and behavioral needs of animals
- animals receive quality feed that will support their normal growth and development (deviation from this may be appropriate if it is a nutritional or related study)
- animals receive daily care from qualified personnel
- specifically, for fish, water quality parameters and life support systems be appropriate to the animal species.

d) For research involving or affecting wild animals, awareness of the unique welfare and husbandry needs of individual wildlife species is required and must be adhered to. CGIAR Researchers must comply with the rules and requirements of agencies that have jurisdiction over wildlife.

<u>Recognition of sentience</u>:

e) CGIAR Researchers must recognize that animals have rights and an intrinsic sentient value which must be respected, especially the capacity to sense and express pain, suffering, distress, lasting harm, and even conscious natural behavior. Therefore, animals used in research and training must be treated humanely, with proper respect and care.

[11] Mellor D. & Beausoleil N. Extending the 'Five Domains' model for animal welfare assessment to incorporate positive welfare states. *Animal Welfare*, 24 (3), 241-253. 2015

[12] Webster J. Assessment of animal welfare: the five freedoms. *Animal Welfare: A Cool Eye Towards Eden.* Blackwell Science: Oxford, UK, 10-14. 1994

### 4.2.6 **Implementing standards, guidelines and best practice**

a) CGIAR recognizes that in some countries, national regulations, standards and guidelines on animal welfare may be lacking. There may be disparities between two countries (for example, between cross-border study sites, or between donor and implementation countries). The World Organization for Animal Health (OIE) Guiding Principles for Animal Welfare, including Chapter 7.8 Use of Animals in Research and Education, can be a useful guide to establish and apply minimum standards.

b) All CGIAR animal research activities and animal care must strive for best practice. Best practice animal care includes guaranteeing appropriate species-specific enclosures, feed, water, temperatures, ventilation, lighting and enrichment for animals involved in research (see section 4.2.5). It also includes appropriate animal handling, veterinary care and pain relief. CGIAR recognizes that in cases of research using privately owned animals (for example, farm livestock), the management practices of owners may not meet the best practice standards adhered to by CGIAR Researchers. In these circumstances, the research activity itself must still adhere to best practice standards and guidelines. Monitoring, reporting and developing competencies are all essential components of animal ethics in research.

Monitoring:

c) Animals must be monitored and assessed at all stages of a project for signs of pain and distress, including deviations from normal behavior. Monitoring is essential to identify unexpected impacts and intervene quickly, to detect planned endpoints as early as possible and to ensure that experimental plans remain on track. Appropriate monitoring protocols and mechanisms for feedback to the approving body must be developed and adhered to.

d) Many species used in CGIAR research, including fish, are prey species. This means that they have subtle pain signals and strong fear responses. Both of these must be considered when adapting animals to research settings, managing animals during the research process and handling animals in field studies.

Reporting and continuous learning:

e) Animal welfare and ethics are continually changing as more research becomes available on how to best care for animals in research and non-research settings. CGIAR commits to the value of learning to improve both animal care and research practice. Annual and end-of-project reporting must be conducted to facilitate this. To be most useful, these should include information such as a summary of the project progress to date, the total and current number of animals used and whether or not the project is meeting its objectives. End-of-project summaries and evaluations for completed projects should include animal care considerations.

Competency and standard operating procedures:

f) All people involved in the care and use of animals in a research project must be either competent in the procedure they perform, or under the direct supervision of a person who is competent to perform the procedure. In order to ensure competency, standard operating procedures for these common activities are needed. This applies to monitoring and husbandry practices at all stages and sites of animal care and use. This also applies to collaborators from partner organizations.

## 4.3 Research involving modern biotechnology

### 4.3.1 Use of biotechnology

a) CGIAR engages in plant, animal and fish breeding using next-generation breeding techniques to develop varieties that increase resilience to climate change and tolerance or resistance to diseases and pests, and to provide better and more diverse nutrition and sustainable livelihoods. CGIAR recognizes that the utilization of modern agricultural technologies is essential to provide increased genetic gains and innovative breeding products to users. The responsible application of new breeding methods can contribute to increased effectiveness and faster plant and animal breeding that benefit societies. CGIAR studies, develops, deploys and monitors these technologies, as well as the products developed through them, in partnership with national research programs that guide variety improvements.

b) Modern biotechnology methods are in constant development and currently include genetic engineering, genome editing and novel plant breeding techniques that are used to develop enhanced traits that may not be part of the species gene pool. [13] They are also used to achieve greater efficiency relative to more traditional breeding techniques. In contrast to genetic engineering, genome editing and novel breeding techniques specifically edit DNA at precise, targeted genomic locations, similar to the process that occurs in conventional breeding, resulting in desirable genotypic and phenotypic changes without the introduction of foreign genetic material.

c) CGIAR is committed to developing products that are safe for humans, animals and the environment. In doing so, Researchers must undertake appropriate safety assessments of all new products introduced into CGIAR breeding programs. CGIAR facilitates the development of multiple products using modern biotechnology methods with nutritionally enhanced and agriculturally important traits that have provided economic and environmental value to many producers around the world. These products have contributed to food security, climate resilience, and reducing adverse environmental impacts, while also complementing other agricultural innovations.

d) CGIAR has a mandate to deliver plant and livestock improvements with the most benefits to partner countries and to facilitate capacity development to allow for the proper handling of genetic material. The Core Ethical Values of CGIAR apply to the

[13] Definitions of these methods can be found in Annex I.

process of transferring new plant varieties to partners and any necessary capacity development.

4.3.2 **Sovereignty and safety**

a) CGIAR recognizes and respects the sovereignty of individual nations to determine if, when and how innovative products will be used and provides the requisite technical support, as requested.

b) CGIAR works with partners to develop an integrated set of solutions for food and agriculture and supports establishing proper decision-making processes. CGIAR Researchers must adhere to international and local rules and standards throughout the development life cycle. When developing products using modern biotechnology, Researchers must provide evidence-based information to inform decisions by stakeholders within the boundaries of their explicit roles and scientific competencies.

The role of CGIAR in product development:

a) Delivery of improved varieties developed using novel biotechnology must be done through a process that includes an assessment of the socio-economic impacts of the introduction of novel traits, product development, safety assessments of introduced material and novel traits, the process of obtaining regulatory clearance and the deployment of new products to farmers.

b) CGIAR's focus is on the research and development stages. However, to fulfill the mandate of providing access to improved agricultural crop varieties to farmers, CGIAR is committed to providing helpful transparent information and data on newly developed products. CGIAR also contributes to developing and supporting the appropriate quality assurance and stewardship practices required by partners who are responsible for obtaining regulatory clearance and product deployment.

c) CGIAR must support the stewardship practices that apply to regulated, confined field trials during the development of new plant varieties. During product development, CGIAR Researchers must adopt principles and management practices for the responsible stewardship of agricultural biotechnologies, such as those established by Excellence Through Stewardship, a global nonprofit organization that provides best practices for agricultural biotechnology. CGIAR partners that take up CGIAR innovations must be provided with relevant documents, capacity development and other types of scientific support to enable national partners to succeed in navigating the regulatory phase.

Policies and protocols:

d) CGIAR must advocate responsible development and use of conventional and innovative technologies. CGIAR recognizes that safety assessments and protocols are required to protect human and animal health and the environment.

e) During the development and safety assessment of agricultural products using new technologies, CGIAR must abide by the regulations of host countries, international

food safety standards, the guidelines developed by the Codex Alimentarius Commission and the provisions of the Cartagena Biosafety Protocol. When working with national partners, CGIAR Researchers must assess the safety of products on a case-by-case basis and in compliance with national regulations and international best practices.

Public dialogue:

f) CGIAR recognizes that as with all innovations, civil society has many questions about products developed using novel biotechnology methods. Consistent with its mission, CGIAR will listen with respect to viewpoints on plant, animal and fish improvements and contribute to informed debates with the appropriate expertise and evidence-based information.

g) CGIAR encourages discussion of the ethical and social implications of scientific developments in biotechnology.

h) CGIAR Researchers deliver innovation, capacity development, policy dialogue and outreach activities related to biosafety issues. Furthermore, CGIAR develops scientific inputs on these issues for national and regional stakeholders, while actively participating in national and global dialogues on biosafety issues with governments, civil society organizations, the media and policy dialogue forums.

### 4.3.3 Access to novel biotechnology products developed by CGIAR

a) CGIAR supports equitable access to affordable, sustainable, high quality and appropriate agricultural modern biotechnologies for all.

Intellectual property rights:

b) In line with its role to develop, use and share international public goods, CGIAR works with partners to secure access to operate with novel technologies in target countries, as well as to ensure equity in the benefits derived from them. For guidance on the sound management of intellectual assets and intellectual property rights, Researchers must refer to the CGIAR Principles on the Management of Intellectual Property Assets and the CGIAR Implementation Guidelines for the CGIAR Principles on the Management of Intellectual Assets.

Socio-economic impacts from the use of modern technologies:

c) CGIAR partners with national institutions to develop varieties with new traits based on the identified needs of countries and regions. CGIAR projects involving the use of novel biotechnology include socio-economic analyses to elucidate potential impacts across society and identify the main adopters of new varieties or technologies (these may include, for example, small-scale farmers or environmental benefits).

### 4.4 Environmental impacts of research

a) Researchers must strive to promote social good and environmental sustainability and prevent or mitigate social and environmental harm through research, capacity development and advocacy. CGIAR research aims to increase the positive environmental impact it generates and continuously reduce its environmental footprint. Researchers must ensure the integration of nationally and internationally recognized sustainability practices into their research and internal operations.

b) Researchers must ensure that their research respects ecosystems, biodiversity and natural resources when designing and conducting research. They must take the necessary steps to ensure that any adverse effects of research are reduced to the greatest extent possible. Researchers must set up research protocols that avoid or reduce potential harm to their study sites and studied ecosystems. [14]

c) Identification, monitoring and reporting on environmental risks must be undertaken as part of risk assessments in proposed research at the design and approval stages. [15] The process for this must be built into the CGIAR Performance and Results Management System.

d) All research activities must comply with the applicable environmental laws and regulations of host countries. Research must be guided by the relevant international frameworks, codes of conduct and international conventions as they relate to the management and protection of the natural environment, including but not limited to:

- the Stockholm Convention on Persistent Organic Pollutants
- the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
- the International Code of Conduct on the Distribution and Use of Pesticides
- the Guidelines on Good Practice for Ground Application of Pesticides
- the Convention on Biological Diversity and its Cartagena Protocol on Biosafety and the Nagoya Protocol
- the Ramsar Convention on Wetlands.

e) Where sentient animals are involved, Researchers must consider both environmental and animal welfare impacts. Sentient animals include all mammals, birds, reptiles and fish, as well as cephalopods and decapod crustaceans. When research may alter the habitat and/or behavior of animals, animal ethics approval may also be required (see section 4.2). Wild species have very reactive fear responses, so the risk of behavioral

[14] Examples of activities with possible impacts on the environment and biodiversity include land clearing for cropping trials, introducing irrigation, fertilizer trials or changing environmental flows, all of which can affect biodiversity, nutrient depletion and water quality, among others.

[15] The Center for International Forestry Research (CIFOR) Environmental and Social Management System (ESMS) and the CIFOR Project Appraisals and Risk Assessment Checklist provide examples of provisions that can be used for carrying out risk assessments. The International Water Management Institute (IWMI) Risk Mitigation Declaration for Possible Impacts on the Environment and Biodiversity is another resource that includes an Environmental Mitigation and Monitoring Plan (EMMP), based on United States Agency for International Development (USAID) procedures.

disturbances from the presence of Researchers is a genuine one. Activities that may indirectly impact wildlife include the introduction of chemicals into the environment, changing habitats and lighting and noise disturbances. Even in situations where animals are not considered to be at risk of impact, these impacts must be considered as they may generate unexpected consequences and would thus be important to include as part of the risk assessment process.

### 4.5 Participatory research

4.5.1 Where participatory approaches are adopted, Researchers must strive to involve farmers, communities and other stakeholders in the design, management, implementation, analysis and application of research to ensure that local needs and priorities are met. In such circumstances, Researchers must support communities through capacity building, farmer information exchange or other appropriate methods with the aim of ensuring quality research results for wider adoption.

4.5.2 **Refraining from creating unrealistic expectations**

a) In their engagement with communities and individuals, Researchers must take care not to create unrealistic expectations among people who participate in research, either in terms of immediate material or non-material benefits or longer-term positive impacts. This is particularly the case when the interaction is framed as 'action research', which involves a joint process of learning between CGIAR Researchers and a group of people that specifically aims to achieve a social transformation for that group.

4.5.3 **Respect for cultural norms and traditions**

a) Researchers must respect the values, culture and traditions of the communities they engage with. They must strive to have a sound understanding of the local context prior to interaction with communities and comply with any customs, protocols and local laws. Researchers must be sensitive to the values and cultures of the groups being studied and how this may affect research participants' understanding of the purpose and nature of research. Researchers have a responsibility not to impose external values, standards or cultural norms onto communities.

b) Researchers do engage in research that challenges certain norms, including gender inequities or patterns of decision-making and authority that reinforce poverty or social exclusion, but they must do so in ways that are grounded in an understanding of the local context and that respond to the goals and priorities that local groups deem legitimate.

4.5.4 **Research involving traditional knowledge and technologies**

a) Local communities and indigenous people who exchange traditional knowledge and technologies with CGIAR must be made fully aware of the research plan that utilizes this knowledge and technologies, and any dissemination plans that include this knowledge and/or technologies.

b) Acknowledgement, confidentiality and anonymity must be discussed and adopted as situations require to ensure that the CGIAR commitment to produce international public goods is not impeded while respecting the ownership of information or technology. This principle includes the recognition that indigenous people have prior proprietary rights and cultural responsibilities for the environment that they have traditionally inhabited or accessed and that they may wish to keep some information confidential.

## 4.6 Access to genetic resources

4.6.1 As per Article 3 of the CGIAR Principles on the Management of Intellectual Assets, CGIAR must recognize the indispensable role of farmers, indigenous communities, agricultural professionals and scientists in conserving and improving genetic resources.

4.6.2 Researchers must observe the principles of the Convention on Biological Diversity (CBD) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol). Researchers must ensure that they follow national policies, laws and regulations on access and benefit-sharing when accessing and using genetic resources and their associated traditional knowledge.

4.6.3 When accessing genetic resources and associated traditional knowledge, Researchers must comply with processes and standards for obtaining prior informed consent as established in applicable national and subnational policies and laws, including those implementing the CBD, its Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture. The Guidelines on the Nagoya Protocol for CGIAR Research Centers provide guidance on complying with national access and benefit sharing (ABS) laws when accessing biological and genetic resources, including obtaining prior informed consent and arriving to mutually agreed terms.

4.6.4 In countries where there are no implementing measures in place, Researchers must proactively seek out ways to fulfil the spirit of these international agreements, and to the extent possible, work with the partner organizations in those countries, the national focal points on ABS and the competent national authorities.

4.6.5 For further guidance on fulfilling obligations when seeking to access and use traditional knowledge associated with genetic resources, Researchers should refer to the Guidelines on the Nagoya Protocol for CGIAR Research Centers.

# 5 Implementation

## 5.1 Arrangements for implementation

5.1.1 This Code will be publicly available on the CGIAR website.

5.1.2 Implementation arrangements for the Code will be developed in a companion document. Together, the Code and the companion document on implementation will constitute CGIAR's Policy on Research Ethics.

5.1.3 Researchers who require guidance on the interpretation or implementation of this Code may request the advice of the CGIAR Chief Ethics Counsel, ethics focal points, legal counsel or focal points of a CGIAR Entity.

## 5.2 Reporting possible ethical misconduct

5.2.1 Individuals who suspect, or may be aware of, possible violations of this Code have a responsibility to immediately bring them to the attention of CGIAR in accordance with the applicable policies and procedures relating to whistleblowing.

5.2.2 CGIAR must not tolerate retaliation against anyone who in good faith raises a concern or reports misconduct. However, knowingly reporting false information is contrary to this Code, and individuals who do so may be sanctioned accordingly.

## 5.3 Addressing and managing ethical misconduct

5.3.1 Ethical misconduct must be managed appropriately, in accordance with established operating procedures, to ensure due follow-up action, as relevant and necessary.

5.3.2 The assessment of potential ethical misconduct must reflect due process and will be strictly conducted on a confidential basis. Any remedial actions must be determined on a case-by-case basis, in accordance with the respective applicable procedures.

## 5.4 Periodic review

5.4.1 The effectiveness of this Code will be reviewed periodically, and not less frequently than every three years.

## Annex I – Definitions

**Animal welfare**
The physical and mental state of an animal in relation to the conditions in which it lives and dies.

**Assent**
Permission given to participate in a research study where the individual is not able to legally consent. Such individuals can include minors and persons with diminished cognitive capacity. They may also dissent, which means they do not agree. Working with children or adults not capable of giving consent requires the consent of the parent or legal guardian and the assent of the subject.

**Benefit**
Something that promotes the wellbeing of an individual or group, or the public generally. A benefit for an individual in the context of CGIAR may include access to genetic resources, technology, water, land and other resources that improve their livelihoods, food security, climate resilience and economic and environmental sustainability. Payment for participation in a study is not considered a benefit of the study and often there is no guaranteed benefit of participation.

**Beneficence**
The principle that governs Researchers which ensures that the research maximizes benefits and minimizes harm to participants. This principle ensures that Researchers have the welfare of the research participant as a goal of any research.

**Confidentiality and personal data protection**
The treatment of information, including personal data, that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

**Consent**
The voluntary agreement of a person or group, based on adequate knowledge and understanding of relevant material, to participate in research. Informed consent is one possible result of informed choice, the other possibility is refusal. Oral consent may be used for persons who cannot read or feel uncomfortable signing forms for cultural reasons. In this case, a written text describing what will be told to subjects when oral consent is necessary should be provided. Consent may only be given by individuals who have reached the legal age of consent (typically 18 years old).

**Cumulative burden**
The impact that repeated procedures, including handling, restraint and recovery time, may have on an animal. Cumulative burden should be assessed in relation to an animal's lifetime experience. The lifetime experience of an animal includes all aspects of health, welfare and care, along with the impact of all scientific procedures.

**Genetic engineering**
Genetic changes resulting from the application of modern biotechnology as defined in the Cartagena Protocol on Biosafety.

**Genome editing**
The use of molecular biology techniques to facilitate precise, efficient and targeted modifications at genomic loci. These techniques include zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs) and type II clustered regularly interspaced short palindromic repeat (CRISPR)/CRISPR-associated protein 9 (Cas9).

**Harm**
Adverse effects to the interest or welfare of an individual, a group, or the public generally. Harm extends to physical harm, discomfort, anxiety, pain and psychological disturbance and includes placing a person at social disadvantage.

**Humane end point**
The clear, predictable and irreversible criteria that allow the early termination of a procedure before an animal experiences harm that is not authorized or scientifically justified.

**Human subject**
A living individual or a group of living individuals about whom a Researcher obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information.

**Intervention**
Physical procedures through which data are gathered and/or manipulations of the human subject or the human subject's environment that are performed for research purposes.

**Justice**
The assurance that there is equal sharing of the burdens and benefits of research.

**Novel plant breeding techniques**
Methods that allow for the development of new plant varieties with desired traits, by modifying the DNA of seed and plant cells. They are called 'new' because these techniques have only been developed in the last decade and have evolved rapidly in recent years.

**Personal data/personally identifiable information (PII)**
Any information relating to any identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to any identifier such as a name, an identification number, location data, an online identifier, or to one or more factors specific to the physical, psychological, genetic, mental, economic, cultural or social identity of that natural person.

**Research**
Any original investigation undertaken in order to gain knowledge and understanding. For example, a systematic study, including research for development, testing and evaluation, designed to develop or contribute to generalizable knowledge. "CGIAR Research" is defined

as "research carried out by the Centers and the CGIAR System Partners in support of the CGIAR Strategy and Results Framework".

**Research manager**
The main Researcher overseeing or conducting the research process.

**Risk**
An event or circumstance that may affect the achievement of objectives. A risk has a cause and effect.

**Sentience**
The awareness and cognitive ability necessary to experience feelings.

**Traditional knowledge**
Knowledge on the conservation and use of agricultural biodiversity that people have developed over time in a given community, based on experience and as a result of local culture and environmental conditions. Traditional knowledge is a dynamic; it evolves as it is transferred through generations.

**Vulnerable people**
Individuals with limited capacity to protect their own interests. They may have inadequate power, intelligence, education, resources, strength or the required attributes to protect their own interests. Examples include illiterate farmers, unemployed or impoverished people, migrants, refugees, children and young people, the elderly, ethnic minorities and women in a traditional patriarchal society.

**3Rs**
The three principles that aim to improve the ethics of animal experimental design: replacement, reduction and refinement.

## Annex II – International treaties and conventions guiding the CGIAR Research Ethics Code


1. Basel Declaration Society. 2010. *Basel Declaration*. Zurich, Switzerland: Basel Declaration Society. Accessed 1 September 2020. https://www.basel-declaration.org/basel-declaration-en/assets/File/Declaration/Declaration_en_Z%C3%BCrich.pdf

2. [CIOMS/WHO] Council for International Organizations of Medical Sciences in collaboration with the World Health Organization. 1993. *International Guidelines for Biomedical Research Involving Human Subjects.* Geneva, Switzerland: CIOMS/WHO. Accessed 1 September 2020. http://www.codex.uu.se/texts/international.html#background

3. Convention on Biological Diversity Secretariat. n.d. *Convention on Biological Diversity*. Montreal, Canada: Convention on Biological Diversity Secretariat. Accessed 1 September 2020. https://www.cbd.int/ and:

    a. Convention on Biological Diversity Secretariat. n.d. *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (2014). Montreal, Canada: Convention on Biological Diversity Secretariat. Accessed 1 September 2020. https://www.cbd.int/abs/

    b. Convention on Biological Diversity Secretariat. 2020. *The Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (2000). Montreal, Canada: Convention on Biological Diversity Secretariat. Accessed 1 September 2020. https://bch.cbd.int/protocol

    c. Convention on Biological Diversity Secretariat. 2019. *Mo' otz Kuxtal Voluntary Guidelines.* Montreal, Canada: Convention on Biological Diversity Secretariat. Accessed 1 September 2020. https://www.cbd.int/doc/publications/8j-cbd-mootz-kuxtal-en.pdf

4. [FAO] Food and Agriculture Organization of the United Nations. 2020. *International Treaty on Plant Genetic Resources for Food and Agriculture* (2001). Rome, Italy: FAO. Accessed 1 September 2020. http://www.fao.org/plant-treaty/en/

5. [FAO] Food and Agriculture Organization of the United Nations. 2003. *International Code of Conduct on the Distribution and Use of Pesticides.* Rome, Italy: FAO. Accessed 1 September 2020. http://www.fao.org/3/y4544e/y4544e00.htm

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8. [ISE] International Society of Ethnobiology. 2020. *The International Society of Ethnobiology Code of Ethics* (2006). Gainesville, United States: ISE. Accessed 1 September 2020. http://ethnobiology.net/code-of-ethics/

9. [IUCN] International Union for Conservation of Nature and Natural Resources. 2020. *The IUCN Red List of Threatened Species*. Cambridge, United Kingdom: IUCN Global Species Programme Red List Unit. Accessed 1 September 2020. https://www.iucnredlist.org/

10. [NIH] National Institutes of Health, United States Department of Health and Human Services. n.d. *The Code of Nuremberg* (1947). Bethesda, United States: NIH. Accessed 1 September 2020. https://history.nih.gov/display/history/Nuremburg+Code

11. Ramsar Convention Secretariat. 2010. *The Ramsar Convention on Wetlands.* Gland, Switzerland: Ramsar Convention Secretariat. Accessed 1 September 2020. https://www.ramsar.org/sites/default/files/documents/pdf/lib/hbk4-18.pdf

12. Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade Secretariat. 2010. *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* (1998). Châtelaine, Switzerland: Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade Secretariat. Accessed 1 September 2020. http://www.pic.int/

13. Stockholm Convention on Persistent Organic Pollutants Secretariat. 2019. *Stockholm Convention on Persistent Organic Pollutants* (2001). Châtelaine, Switzerland: Stockholm Convention on Persistent Organic Pollutants Secretariat. Accessed 1 September 2020. www.pops.int

14. [UN] United Nations. n.d. *The Universal Declaration of Human Rights* (1948). New York, United States: UN. Accessed 1 September 2020. http://www.un.org/en/universal-declaration-human-rights/index.html

15. [UN] United Nations. 2008. *UN Declaration on the Rights of Indigenous Peoples*. New York, United States: UN. Accessed 1 September 2020. https://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf

16. [UNICEF] United Nations Children's Fund. 2013. *UNICEF Ethical Research Involving Children*. Florence, Italy: UNICEF. Accessed 1 September 2020. https://www.unicef-irc.org/publications/706-ethical-research-involving-children.html

17. [WCRI] World Conferences on Research Integrity. 2020. *The Singapore Statement on Research Integrity* (2010). Accessed 1 September 2020. https://wcrif.org/guidance/singapore-statement

18. [WMA] World Medical Association. 2020. *The World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (1964). Ferney-Voltaire, France: WMA. Accessed 1 September 2020. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects

## Annex III – Research involving human subjects

Research involving human subjects is defined as research undertaken about or on a living individual or a group of living individuals. It includes:

- gathering data about humans
- using methods such as interviews, focus groups, questionnaires, ethnographies and participant observations
- intervening with human subjects through experiments and manipulation of people or peoples' environments
- observing or recording private behavior, including behavior that individuals have a reasonable expectation would not ordinarily be observed or recorded
- obtaining personally identifiable information (PII) on individuals, such as school records, names and/or domiciles, income, or identifiable information collected by another Researcher or organization
- conducting studies on nutrition or similar topics through interacting or collecting any type of samples or data from human subjects
- influencing change or modification of current habits for the purpose of research.

**Prior informed consent** [16]

The language and documentation of prior informed consent, particularly the explanation of the research activity, its purpose, its duration, any experimental procedures, the risks, the benefits and any alternatives, must be presented in a manner that is understandable to the population asked to participate. Participants must be provided with the opportunity to ask questions about the research. They need to be assured that their anonymity and confidentiality will be safeguarded, unless they explicitly agree to be identified.

The process of seeking consent must be context-specific, taking into consideration individual or community needs. Among other considerations, Researchers shall consider power structures within communities and households to determine whether informed consent is required from community leaders and/or household heads.

Evidence of a completed prior informed consent process must be obtained in written form or through verbal consent in specific circumstances when written consent cannot be provided. In the case of visually impaired people or persons with limited ability to read and write, verbal consent must be obtained and documented. In such cases, the following must be observed:

i. Researchers must keep a record with sound evidence of the reason for the need to waive written consent. This could include evidence that the participants or their community express a preference for verbal consent versus written consent (such as a letter from a village leader or a community representative).
ii. The waiver will not affect the rights and welfare of the research participants.

[16] Source: The International Maize and Wheat Improvement Center (CIMMYT) Ethics in Research Policy.

iii. Researchers must ensure that more than one Researcher is present who can attest to, and sign to verify, consent. In the absence of this, a witness from the community can attest to, and sign to verify, consent.
iv. Research activities must not present more than minimal risks and involve procedures for which consent would not normally be obtained outside of the research context.

Research managers must ensure that individuals in charge of obtaining consent undergo specialized training on procedures for taking prospective participants through an informed consent process.

Where a proposed participant is a minor aged 13 to 17 years who is possessed of sufficient understanding to grant informed consent but is precluded from granting such consent solely on the grounds of age, Researchers must obtain assent from the minor, in addition to permission from a parent or guardian.

In the case of children aged 12 years or younger, consent from a parent or guardian must be obtained. Although in many instances the consent of the mother is sought, there are settings or situations where the consent of the household head is required prior to securing that of the child's mother, if she is not the household head.

No informed consent can include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the Researchers, the sponsor, the institution or its agents from liability for negligence.

Participant Information Sheet requirements

Human subjects involved in any CGIAR research activity must have a clear understanding of the research purpose, their role, associated risks and other implications before giving their prior informed consent to participate. Such understanding is achieved by conveying in the local language (or when applicable, dialect) the following information with a Participant Information Sheet (PIS):

- the aims of the study and the methods to be used
- the institutional affiliations
- the contact information of the Researcher(s)
- the reason or method of selection of a participant
- the geographical scope of the study
- the type of information that will be discussed and collected
- how the results will be reported and shared
- the treatment to be given to personal data
- the anticipated benefits for participants, their community and society
- the anticipated risks and possible inconvenience for participants
- the time it will take to participate in the study
- foreseen compensation, if any

- the right to abstain from participating in, and to withdraw from the study at any time, without reprisals
- any additional element of informed consent, as may be required by the nature of the project.

Informed Consent Form [17]

While consent forms may differ according to the project, they are required to include at least the following or similar statements:

- I have read and understood the Participant Information Sheet (PIS).
- I have been given the opportunity to ask questions and have had them answered to my satisfaction.
- I agree to take part in this project.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason.
- A statement that asks the participant to consent to procedures for handling any personal data collected (including, for example, statements on confidentiality and anonymization).
- A statement that asks the participant to consent to proposals for data storage, archiving, sharing and re-use for future research.
- A statement that asks the participant to consent to any planned audio or visual recording, including photos (if relevant).

Image/Video/Audio Release Form [18]

For Researchers to use image, video or audio recordings obtained as part of research activities, they must obtain written consent from persons being recorded. A sample statement is provided below.

By signing this form, I confirm consent to photographs/videos/audio taken which show me

on (date): _____ at (location) _____

I grant (CGIAR entity) _____ and project partners the right to use images on websites or printed material, for non-commercial purposes only.

_____

Name Age (if above 18 years)

[17] Source: The International Rice Research Institute (IRRI) Informed Consent Guidelines.

[18] Source: The International Water Management Institute (IWMI) IRB Guidelines for Audio, Video or Digital Recordings.

_____

Contact information (email, phone, or town/address)

_____

Signature Date

IF SUBJECT IS UNDER 18 YEARS OF AGE:

I confirm that I am the legal guardian of the child named above and therefore may grant permission for this subject release on behalf of the child:

_____

Name of Legal Guardian / Relationship to Child / Date / Signature of Guardian

WITNESS:

_____

Name of Witness / Organization Affiliation / Date / Witness Signature