



ACF - INTERNATIONAL

ACF ETHICS AND RESEARCH PRINCIPLES AND GUIDELINES



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Ethics Guidelines

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ACRONYMS

ACF	Action contre la Faim
CIOMS	Council for International Organizations of Medical Sciences
DSMB	Data and Safety Monitoring Board
GMO	Genetically Modified Organisms
IEC	International Executive Committee
ISC	International Scientific Council
MoU	Memorandum of Understanding
RPCM	Research Project Cycle Management
WHO	World Health Organization



SUMMARY

This document provides **guidelines on ethics in relation to research activities in ACF**. As the organisation is enhancing its research capabilities by expanding the number and breadth of research topics it is dealing with, **it is imperative to acknowledge the dimension of ethics in this effort**. This document introduces 6 main principles for ethics in ACF Research activities, in line with the ACF Charter of Principles:

- ACF research is responsive to the needs of vulnerable people,
- ACF research is ethically justified and scientifically valid,
- ACF research is culturally-sensitive in its research undertakings,
- ACF research promotes the strengthening of capacities in the host country's target communities,
- ACF research makes an effort to ensure the availability of the knowledge generated and product developed locally and promotes a wide sharing of research results,
- ACF ensures by all means possible, avoidance of research bias due to conflict of interest with other stakeholders and that research is not profit-driven.

This document provides guidance on the application of each of these principles in ACF and gives some highlights on particular situations that can arise in the field.

It provides appropriate ACF internal guidance for a research proposal, a participant information sheet, a consent form, standard clauses to be included in a memorandum of understanding, the vetting process of a possible for-profit company as a sub-contractor.

APPROVAL AND REVISIONS

These guidelines are under the responsibility of the Technical Directors of ACF. The Technical Directors are responsible to ensure that whoever is involved in research is aware of these guidelines. The International Scientific Council can be consulted in case of any doubt on the application of these guidelines in the field.

The guidelines need to be updated:

- every 3 years,
- and/or after the revision of the ACF Research Policy,
- and/or after major updating of the International Guidelines on Bioethics,
- and/or after the ACF's internal guidelines for research.

Note that any updates of these guidelines must involve a revision of internal guidelines for research. These guidelines have been validated in May 2012.

Next planned revision date: **May 2015.**



PRESENTATION OF THIS DOCUMENT

INTRODUCTION

ACF's fields of intervention

ACF is a humanitarian organisation created in 1979 with the overall mission **to save lives by eradicating hunger through the prevention, detection and treatment of undernutrition, especially during and after emergency situations of disaster**. The purpose of acting for “a world without hunger and to ensure that children and adults have access to sufficient food and water and are able to attain these with dignity” was restated in its 2012-2015 International Strategic Plan.

To ensure its mission, ACF analyses the needs, risks and their evolution **to those most vulnerable to undernutrition and humanitarian crises, through a community-based approach**. **Recognizing the conceptual framework of undernutrition (Black et al, 2008) to ensure nutrition security to undernourished populations, ACF implements multi-sectoral interventions** in the fields of: Nutrition and health ; Food security and livelihoods ; Care practices and mental health ; Water, sanitation and hygiene. In each of these areas, ACF provides technical expertise **to the benefit of the communities in which ACF works**.

ACF applies in its field of intervention, humanitarian principles defined in its Charter (Annex I): independence, neutrality, non-discrimination, free and direct access to victims, professionalism, and transparency.

The organisation puts great emphasis on the quality of interventions. It makes all the necessary efforts to identify and implement sustainable solutions at field level. In order to guarantee the improvement of the quality, impact and coverage of field interventions, special efforts are made to put **research and innovation** in a good position in its different areas of action.

ACF research and vulnerable people

ACF research aims at responding to the most at-risk of undernutrition as well as humanitarian crises needs and demands. This involves applied research which must bring appropriate tools and methods to improve the interventions ACF undertakes in the field. For this reason it is necessary that ACF Research involves local communities and capacities.

ACF considers it is fundamental to ensure the appropriateness and relevance of its research activities with the main purpose to ensure **the health and well-being of the communities that cooperate in such activities**. **Given the particularities and challenges of the contexts where ACF is active, it also considers imperative to provide an ethical framework that ensures** the application of the current, internationally recognized ethical principles in its work.

OBJECTIVES OF CURRENT GUIDELINES

This document provides **guidelines on ethics in relation to research activities in ACF**. As the organisation is enhancing its research capabilities by expanding the number and breadth of research topics it is dealing with, **it is imperative to acknowledge the dimension of ethics in this effort**. Research that follows proper conduct criteria is both valid and ethical research, but it is not uncommon for researchers to find themselves in situations that do not offer obvious perspectives of the correctness of the research conduct. This is particularly true for researchers that work in different cultures and/or are faced with unconventional surroundings and communities. **ACF staff, due to the nature of their work, is more often than not faced with situations that are unconventional or even extreme as research settings**. For this reason, the need to have guidelines for ethical conduct of research is even more topical and urgent. ACF's research undertakings involve human beings, quite often "vulnerable" people in need, and as such, the design and implementation of research requires a close scrutiny to ensure that it is done with the highest standards. These guidelines are **designed to raise awareness of ethics issues in relation to research that ACF staff are commonly undertaking, and also offer a practical step-by-step guide for preparing research protocols that reflect this awareness**.

It should be mentioned that this document will not bring answers to every ethical issue that can arise in ACF's research projects. This would be neither possible nor meaningful since **each situation needs to be considered individually**. **It is important to keep in mind that every person involved in the research has to ponder on the potential ethical issues/decisions** when facing an ethical issue in its research activity.

Taking into account these elements, the guidelines will avoid illustrations and examples that are idiosyncratic by nature.

TO WHOM ARE THESE GUIDELINES ADDRESSED AND WHEN IS IT NECESSARY FOR ACF STAFF TO REFER TO THESE GUIDELINES?

Any ACF staff involved in all scientific activities has to adhere to the **ACF ethical research principles**. In this regards, these guidelines also apply to institutional partners and their employees or students that are involved in ACF research.

HOW HAVE THESE GUIDELINES BEEN DEFINED?

These guidelines have been compiled by the ACF France Research Department in 2011, discussed and debated during 2 ACF International Scientific Council meetings (October, 27th 2011 and March, 5th 2012). It has been validated in May, 2012 by the ACF Technical Directors.

They have been designed in light of:

- **ACF's Charter of Principles** (Annex I),
- Three **international reference documents** in research ethics:



- "Ethical Principles for Medical Research Involving Human Subjects", issued by the World Medical Association in 1964, is the **fundamental document in the field of ethics in biomedical research** and has influenced the formulation of international, regional and national legislation and codes of conduct. The reference document is the 2008 Declaration of Helsinki (World Medical Association (2008) - Available from: <http://www.wma.net/en/30publications/10policies/b3/17c.pdf>,
- "International Ethical Guidelines for Biomedical Research Involving Human Subjects", Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) in 2002 in Geneva (http://www.cioms.ch/publications/layout_guide2002.pdf),
- "The ethics of research related to healthcare in developing countries" elaborated in 2002 by the **Nuffield Council on Bioethics**. This council is an independent UK body that examines and reports on ethical issues in biology and medicine. This report is particularly relevant to research undertaken by ACF as it focuses on research undertaken in developing countries (http://www.nuffieldbioethics.org/sites/default/files/HRRDC_Follow-up_Discussion_Paper.pdf).

WHAT IS *NOT* INCLUDED IN THESE GUIDELINES?

In all its field interventions, ACF follows humanitarian ethical principles, which are described in ACF's operational and technical policies.

Every ACF intervention espouses the international humanitarian standards (Code of Conduct of the International Red Cross and Red Crescent 1994, People in Aid - Code of Conduct etc.). Their implementation might require specific guidance which will not be detailed in this document.

HOW FAR IS ETHICS LINKED TO LEGAL ISSUES?

Ethical rules do not necessarily have a legal value. These ethics guidelines are therefore moral values and principles **ACF deliberately chooses to follow**. The provisions resulting from these guidelines are consequently complementary to the law but are no substitute to the law.

These guidelines shall not prevent an ACF researcher from seeking legal advice whenever necessary in order to make sure the research program is implemented in accordance with legal provisions.

Part 1

PREAMBLE : WHAT IS ETHICS?



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REMINDER ON GLOBAL DEFINITIONS

The field of **ethics** (or moral philosophy) involves systematizing, defending and recommending concepts of right and wrong behaviour (Fieser, 2009). **Applied ethics** is the branch of ethics which consists of the analysis of **specific controversial issues**. In recent years applied ethical issues have been subdivided into convenient groups such as medical ethics, business ethics, environmental ethics and sexual ethics. **Medical ethics** issues are more extreme and diverse than other areas of applied ethics. Health care workers are indeed in an unusual position of continually dealing with life and death situations. **Biomedical ethics** focuses on a range of issues which arise in clinical settings.

N.B.: The terms **Biomedical ethics** and **Bioethics** are interchangeable in many circumstances. While Biomedical ethics is used to describe the study of moral values and judgments as they apply in the Biological and Medical Sciences, Bioethics is used to describe the wider field of studying ethical questions that deal with the relationships between Life Sciences, Medicine, Law and Philosophy, predominantly.

THREE MAIN PRINCIPLES FOR BIOETHICS

According to the CIOMS, which is the reference document for the International Ethical Guidelines for Biomedical Research Involving Human Subjects, all research activities involving human subjects should be conducted in accordance with three basic ethical principles, namely **respect for persons, beneficence and justice**. Respect for persons incorporates at least two fundamental ethical considerations, namely:

- a) **Respect for autonomy**, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and
- b) Protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Beneficence refers to the ethical obligation to maximize benefit and to minimize harm. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the researchers be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, non-maleficence (do no harm).

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research.

It is generally agreed that these principles, which in the abstract have equal moral force, guide the conscientious preparation of proposals for scientific studies. In varying circumstances they may be expressed differently and given different moral weight, and their application may lead to different decisions or courses of action. **The present guidelines are directed at the application of these principles to research involving human subjects in ACF's fields of action.**

Part 2

ACF ETHICAL PRINCIPLES FOR RESEARCH



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PRINCIPLE 1. ACF research is responsive to the needs of vulnerable people

ACF research is responsive to vulnerable people needs, at the individual and community levels and addresses the health and wellbeing needs of the communities in which ACF works.

The CIOMS guidelines define *vulnerable persons* as those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, education, resources, strength, or other needed attributes to protect their own interests.

PRINCIPLE 2. ACF research is ethically justified and scientifically valid

ACF research **complies with ethical rules and standards set at national and international levels.**

In particular, ACF recognizes the CIOMS principle that scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit. ACF conducts a risk analysis before the implementation of research in the field.

ACF research conforms to and follows general valid scientific principles. It is designed according to established scientific methodologies and based on adequate knowledge of the relevant scientific literature.

ACF recognizes the authority of any locally established ethics/research body and follows the laws and regulations of the host country where these do not appear to contradict the International Ethics Guidelines that this document is based upon.

PRINCIPLE 3. ACF research is culturally-sensitive in its research undertakings

ACF takes into consideration cultural differences and respects to cultural sensitivities in its research activities. ACF is aware of and recognizes that there might be cultural differences between research implementers, workers and participants in the host country.

PRINCIPLE 4. ACF research promotes the strengthening of national and local organizations responsible for research in target communities

By nature, ACF research is translational and operational, meaning that it aims at producing and/or advancing tools and methods that will meet the needs of vulnerable people.

ACF makes all necessary efforts to strengthen the national and local capacity to benefit from research results and to design and conduct research that contributes to the strengthening of local research and ethics review capacities.

In particular, ACF recognizes the importance of partnerships with national and scientific organisations.

Moreover, it promotes the development and support of local expertise so that knowledge and material obtained for the purposes of a research project can continue to be used and maintained locally.

PRINCIPLE 5. ACF research makes an effort to ensure the availability of any knowledge generated and product developed locally and promotes a wide sharing of research results.

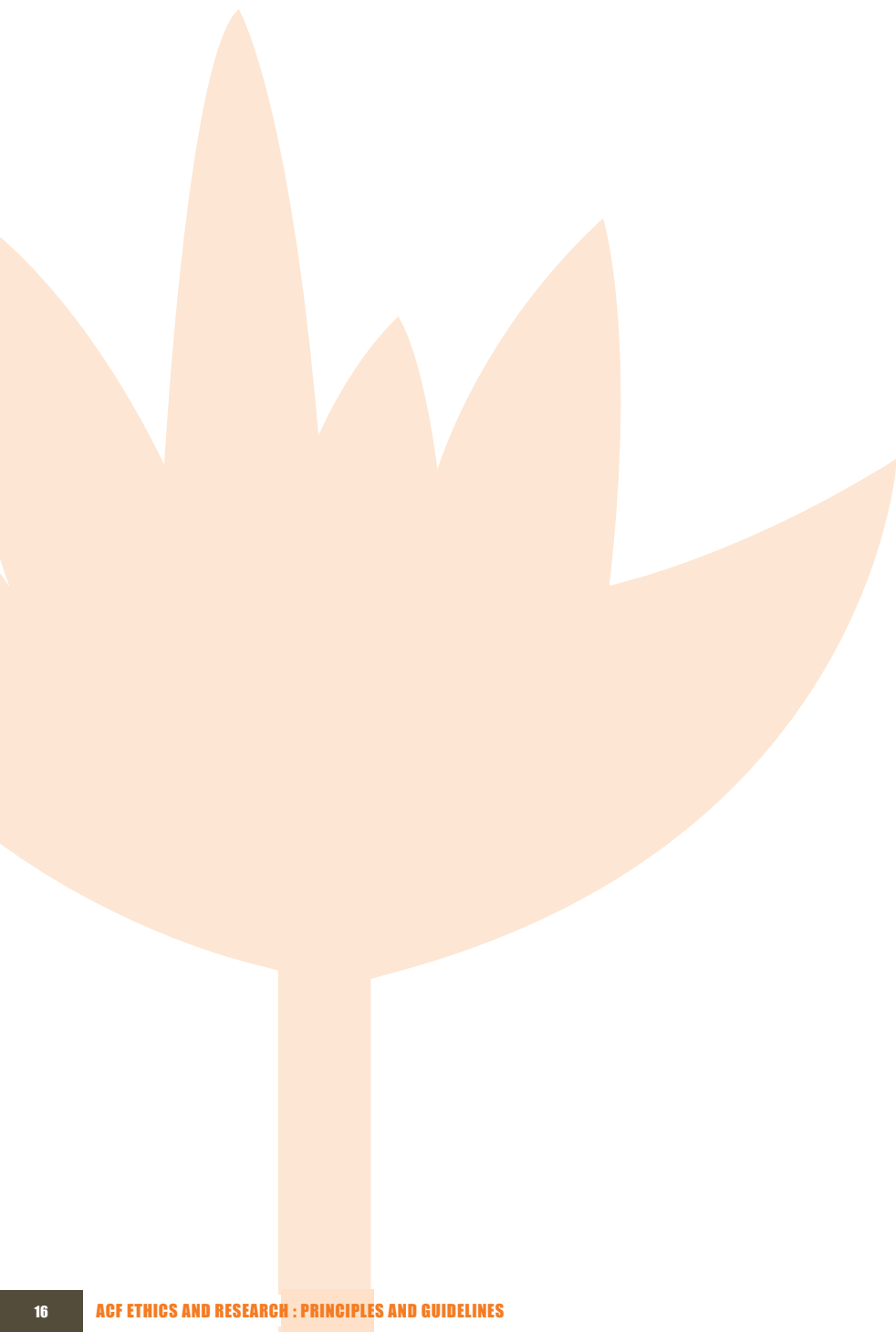
Before undertaking research in a population or community with limited resources, **ACF makes every effort to ensure that any intervention, product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.** In particular, ACF informs local authorities and communities and participants about the research results at the end of a study.

ACF recognizes the principle of sharing and publication of data. Research results are accurately reported and published in the public domain. ACF makes every effort to enable the participant communities to benefit, where possible, from its research activities.

PRINCIPLE 6. ACF ensures by all means possible, avoidance of research bias due to conflict of interest with other stakeholders and that research is not profit-driven.

ACF will not make a profit out of product or processes deriving from its research. Income generation, product – patent is shared by mutual agreement.

ACF has an umbrella charter of principles that apply to all its activities, including the ethics of collaboration.



Part 3

GUIDANCE ON HOW TO APPLY THE PRINCIPLES IN THE FIELD WITH HIGHLIGHTS ON SPECIFIC PRACTICAL SITUATIONS



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PRINCIPLE 1. ACF research is responsive to the needs of vulnerable people

What does it mean?

The CIOMS guidelines state that the ethical requirement of “responsiveness” can be fulfilled only if successful interventions or other kinds of benefit are made available to the communities. Ethically, it is not sufficient simply to determine that a problem is prevalent in the target population and that new or further research is needed: **successful interventions or other kinds of benefit are to be made available to the target population.** This is applicable especially to research conducted in countries where governments lack the resources to make such products or benefits widely available. If the knowledge gained from the research in such a country is used primarily for the benefit of populations that can afford the tested product, the research may rightly be characterized as exploitative and, therefore, unethical.

Additionally, **if an investigational treatment has been shown to be beneficial**, ACF should continue to provide it to the subjects after the conclusion of the study, or at least makes every effort to make it generally available to the community or population after the study.

How does ACF ensure this principle?

- ACF is aware about the needs, values and expectations of the communities/populations who participate in the research, and **about the local health priorities in the area where research takes place,**
- ACF research priorities are based on field needs,
- ACF research needs are selected and defined on the basis of **communities** needs through local **consultations and assessments,**
- ACF makes all the effort to **include representatives of stakeholders of the host country in its research** and ethics groups, as well as representatives of the communities from which subjects are drawn and non-governmental organizations such as health advocacy groups...),
- In order to achieve this, ACF defines research, as much as possible, on need assessment based on **participatory approaches.** This means that local communities should be consulted and involved in the design of the research protocol.

PRINCIPLE 2. ACF research is ethically justified and scientifically valid

What does it mean?

The CIOMS guidelines reminds that the ethical justification of research involving human subjects is the prospect of discovering new ways of benefiting people's health and well-being. **Such research can be ethically justifiable only if it is carried out in ways that respect and protect, and are fair to, the subjects of that research and are morally acceptable within the communities in which the research is carried out.**

Moreover, because scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit, researchers and sponsors must ensure that proposed studies involving human subjects conform to generally accepted scientific principles and are based on adequate knowledge of the pertinent scientific literature.

"Research is scientifically valid": ACF research conforms to general validity principles for research.

"Research is ethically justified": ACF research recognizes and adopts the international research ethics standards (i.e. Helsinki declaration, CIOMS Guidelines). Moreover, it acquaints itself with local ethics regulations and ensures that the researcher follows such regulations in line with ACF's principles.

How does ACF ensure the application of this principle?

Research is scientifically justified

- ACF leads a **scientific literature review** on the research question. It is the first step in defining the research project.
- ACF **collaborates with scientific partners** to design the research methodology and implement its research projects. This includes the analyses of results.
- ACF ensures the **choice of an appropriate scientific methodology**. Specific attention is given to the statistical analysis, which is often an issue in the field, especially when implementing Randomized Control Trials.
- ACF uses **all necessary means to ensure proper implementation of the scientific methodology in the field**. In particular, ACF identifies the required resources and competencies for the research project, assesses its own capacities and ensures adequate means to undertake the research project.
- ACF **organises scientific peer-reviews** of the research proposals and final research reports. Careful attention is given to the sample size calculations.

ACF recognizes the importance of a **good quality management system** to undertake research activities and updates its internal processes and tools on a frequent basis.



Research is ethically justified

It should be stressed that research in emergency settings should be avoided as the researchers are unlikely to be able to guarantee fully the basic Bioethics principles in relation to the target population. If, however, the researchers deem necessary that research should take place in an emergency context, they should provide concrete arguments for their choice on the emergency setting. They will be asked to communicate these arguments to the ACF Research Department in charge of the research before any decision to implement the research.

How does ACF ensure a research proposal is “ethically valid”?

ACF ensures a research proposal is ethically valid before the implementation of research in the field by getting the clearance of the local ethics review committee in the host country and the ethics review committee of the scientific partner's organisation.

Do all the ACF research activities have to be ethically reviewed?

The international guidelines stipulate that only research involving human beings must be ethically reviewed. In order to identify when a research has to be ethically reviewed, the researcher must fill the check-list in Annex II during the drafting of the research proposal. If there is any doubt on the need for submitting the research proposal to an ethics review committee, please refer to the ACF Research Department in charge of the research.

What shall I do if there is no local ethics review committee in the host country?

If there is no local ethics review committee in the host country, CIOMS specifies that the ethical requirement that research be responsive to the needs of the **population** or **community** in which it is carried out calls for decisions on what is needed to fulfil the requirement. As such, the researcher needs to identify in collaboration with the operational and technical teams the “highest” local health bodies and/or organizations and/or communities and/or teams and/or persons (e.g. a medical officer of health for district) that can give the agreement for the research implementation in the field. The identified body/person must be able to write and/or read and sign a letter approving the research or at least indicating that he/she has been informed that the research is going to take place. A record with minutes of a meeting at which all the research was explained in a more global way can also be signed. Collecting agreements from both political and technical (health) bodies is recommended.

What shall I do if there is no ethics review committee affiliated to my scientific partner organisation?

The researcher must identify an ethics review committee in the country of the ACF's Headquarter leading the research which has the ability to ethically validate the research proposal.

What shall I do if there is no ethics review committee entitled to give ethical clearance?

In this case, please, refer to the Research Department following your research project, which will help you to define the appropriate process.

What are the ACF ethical requirements for research?

The ACF ethical requirements for the implementation of research are the international research ethics standardized ones (described in Helsinki declaration, CIOMS Guidelines). They are the following:

■ ACF assesses benefits and risks of research participants

Most health research interventions involve risks and burdens. A detailed risk analysis is achieved by the research team before the research implementation. This involves the specific issue of conflict and insecurity that remains under the responsibility of the operation teams. It is important to remain that research in the field follows the security conditions of the mission. ACF must reasonably weigh potential benefits and risks and must ensure that risks are minimized. ACF will take reasonable efforts to ensure that all research participants fully understand the burden and benefits of a research and are in agreement with the possible direct and/or indirect implications. As stated in the CIOMS guidelines:

- **Interventions or procedures that hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual subject must be justified by the expectation that they will be at least as advantageous to the individual subject**, in the light of foreseeable risks and benefits, as any available alternative. Risks of such 'beneficial' interventions or procedures must be justified in relation to expected benefits to the individual subject.

- Risks of interventions that do not hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual **must be justified in relation to the expected benefits to society (generalizable knowledge)**. The risks presented by such interventions must be reasonable in relation to the importance of the knowledge to be gained.

Equitable distribution of burdens and benefits in the selection of groups of subjects in research

ACF must ensure an **equitable distribution of burdens and benefits** in the selection of groups of subjects in research. Although inequalities between groups do exist and it is not the aim of research to compensate for it, it should be clear that the selection of the participants should not result in their being disadvantaged in relation to other participants in the research project.

Risks to groups of persons

Research in certain fields, such as epidemiology or sociology, may present **risks to the interests of communities, societies, or racially or ethnically defined groups**. Information might be published that could stigmatize a group or expose its members to discrimination. This should be highlighted in the risk analysis. This might involve **the need to publish the resulting data in a manner that is respectful of the interests of all concerned**.



■ Particularity of Randomized Controlled Trials (RCTs): ACF ensures minimizing risk associated with participation in an RCT

Assessing the risks induced by the implementation of research in the control group without any intervention

In randomized controlled trials, by definition, subjects risk being allocated to receive the treatment that proves inferior. They are allocated by chance to one of two or more intervention arms and followed to a predetermined end-point.

It is **important for ACF to design the control group in a way which is not “harmful” for the people involved in the control group.** That also includes:

- identifying the **risk & detection of diseases** induced by the research,
- the definition of a **predetermined "end-point"**: "harmfulness",
- the possibility of **further reference to health and healthcare structures.**

Implementation of an equivalency trial

When it appears too dangerous to define a control group without any intervention, CIOMS reminds that an **"equivalency trial"** is possible, which would compare an investigational intervention with an established effective intervention and produce scientifically reliable data. An equivalency trial in a country in which no established effective intervention is available is not designed to determine whether the investigational intervention is superior to an established effective intervention currently used somewhere in the world; its purpose is, rather, to determine whether the investigational intervention is, in effectiveness and safety, equivalent to, or almost equivalent to, the established effective intervention.

How to define the best standard of care for the control group?

International guidelines stipulate that when research into preventive measures is conducted, wherever appropriate, participants who develop the disease being studied should be offered a universal standard of care for the disease under study. Where it is not appropriate to offer a universal standard of care, the minimum standard of care that should be offered is the best available intervention as part of the national public health system for that disease.

■ Referring to healthcare services

When not available to provide proper healthcare, ACF must define how and to which healthcare services participants will be referred to, if necessary. This refers to cases of incidental findings or unintended side-effects as part of the project process. Relevant accessible health care provisions should be built-in the project design.

■ To minimize the risk, it is also possible for the researcher to provide in the research protocol for the monitoring of research data by an independent board (Data and Safety Monitoring Board – DSMB)

The CIOMS indicates that in some cases a DSMB is called upon to perform «conditional power calculations», designed to determine the probability that a particular clinical trial could ever show that the investigational therapy is effective.

To minimize risk when the intervention to be tested in a randomized controlled trial is designed to prevent or postpone a lethal or disabling outcome, the researcher must not, for purposes of conducting the trial, withhold therapy that is known to be superior to the intervention being tested, unless the withholding can be justified by the standards set forth in CIOMS. Also, the researcher must provide in the research protocol for the monitoring of research data by an independent board (DSMB); one function of such a board is to protect the research subjects from previously unknown adverse reactions or unnecessarily prolonged exposure to an inferior therapy. Normally, at the outset of a randomized controlled trial, criteria are established for its premature termination (stopping rules or guidelines).

■ What about the assessment of risk linked with the potential use of Genetically Modified Organisms (GMOs)?

ACF should not use GMOs in its research. If there is any suspicion that GMOs are being used in a research activity, the researcher must refer to ACF's positioning on GMOs and contact the ACF Research Department before moving forward with the research.

■ Registration of Randomized controlled trials

ACF Randomized Controlled Trials are registered on the appropriate national and/or international database.

■ ACF ensures the safeguarding confidentiality

ACF establishes safeguards of the confidentiality of the subject's research data. Subjects should be told the limits, legal or other, to the ACF's ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.

■ ACF defines an acceptable compensation for participants

International guidelines state that participants could benefit from some compensation for lost earnings, travel costs and other expenses incurred as a result of taking part in a research project and they may also receive free medical services. Nevertheless, the payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in a research project that they would normally refuse to ("undue inducement"). All payments, compensations and medical services provided to participants must be discussed and defined in collaboration with the operational staff in charge of the country. They must be stated clearly in the research protocol and submitted to the appropriate ethics review committee.

■ ACF obtains the informed consent of participants

CIOMS guidelines state that for all research involving humans the researcher must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by the respective ethics review committee. **Special justification is required for inviting vulnerable individuals to serve as research subjects** and, if they are selected, the means of protecting their rights and welfare must be strictly applied.



What is informed consent?

Informed consent is a **decision to participate in research, taken by a competent individual who has received the necessary information and who, after considering the information**, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation. A model of consent form is presented in Annex IV. A person is considered to be competent if he/she is able to understand information about the proposed research.

The researcher be consistent is responsible for **ensuring the adequacy of informed consent from each subject**. The person obtaining informed consent should be knowledgeable about the research and capable of answering questions from prospective subjects. Researchers in charge of the study must make themselves available to answer questions at the request of subjects.

What information should be given to participants?

Before requesting an individual's consent to participate in research, **the researcher must provide the following information**, in language or another form of communication that the individual can understand:

- that the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that **participation is voluntary**,
- that the individual is **free to refuse to participate** and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled,
- the **purpose of the research**, the procedures to be carried out and how the research differs from routine procedures,
- the **expected duration of the individual's participation** and whether money or other forms of material goods will be provided in return for the individual's participation,
- that, after the **completion of the study, subjects will be informed of the findings of the participation in the research in general**,
- any **foreseeable risks, pain or discomfort**, or inconvenience to the individual (or others) associated with participation in the research,
- the **expected benefits of the research** to the community or to society at large, or contributions to scientific knowledge,
- the steps that researchers have taken to **safeguard confidentiality** and anonymity for the participants,
- the sponsors/donors of the research, the institutional affiliation of the researchers, and the nature and sources of funding for the research,
- whether it is planned **that biological specimens collected** in the research will be destroyed at its conclusion, and, if not, **details about their storage (where, how, for how long, and final disposition)** and possible future use, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed,
- whether **commercial products** may be developed from the research and whether the participant will receive monetary or other benefits from the development of such products,
- that an **ethics review committee** has approved the research protocol.

A model is proposed in Annex V

Special limitations on risk when research involves individuals who are not capable of giving informed consent

When there is ethical and scientific justification to conduct research with individuals incapable of giving informed consent, the risk from research interventions that do not hold out the prospect of direct benefit for the individual subject should be no more likely and not greater than the risk attached to routine medical or psychological examination of such persons. Slight or minor increases above such risk may be permitted when there is an overriding scientific or medical rationale for such increases and when an ethical review committee has approved them.

What shall I do if the participant cannot sign the consent form?

In rare cases where written consent is impossible to obtain (due, for instance, to local customs or political conditions) **a good justification should be given for the necessity of undertaking research alternative safeguards** taken to respect participant autonomy. This should be reviewed by the respective ethics review committee that will decide whether written consent can be waived in the particular case. In any case, the researcher should retain proofs that oral consent has been obtained from participants (e.g. finger print, signature of independent witnesses or recording consent in audio form).

Are there exceptions when research participants are vulnerable people?

The process of consent is not different for vulnerable persons that are invited as research participants. Nevertheless particular attention should be given in presenting the information in a form that participants can understand (e.g. illiterate people, children) and **local customs of communication should be respected** (e.g. involvement of community elders). In case of children participating in research an assent (implicit or written direct agreement to participate) is required, along with the written consent of legal carers. In any case, **the wish of participants to discontinue participation in the research should be respected** even if legal carers are opposed to it.

Shall I need to obtain the consent of the spouse, the clan or the community?

The answer is “yes”, depending on the culture of the communities where the research is to be implemented. In certain cultures, informed consent is not only at the individual level; it has to encompass the spouse, the clan, the community. The spouse, the community chief or a traditional leader may also be required to approve the research. ACF must follow the local habit and cultures to obtain the informed consent. This kind of consent can be oral and does not imply a need for a written agreement. Furthermore, this does not preclude or replace the duty to obtain the written individual consent for the research.

Should consent always include a written agreement between participant and researcher?

As a rule the answer is yes. A signed agreement is the standard and best option of receiving consent from participants.

What shall I do if there is any suspicion that local authorities' perspective on the research project contravenes the principles of these guidelines?

If there is any suspicion that local authorities' perspective on the research project contravenes the principles of these guidelines, he/she should inform the HQ ACF Research Department in charge of the research before commencing the research.

How can I make sure my research follows these ethics requirements?

ACF has defined a list of all the information that shall be provided before beginning any research (Annex III). Each Headquarter may use this format or adapt it to their needs.



Principle 3. ACF research is culturally-sensitive in its research undertakings

What does it mean?

The Nuffield Council of Bioethics states that the **variety of beliefs and practices that exist may challenge the notion of overarching ethical principles**, namely, the belief that certain basic ethical principles are universal and should be followed in any case. This in turn prompts an analysis of the relationship between the requirement of sensitivity to cultural differences and the concept of moral relativism, the view that different moral codes cannot be critically compared and evaluated.

According to the Nuffield Council of Bioethics, **recognition of the existence of diverse cultures and communities with different moral codes should not lead to moral relativism**. The relativist position mistakenly suggests that because a particular set of moral norms is embedded in the culture, it must be accepted uncritically. This is to confuse two distinct questions:

- What does the local culture prescribe?
- What is the right thing to do bearing in mind the local culture?

Ethical judgements are of this second type. Thus, sensitivity to the values inherent in local practices does not require uncritical acceptance of them.

How does ACF ensure the application of this principle?

In order to enhance the cultural sensitivity of research, ACF encourages the **implementation of participatory approaches in its conception and design**. All relevant stakeholders (researchers, sponsors, participants, the local community and the local authorities) **should work in partnership before research begins. They should consider the importance of the research questions, procedures for obtaining consent, the provision of an appropriate standard of care, and the sustainability of arrangements** once research is complete. In case of cultural-driven differences in conception and execution, stakeholder involvement guarantees the search for compromises that will allow respect for both local cultural norms and prescribed ethical principles of research.

Principle 4. ACF research promotes the strengthening of national and local organizations responsible for research in target communities

What does it mean?

ACF should make every effort to **enhance capacity-building at the institutional and community levels**. It is recognized by the Nuffield Council on Bioethics that genuinely collaborative research projects generate opportunities for training and for developing human resources. Such collaborations can increase self-reliance in developing countries, thereby enabling local specialists to identify areas needing research and to develop local solutions to public health problems. The development of operational guidelines for healthcare, systems for surveillance and management flow-charts are potential by-products which in turn contribute to the improvement of healthcare systems and the ability of countries to respond to their public health needs.

How does ACF ensure the application of this principle?

- ACF makes all the effort to **include representatives of stakeholders of the host country in its research programs** (national government, health ministry, local health authorities, concerned scientific and ethics groups, representatives of the communities from which subjects are drawn, non-governmental organizations, health advocacy groups...). Specifically, ACF might promote the development of local researchers where and when it possible.
- ACF defines as far as possible a capacity strengthening plan for the countries participating to and/or hosting the research.

How can ACF enhance capacity-building when there is not a systematic plan for this in the intervention country?

It is sometimes the case, particularly in low-resources countries, the Nuffield Council of Bioethics reminds that there is no systematic plan for developing expertise in health-related research. **ACF research is not expected to fulfil the gap left by national authorities but it is nevertheless expected that the research design will take into consideration the local situation and make an effort to improve it. This can take the form of specific training sessions and/or feedback sessions.** There is no prerogative in the manner of creating local capacity building except that effort is undertaken to leave behind know-how that can benefit the local communities after the end of the research project.



PRINCIPLE 5. ACF research makes an effort to ensure the availability of any knowledge generated and product developed locally and promotes a wide sharing of research results

What does it mean?

Ensuring the availability of the knowledge generated and product developed locally: First of all, it is important to note that the CIOMS guidelines recognize that the issue of "**reasonable availability**" is complex and needs to be determined on a case-by-case basis. Relevant considerations include the **length of time for which the intervention or product developed**, or other agreed benefit, **will be made available to research subjects, or to the community or population concerned**; the severity of a subject's medical condition; **the effect of withdrawing the study drug** (e.g., death of a subject); the cost to the subject or health service; the cost-effectiveness of any new intervention, and the question of **undue inducement** if an intervention is provided free of charge.

Then, the Nuffield Council on Bioethics reminds that it is policy-makers who fundamentally have the prime responsibility to implement changes in their countries and to seek evidence to inform their decisions. Still, in general, if there is good reason to believe that a **product developed or knowledge generated** by research is unlikely to be reasonably available to, or applied to the benefit of, the population of a proposed host country or community after the conclusion of the research, it is unethical to conduct the research in that country or community. This should not be construed as precluding studies designed to evaluate novel therapeutic concepts.

Promoting a wide sharing of research results: Results of research should be accurately reported and published, regardless of their being in support or not of the desirable outcome. Moreover, results should be made public and in a form that can be used as feedback to the participating communities/individuals.

How such information is provided will vary in different circumstances, but as well as a written report and a verbal presentation, **researchers have an obligation to answer any questions that participants or other members of the community may have about the nature and significance of their findings. The appropriate forum for this is often a public meeting.** It should be noted that failure on the part of researchers to present the results of a trial is a frequent reason for participants' unwillingness to participate in any subsequent research.

How does ACF ensure the application of this principle?

- ACF makes every effort to ensure **that any intervention or product developed, or knowledge generated, will be made available for the benefit of that population or community,**
 - o In particular, ACF makes all the efforts to describe how provision will be taken for continued access of participants to the investigational treatment after the study, indicating its modalities, the individual or organization. ACF considers for this: **the length of time for which the intervention or product developed**, or other agreed benefit, **will be made available to research subjects, or to the community or population concerned**; **the severity** of a subject's medical condition; **the effect of withdrawing the study drug** (e.g., death of a subject); the cost to the subject or health service; the cost-effectiveness of any new intervention, and the question of **undue inducement** if an intervention is provided free of charge, etc.,
 - o ACF promotes the development and support of expertise so that equipment obtained for the purpose of a research project can continue to be used and maintained by the community,

- ACF **accurately reports and publishes research results**, regardless of their being in support or not of the desirable outcome. Research results are made public and in a form that can be used as feedback to the participating communities/individuals,
 - o In particular, ACF informs participants and local authorities about research results at the end of the research,
 - o If feasible, this is done by the **organisation of a public meeting**. This must be accompanied by an explanation of the implications of the results for future healthcare or prevention of disease in the community when appropriate,
- ACF can implement **training and/or feedback sessions** to facilitate the appropriateness of research results and/or knowledge by the communities at the end of the research project,
- ACF recognizes and promotes the ethical link between research and advocacy for the most at-risk populations. This is why, on the basis of research results, ACF makes **recommendations** on the way **to present findings such that policy-makers can understand their implications** when relevant, and, at the least, if findings can be used for advocacy purposes with respect to the future provision of the intervention. Potential advocacy projects arising from research projects will be led by the operational teams.

What about research dedicated to contexts with extremely limited resources?

As a rare exception, for example, research may be designed to obtain preliminary evidence in an intervention that could benefit for vulnerable people **that are confronted to issues that occur only in regions with extremely limited resources, and it could not be carried out reasonably well in more developed communities**. CIOMS mentions that such research may be justified ethically even if there is no plan in place to make a product available to the population of the host country or community at the conclusion of the preliminary phase of its development. If the concept is found to be valid, subsequent phases of the research could result in a product that could be made reasonably available at its conclusion.

The Nuffield Council on Bioethics also gives some suggestions on specific possible actions in this case: **present findings in such a way that policy-makers can understand their implications** and, at the least, the findings can be used for advocacy purposes with respect to the future provision of the intervention. If findings do not necessarily lead to action then it is still ethical to undertake the research as ACF ensures findings are disseminated and used for advocacy. ACF must avoid Non feedback and unlikely actions of research.

When public publication/dissemination/sharing of results is identified as a risk for the people/communities involved in research, is it still ethical to undertake the research?

The appropriate ethics review committee will need to be consulted to ensure that the interests of all concerned are given due consideration in publication and feedback of research results. For instance, research in certain fields, such as epidemiology or sociology, may present **risks to the interests of communities, societies, or racially or ethnically defined groups**. Information might be published that could stigmatize a group or expose its members to discrimination. CIOMS indicates that **plans to conduct such research should be sensitive to such considerations, to the need to maintain confidentiality during and after the study, and to the need to publish the resulting data in a manner that is respectful of the interests of all concerned**, or in certain circumstances not to publish them.

While ACF is not in a position to translate its research findings into action when an intervention proves to be efficacious, it **can draw attention to problems which have been neglected, or conditions whose impact has been underestimated, and demonstrate that there are feasible solutions**.



PRINCIPLE 6. ACF ensures by all means possible, avoidance of research bias due to conflict of interest with other stakeholders and that research is not profit-driven.

What does it mean?

ACF ensures by all means possible, avoidance of research bias due to conflict of interest with other stakeholders:

A conflict of interest is a situation in which a person or partner has a private/personal interest sufficient to appear to influence the objective implementation of the scientific research.

Moreover, ACF research shall remain in accordance with the association's principles and Charter of principles (Annex I) and shall enable the largest possible number of people to benefit from the research.

The risk of a conflict of interest is particularly significant when a for-profit company is involved. It may indeed happen that this for-profit company, associated to the program, tries to influence the research so that the results shall be consistent with its own particular interests. In this case, the for-profit company may try to prevent ACF researchers to control and define the research protocol, to get access to the raw data, to produce an unbiased data interpretation, or to get the results published, if they are unfavourable to the for-profit company's product or trade policy.

Indeed, CIOMS reminds that, as the persons directly responsible for their work, researchers should not enter into agreements that interfere unduly with their access to the data or their ability to analyse the data independently, to prepare manuscripts, or to publish them. Researchers must also disclose potential or apparent conflicts of interest on their part to institutional committees designed to evaluate and manage such conflicts.

This risk of bias may also be associated with other sources of support, such as government or foundations. CIOMS mentions that sponsors of research or researchers cannot, in general, be held accountable for unjust conditions where the research is conducted, but they must refrain from practices that are likely to worsen unjust conditions or contribute to new inequities. Neither should they take advantage of the relative inability of low-resource countries or vulnerable populations to protect their own interests, by conducting research inexpensively and avoiding complex regulatory systems of industrialized countries in order to develop products for the lucrative markets of those countries.

ACF ensures that research is not profit-driven:

ACF research is not profit-driven means that ACF research results are shared to the largest possible number of people.

How does ACF ensure the application of this principle?

How does ACF ensure that a partnership will not induce biased research?

- Prior to any partnership or sub-contracting, ACF researchers analyses the aims pursued by the potential partner and disclose all possible inconsistent interest(s) that this potential partner might have.
- Whenever their other occupations may lead to question their neutrality, ACF researchers shall also disclose potential or apparent conflicts of interest on their part to the ethical review committee, in order to evaluate and manage such conflicts.
- ACF signs a **Memorandum of Understanding** with each collaborative partner of the research. It defines the roles and responsibilities of each organisation. It will include standard clauses presented in Annex VI.
- These ethical guidelines are attached to the Memorandum of Understanding, and the sub-contractor must commit to act, while implementing the research, in accordance with these guidelines.

What may be decided when a for-profit company wishes to get involved in an ACF research program?

Prior to any decision, one must make sure that this for-profit company meets ACF ethical requirements and must review the for-profit company's activities, following the vetting process attached as Annex VII to these guidelines.

Then, it is important to go through the procedure exposed above. Research partnerships, including funding, with for-profit companies, enabling them to get involved in the conduct of the research, are not acceptable, in any case.

For-profit companies may only be associated to ACF research programs as sub-contractors (providing services).

This involvement shall however be carefully defined, via a detailed contract, using the recommendations found in Annex VI of these guidelines.

This agreement shall ensure that ACF researchers remain in control of the research program and exclude any involvement of the for-profit company, in particular, in the data interpretation and the results publishing decisions.

What about the sharing of benefits of research results?

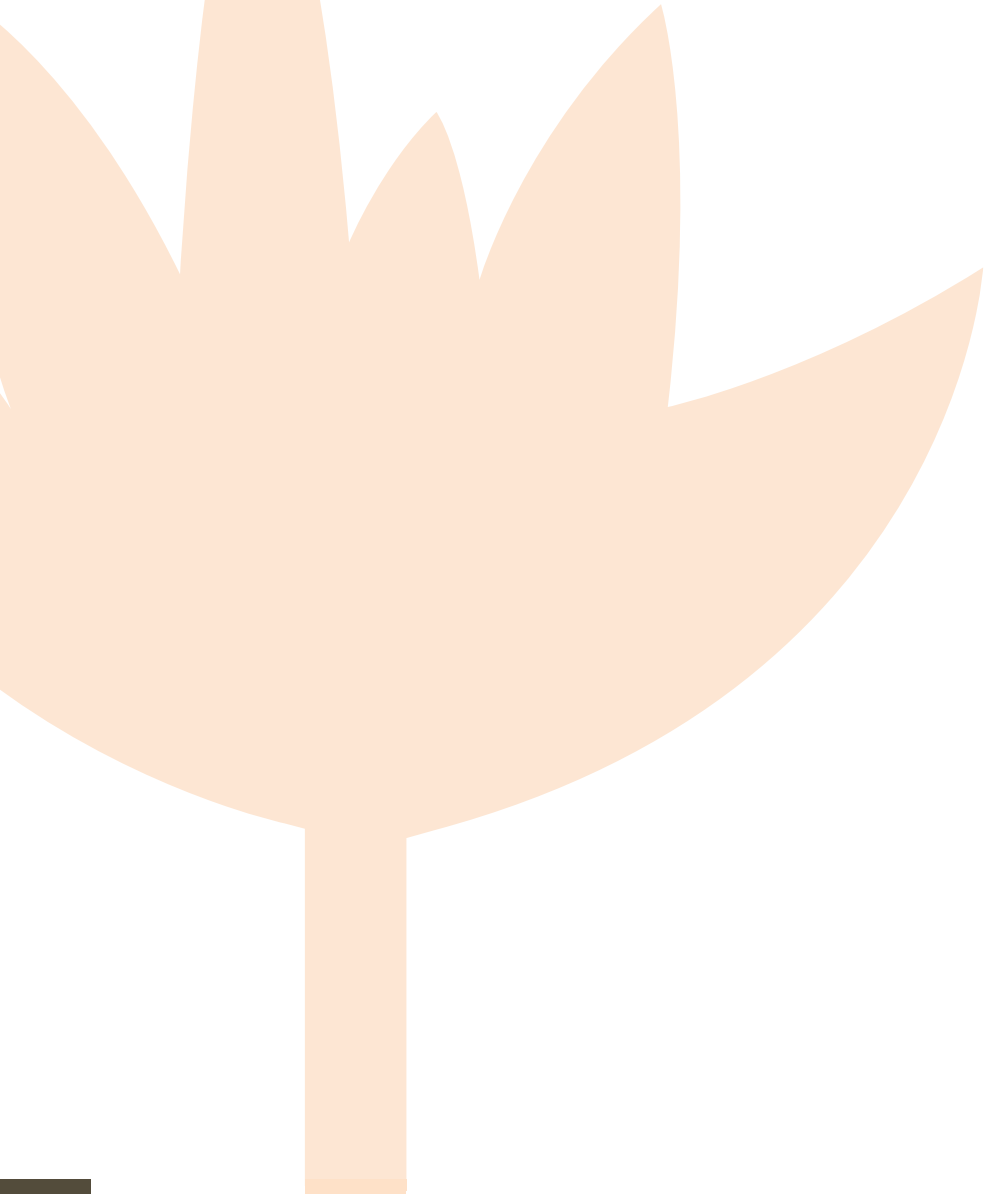
ACF shall make sure that the scientific produced knowledge resulting from its research programs will be used for the benefit of largest possible number of people.

ACF researchers should be aware that various stakeholders involved in research including participants, health professionals, and for-profit companies, may all have a for-profit interest in the results.



Therefore, when intellectual property or potential profits are likely to result from the research, it is advisable to conduct a benefit sharing agreement between ACF partners, providing that ACF will be allowed, in any case, to share the results with the largest possible number of people (see recommendations in Annex VI of these guidelines).

"Treat people as an end, and never as a means to an end" – Kant



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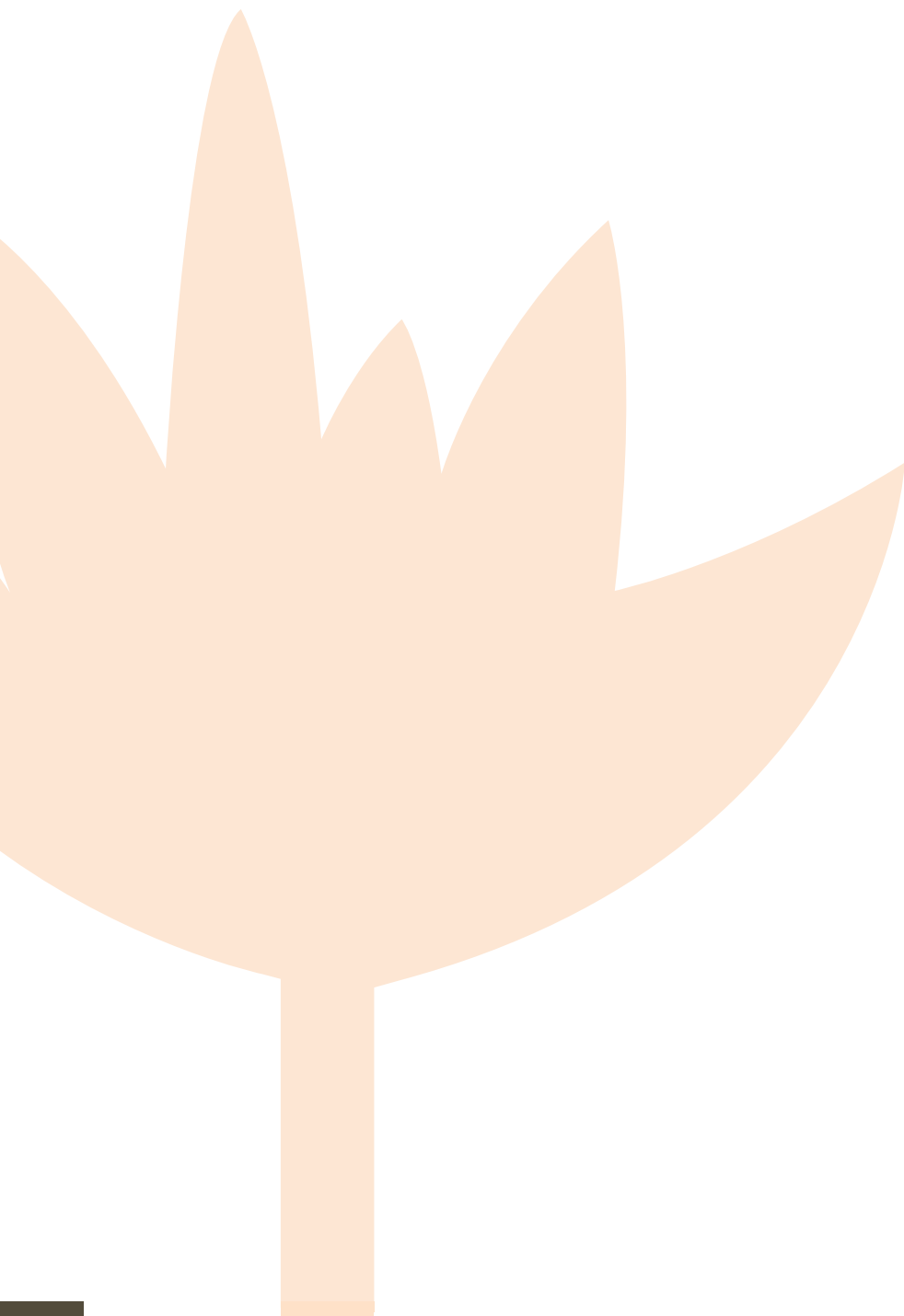
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Annexes



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Annex 1: The ACF-IN Charter of Principles

ACF-IN is a non-governmental organization. Private, non-political, non-denominational and non-profit making, it was set up in France in 1979 to intervene in countries throughout the world.

ACF-IN's vocation is to save lives by combating hunger, disease, and those crises threatening the lives of helpless men, women and children.

ACF-IN intervenes in the following situations:

- In natural or man-made crises which threaten food security or result in famine,
- In situations of social/economic breakdown linked to internal or external circumstances which place particular groups of people in an extremely vulnerable position,
- In situations where survival depends on humanitarian aid

ACF-IN intervenes either during the crisis itself, through emergency actions, or afterwards, through rehabilitation and sustainable development programmes.

ACF-IN also intervenes in the prevention of certain high-risk situations.

The ultimate aim of all of ACF-IN's programmes is to enable beneficiaries to regain their autonomy and self-sufficiency as soon as possible.

ACF-IN respects the following principles:

■ INDEPENDENCE

ACF-IN acts according to its own principles so as to maintain its moral and financial independence. ACF-IN's actions are not defined in terms of domestic or foreign policies or in the interest of any particular government.

■ NEUTRALITY

A victim is a victim. ACF-IN maintains strict political and religious neutrality.

Nevertheless, ACF-IN may denounce human rights violations that it has witnessed as well as obstacles put in the way of its humanitarian action.

■ NON DISCRIMINATION

ACF-IN refutes all discrimination based on race, sex, ethnicity, religion, nationality, opinion or social class.



■ **FREE AND DIRECT ACCESS TO VICTIMS**

ACF-IN demands free access to victims and direct control of its programmes.

ACF-IN uses all means available to achieve these principles and will denounce and act against any obstacle preventing it from doing so. ACF-IN also verifies the allocation of its resources to ensure that the resources reach those individuals for whom they are destined. Under no circumstances can partners working together with or alongside ACF-IN become the ultimate beneficiaries of ACF-IN aid programmes.

■ **PROFESSIONALISM**

ACF-IN bases the conception, realisation, management and assessment of its programmes on professional standards and its years of experience to maximise its efficiency and the use of resources.

■ **TRANSPARENCY**

ACF-IN is committed to respecting a policy of total transparency to beneficiaries, partners and donors and encourages the availability of information on the allocation and management of its funds. ACF-IN is also committed to providing guarantees of its good management.

All members of ACF-IN adhere to the principles of this Charter and are committed to respect it.

Annex 2 : Ethics Review - Activity Checklist

This checklist is an aid to determining whether an activity (research, commercial, knowledge transfer, evaluation, audit or teaching and learning) needs to be referred to the Ethics Review Committee. The checklist can be used whether you are applying as part of governance checks (i.e. for contract approval or research degree registration) or for approval to start the activity. If you are unsure whether to answer ‘Yes’ or ‘No’ to a question, you should answer ‘Yes’. If, on completion of the checklist:

- *any* question is answered ‘Yes’, then you must apply to the Ethics Review Committee;
- *all* questions are answered ‘No’, then it may not be necessary to apply to the Ethics Review Committee *unless* you have concerns about the ethical nature of the activity. However, it is still incumbent on you to observe the ACF’s Ethical Principles in the conduct of the activity and to record that:
 - o a review has taken place of the ethical aspects of the activity; and that no ethical issues have been identified.

Project title:
.....

Form completed by:

Responsible staff member
Department
Signature
Date

Question	Response
1. Circle an appropriate response for each section/question	
a) Is this a research activity (i.e. one designed and conducted to generate new knowledge) EITHER involving humans as research participants (and/or including use of their data) OR using human tissue samples?	YES\NO
b) Will any information gathered be used as generalisable data to inform services/areas other than that which it was collected from?	YES\NO
c) Will any data/information be used in publications or presentations e.g. Journals, conferences etc?	YES\NO
2. Will the activity require separate and specific ethics clearance from the ethics committee of an external organisation (e.g. collaborating partner, local authority)? <u>Please note</u> that a decision by an external ethics committee that your project is not research i.e. service evaluation, does not mean that it may not have ethical considerations that will need reviewing by a an Ethics Committee.	YES\NO
3. Does the activity involve participants who are	
a) unable to give their informed consent (e.g. people with severe learning disabilities, unconscious patients etc.)	YES\NO
b) who may lack capacity to give valid consent (e.g. children, people experiencing mental health difficulties)?	YES\NO
c) due to functional problems, unable to give written consent?	YES\NO




Question Circle an appropriate response for each section/question		Response
4.	Does the activity raise issues involving the potential abuse or misuse of power and authority which might compromise, for example, the validity of participants' consent and/or relationships with local authorities?	YES\NO
5.	Will the activity put staff, students and/or participants at a higher risk of physical, social, emotional or psychological harm than they would otherwise encounter?	YES\NO
6.	Does the activity involve staff, students and/or participants in the potential disclosure of any information relating to illegal activities; the observation of illegal activities; or the possession, viewing or storage of images or information (whether in hard copy or electronic format) which may be illegal?	YES\NO
7.	Will deception of the participant be necessary during the activity?	YES\NO
8.	Will the activity involve invasion of privacy or access to confidential information about people without their permission?	YES\NO
9.	Does the activity involve scientific procedures being applied to a vertebrate animal (other than humans) or an octopus?	YES\NO
10.	Does the activity involve work with micro-organisms?	YES\NO
11.	Does the activity involve genetic modification?	YES\NO
12.	Does the activity relate to military equipment, weapons or the Defence Industry?	YES\NO
13.	Does the activity involve the excavation and/or study of human remains?	YES\NO
14.	Does the activity involve collection of rare plants?	YES\NO
15.	Is the activity (e.g. art) likely to shock or offend?	YES\NO
16.	Are you aware of any ethical concerns about the company/organisation funding the activity e.g. its product has a harmful effect on humans, animals or the environment; it has a record of supporting repressive regimes; does it have ethical practices for its workers and for the safe disposal of products?	YES\NO

Annexe 3 : ACF Research Proposal - Guidance note

This model lists all the information that must be provided before the start of any research project. Each Headquarter may use this format or adapt it to their needs.


TITLE
SUBTITLE

Authors : 

XXXXXXX

Version n°X
Date



If ACF-IN document, use:


**Project title:**

Start date:

End date:

Length of project (number of months):

Project Sponsor (name, title, address):

Project manager (name, title, address):

If a project manager needs to be recruited, include expected recruitment date

Partnership:

Names, addresses, institutional affiliations, qualifications and experience of the principal investigator and other investigators;

Country (ies) /missions involved in the research project:

List the ACF missions that will be involved in the research project and their level of involvement.

Note whether there are areas included in the research in countries in which ACF is not currently present.

Research summary (1/2 page max):

Brief, clear summary in lay/non-technical language, stating significance and broader impacts of proposed project.

- In French/Spanish/English (depending on the language of the country):
- In main local language:

I. CONTEXT (6 pages max.)

DESCRIPTION OF THE HUMANITARIAN ISSUE

- Describe country, region, and humanitarian context faced by the community or communities for which ACF is developing the research project

Include a brief description of the context in which the issue was initially identified and attempts by ACF to address the problem.

- Identify the humanitarian issues encountered that require the implementation of the research project
This paragraph should clearly describe the operational issue that has led to the research question (limitations in current local practices, etc...). Include all humanitarian issues which ACF is addressing in this operational context that are relevant for the research project.

- Describe the community or communities who are concerned by the issue (customs, traditions, etc...) *In this chapter describe the population(s) and /or community(ies) that are by concerned by the issue. Please, be specific e.g. customs and traditions, values and expectations, that might have an impact on the proposed study.*

CURRENT PRACTICAL AND SCIENTIFIC KNOWLEDGE ON THE RESEARCH SUBJECT

This section includes a comprehensive literature review, relating the research to the current state of knowledge on the topic. It also includes known knowledge from other unpublished sources.

- Current technical knowledge
Indicate the existing practical knowledge, potential past and present experiences or practices that have been experimented within ACF in an attempt to address the research question.

- Current scientific knowledge
Indicate the existing scientific knowledge and the status of on-going scientific research relevant to the research subject and contributing or not to the operational questions. Include on-going studies that have not yet been published, scientific publications, including the nature, the extent, and the relevance of similar previous or on-going studies such as clinical ones.

OTHER ON-GOING PROJECTS RELATED TO RESEARCH TOPIC

ACF makes all the efforts to ensure that the need is not already being met by other existing initiatives.

- External to ACF

List all on-going local, national and international initiatives related to the research needs and justify why the research question is still valid despite these on-going initiatives. It must be clear that the research project will take into consideration these initiatives, by defining the project on the basis of these existing initiatives and/or by coordinating with them.

Include research carried out by different actors on the topic, in the given country and/or region. Are there any local universities working on the same question?

Is there any interest or possibility in working with these institutions? If no, explain why.



Justify why ACF is legitimate/the best actor to undertake/participate in the research project in the given area.

■ Internal to ACF

Briefly describe other on-going initiatives within ACF and related to the research subject.

Include all on-going working groups (international platform, on-going research project, etc...) within ACF and related to the research subject.

- Any contacts already established with the Ministries of Health? Other Ministries? Other legal authorities?

IDENTIFYING THE RESEARCH NEEDS

State clearly and succinctly what are the humanitarian research needs.

INTERESTS / BENEFITS

Research benefits for the different actors: local, national and international (institutional, humanitarian, civil society, scientific, etc...)

Research findings contribute to the improvement of practices and or knowledge of local or national actors with in the country, as well as the international community.

Please, state in this chapter the different local, national and international actors benefiting from the research results and how these will benefit from the research at the end of the project.

- Describe the geographic regions and populations that will potentially be affected by the research results

- Describe the interests/benefits of the research for the local population

Describe the potential benefits of the research for research subjects, the potential benefits of research for the local population, including new knowledge that the study might generate.

Note it is important to involve the communities at the earliest possible stage in defining the research needs – tools need to be developed facilitating this, and this aspect needs to be addressed globally.

- Describe interests/benefits of the research for the national population and the international community

- What are the benefits for ACF

In this chapter, specify how the research results will contribute to implementing:

- the ACF-IN 2015 Strategy
- the strategy (ies) for the countries involved
- the ACF technical and research strategies

Include the sectors relevant to ACF activities that will potentially be interested by the research results.

What is the added value of the project for ACF (new knowledge, expertise, etc...)?

LINK WITH THE LOCAL, NATIONAL AND INTERNATIONAL HEALTH PRIORITIES

Identify/list the national/institutional/local/regional/communities' **health priorities** in the area of the research and indicate **how they are related** with the research question.

INTENDED IMPACT

Impact is defined here as the mid- to long-term intended and unintended effects of the project on its wider environment, and whether or not the project made a difference to the problem it sought to address XX.

Describe the intended operational impact for the project.

RESEARCH OUTCOME

An **outcome** is defined as the observable behavioural, institutional and societal changes influenced directly or indirectly, partially or totally by the outputs that potentially contribute to the improvement in people's lives or of the environment envisioned in ACF's mission. For example, a policy and/or practice change. ACF can only *influence* outcomes.

Describe the intended research outcomes.

STRENGTHENING CAPACITIES

Indicate how the project and ACF will strengthen the capacities of the research subjects and the population or community involved. Research must make all the efforts to ensure the availability of the knowledge generated/product developed and ACF must promote a wide-sharing of research results.

Key points to keep in mind and include in the proposal:

- How will ACF ensure that the national and local actors will take ownership of the results/knowledge/ know-how? Please indicate according to each actor.
- How will ACF ensure that the population/communities will take ownership of the results/knowledge/ know-how?



II. SCIENTIFIC AND ETHICAL FRAMEWORK (8 pages max)

Identifying the research question

The initial research question is presented in detail from a scientific point of view.

Research objectives

Define the objectives of the trial or study, its hypotheses or research questions, its assumptions, and its variables.

Overall objectives

Describe the overall operational objectives.

Specific objectives

Describe the specific objectives, intended to contribute to the overall objectives.

■ Hypotheses

Please outline the main scientific hypothesis and all secondary hypotheses that will be tested.

■ Scientific Methodology

This section is dedicated to outlining the scientific methodology selected for the research project:

Scientific method selected

Describe in detail the scientific methodology chosen for testing the scientific hypotheses.

In some cases it will be necessary to include a statistical analysis plan.

Data collection

Outline the data collection in the field, including the strategy for ensuring the quality of the data collection.

A plan for verifying data entering must be defined for each research project (eg. Double computer verification, training on managing databases, etc...).

List the countries and the sites selected for the implementation of the research project

Include geographic sites where the research will be conducted specifying:

- Relevant demographic and epidemiological information specific to the region(s) and/or the country(ies) involved.
- Explain why the research project should be conducted in these regions/countries and not elsewhere. Include any studies carried out on the needs, and why a humanitarian action is needed in this particular location.
- In what way the selected site(s) will allow for conducting safe and appropriate research?

Include what safety measures will be put in place and followed by the mission(s).

Analysing the results

A description of the method used for analysing results and who is responsible for the analysis.

Includes a plan for the analysis, with a section explaining the choice of the analytical tools and the statistical methods.

Research outputs:

An output is defined as the immediate result of an activity or intervention – the processes, goods and services. For example, workshops, training manuals, research and assessment reports, guidelines and action plans, strategies and recommendations. ACF controls its outputs.

Describe the research outputs.

Ethical Framework

Need to indicate by category the following considerations:

a. Recruitment process

- The process of recruitment, e.g., advertisements, and the steps to be taken to protect privacy and confidentiality during recruitment;
- Rules or criteria according to which subjects may be removed from the study or clinical trial, or (in a multi-centre study) a centre may be discontinued, or the study may be terminated;
- An account of any economic or other inducements or incentives to prospective subjects to participate, such as offers of cash payments, gifts, or free services or facilities, and of any financial obligations assumed by the subjects, such as payment for medical services;

b. Informed consent (see consent form in appendix)

- The means proposed to obtain individual informed consent and the procedure planned to communicate information to prospective subjects, including the name and position of the person responsible for obtaining consent;
- When a prospective subject is not capable of informed consent, satisfactory assurance that permission will be obtained from a duly authorized person, or, in the case of a child who is sufficiently mature to understand the implications of informed consent but has not reached the legal age of consent, that knowing agreement, or assent, will be obtained, as well as the permission of a parent, or a legal guardian or other duly authorized representative;
- Plans to inform subjects about the results of the study;
- Provision for continuing access of subjects to the investigational treatment after the study, indicating its modalities, the individual or organization responsible for paying for it, and for how long it will continue;

c. Confidentiality

- The provisions for protecting the confidentiality of personal data, and respecting the privacy of subjects, including the precautions that are in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives without the consent of the subject;
- Information about how the code, if any, for the subjects' identity is established, where it will be kept and when, how and by whom it can be broken in the event of an emergency;
- Any foreseen further uses of personal data or biological materials;



d. Risk/liability issues

- For research carrying more than minimal risk of physical injury, details of plans, including insurance coverage, to provide treatment for such injury, including the funding of treatment, and to provide compensation for research-related disability or death;
- Methods of recording and reporting adverse events or reactions, and provisions for dealing with complications;
- For research on pregnant women, a plan, if appropriate, for monitoring the outcome of the pregnancy with regard to both the health of the woman and the short-term and long-term health of the child.
- A statement that any proven evidence of falsification of data will be dealt with in accordance with the policy of the sponsor to take appropriate action against such unacceptable procedures.
- Plans and procedures, and the persons responsible, for communicating to subjects information arising from the study (on harm or benefit, for example), or from other research on the same topic, that could affect subjects' willingness to continue in the study;
- Plans for monitoring the continuing safety of drugs or other interventions administered for purposes of the study or trial and, if appropriate, the appointment for this purpose of an independent data-monitoring (data and safety monitoring) committee.

Ethical Submission of the research proposal

- An ethical review is a prerequisite for setting up new research projects.

Please indicate here the national and/or international Ethics Committees the research proposal will be submitted to. In case there is no ethics committee in the country, an ad-hoc Ethics Review Committee will be constituted.

II. RESEARCH PROJECT IMPLEMENTATION AND MANAGEMENT PLAN (15 pages max)

The different steps of the research project must follow the steps of the research project cycle management.

Each of the elements listed below are involved in project implementation and management, and must be thought out and evaluated during the initial identification phase of the project cycle, so as to measure their potential relevance to the project. According to the context, these elements may be adapted or justified.

STAKEHOLDER ANALYSIS AND PARTNERSHIP(S) STRATEGY

A **stakeholder** is any individual, group of people, institution or firm that **may, directly or indirectly affect or be affected by the project**.

A stakeholder analysis is a process by which stakeholders are identified, described, prioritized and categorized. Each stakeholder may have different interests, concerns and capacities and these need to be clearly understood in the process of identifying needs and setting objectives. This exercise is useful in managing the project, in communicating and disseminating project results, and in bridging research and advocacy.

Partners are also stakeholders. **They are formally associated to the research project.** They are identified and reviewed according to the ACF partnership guidelines so as to ensure they meet the ACF charter and have a positive and synergistic impact on ACF research objectives.

Please indicate all the stakeholders and partners for the research project (scientific, operational, technical, etc...):

- List all the stakeholders and how they are affected by the project, benefits, constraints, engagement strategy and follow up, level of commitment, interest, importance and, and constraints.
See appendix 1a for analysis matrix.
- Outline the research partnership strategy (see also appendix 1b for analysis matrix tool.)
 - Analysis of the field competencies required for the implementation of the research project
 - Identification and justification (including their the added-value for the communities) of each partnership
 - Specific attention must be given to the private partnerships and explain why there is not any conflict of interest

TECHNICAL AND SCIENTIFIC INTELLIGENCE PLAN

Include a plan outlining the actions to be undertaken and the timeline relating to technical and scientific intelligence to be conducted over the span of the project's life cycle.

- Identify relevant international groups working in the same field
- Identify and potentially subscribe to relevant newsletters
- Identify future international conferences in the relevant field, over 2 years

PLAN FOR DISSEMINATION OF RESULTS

This part outlines how result findings will be translated into concrete and sustainable (if applicable) operational tools/expectations and transmitted to the target populations and all the actors involved.

Outline a plan covering the dissemination of result findings, keeping in mind:

- Research results are shared and made available for all;
- Research results are accurately reported and published - even when there are no "positive" results, including in peer-reviewed journals.



Research Outputs	Who (internally/externally)	When	How

INTERNAL AND EXTERNAL RESULTS COMMUNICATION PLAN

The internal and external communication strategy is presented in a plan format, highlighting responsibilities and deliverables all along the project cycle.

ADVOCACY

In connection with the advocacy department, identify how the research project may potentially tie-in with advocacy actions.

The stakeholders analysis (see appendix 1) will also help in planning and providing information for advocacy.

CAPITALISING ON EXPERIENCES AND LESSONS LEARNED FOR ACF

From the inception of the project, the types of experiences and results that will be useful to share within ACF must be identified.

At the end of the project, a global “lessons learned” summary is included in the final report and communicated to the team, aiming at continuous improvement. Lessons learned are tracked all along the project.

TRAINING PLANS AND TOOLS

Include a plan detailing trainings planned and tools to be created and shared.

PROJECT MONITORING AND EVALUATION PLAN

The project progress in terms of finances, resource use, implementation, results and management risks is to be monitored and reviewed on a regular basis.

Monitoring is the ongoing analysis of the project progress towards achieving the planned results, and involves both formal and informal activities.

An **evaluation** is a periodic assessment of the efficiency, effectiveness, impact, relevance and sustainability of the objectives and results. It is conducted as objectively as possible, at specific intervals during and after the project (e.g. mid-term, end and post-project).

A monitoring schedule or plan is outlined in the proposal, including how learning events following M&E will be integrated during the project implementation.

ACF carries out a **post-project evaluation** of the research impact in the communities 6 months to 1 year after research has ended in order to assess whether vulnerable people needs have been met. An evaluation plan is outlined in the research proposal describing how the impact of the research results on the communities will be assessed after the research implementation.

Points to keep in mind:

- *In the case of a negative outcome, an assurance that the results will be made available, as appropriate, through publication or by reporting to the drug registration authority is important.*

- *Circumstances in which it might be considered inappropriate to publish findings, such as when the findings of an epidemiological, sociological or genetics study may present risks to the interests of a community or population or of a racially or ethnically defined group of people.*

PROJECT STRUCTURE AND GOVERNANCE

This section describes the role and responsibilities of each person involved in the research project. It will be useful to include a summary diagram, as shown below.

- Diagram of the project governance, including possible members:

The project manager: is responsible for the global coordination of the research project and the different groups involved, and for the advancement of the project.

Steering committee meetings:

It is the group empowered to make and validate key project decisions.

It validates the research proposal & the final research report, and is regularly informed in the progress.

The committee should meet at different intervals during the duration of the project: the launch of the project, half-way, at the end, and every 6 months during the project.

The committee also meets every time there is a critical decision to be made directly concerning the objectives of the project.

Ethics Review Committee:

The Ethics Review Committee is a committee specifically dedicated to the research project that can be solicited for reviewing the research proposal and final reports, as well as for advice on specific ethical issues arising during the research implementation. *The necessity of constituting a specific Ethics Review Committee for the research project must be discussed with the research department (as indicated in the Ethics & Research guidelines).*

Scientific Peer-Review:

It is the group solicited for scientific advice, especially for the research protocol and report.

The scientific Peer-review group is constituted of different recognized scientists who are going to review the scientific methodology and results.

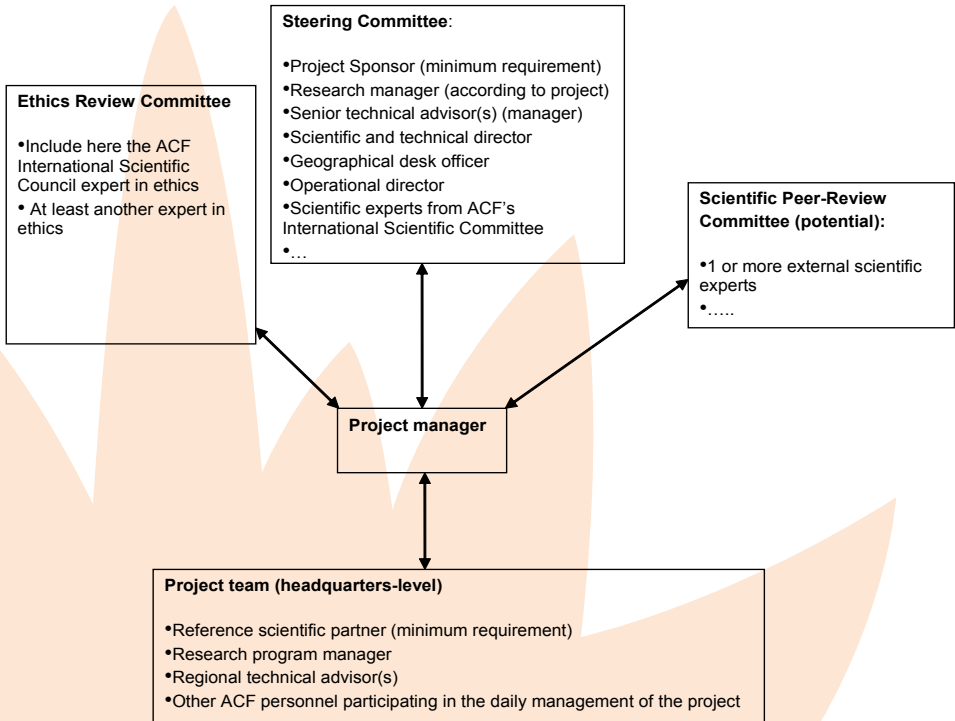
Project team:

It is the group involved in the daily management and implementation of the project.

Work groups:

In addition to the project team, different work groups may be useful to address specific issues related to the project and attaining the objectives.

Please indicate the names, positions and institutions of the people involved in each committee/team in the diagram.



Time required for each participant:

Participant	Role	Time allocated	Year n	Year n+1...

RISK ANALYSIS

This section aims at describing and anticipating potential obstacles in the successful implementation of the project.

What will be the key factors for the implementation of the research project?

(Identify the different kinds of risks – e.g. Security, Information, dissemination, partners involved, etc...)

What will be the management of potential risks:

Risks	Potential adverse impact	Risk level (H/M/L)	Risk management strategy (Plan B, Scenario 2...)

H = High, M=Medium, L=Low

ADMINISTRATIVE, PERSONNEL, FINANCIAL, LOGISTICS ASPECTS

Budget

Include the overall budget here (see appendix 2 for template).

Legal aspects/partnership(s)

Consult with intellectual property lawyer - there should be a MoU clarifying that all partners must follow ACF's ethical considerations.

Points to include/reflect in this section of the proposal:

- Income generation, product – patent is shared by mutual agreement.
- The arrangements for dealing with financial or other conflicts of interest that might affect the judgement of investigators or other research personnel: informing the institutional conflict-of-interest committee of such conflicts of interest; the communication by that committee of the pertinent details of the information to the ethical review committee; and the transmission by that committee to the research subjects of the parts of the information that it decides should be passed on to them;
- Particularly in the case of an industrial sponsor, a contract stipulating who possesses the right to publish the results of the study, and a mandatory obligation to prepare with, and submit to, the principal investigators the draft of the text reporting the results;
- The arrangements for dealing with financial or other conflicts of interest that might affect the judgement of investigators or other research personnel: informing the institutional conflict-of-interest committee of such conflicts of interest; the communication by that committee of the pertinent details of the information to the ethical review committee; and the transmission by that committee to the research subjects of the parts of the information that it decides should be passed on to them;

Financial strategy

At the beginning of the research project, the funding strategy must be defined and described in detail.

NB : Information to include and reflect upon in this section:

- The source and amount of funding of the research: the organization that is sponsoring the research and a detailed account of the sponsor's financial commitments to the research institution, the investigators, the research subjects, and, when relevant, the community;
- A statement that any proven evidence of falsification of data will be dealt with in accordance with the policy of the sponsor to take appropriate action against such unacceptable procedures.

Personnel

- **Recruitment plan:** for the headquarters and the field, including deadlines and personnel to be recruited and when etc. (Reference document: ACF Recruitment procedure)

Logistics

- List any aspects tied to logistics: material and/or equipment required on site for the research (Reference document: Logistics procedure Kit Log v3).

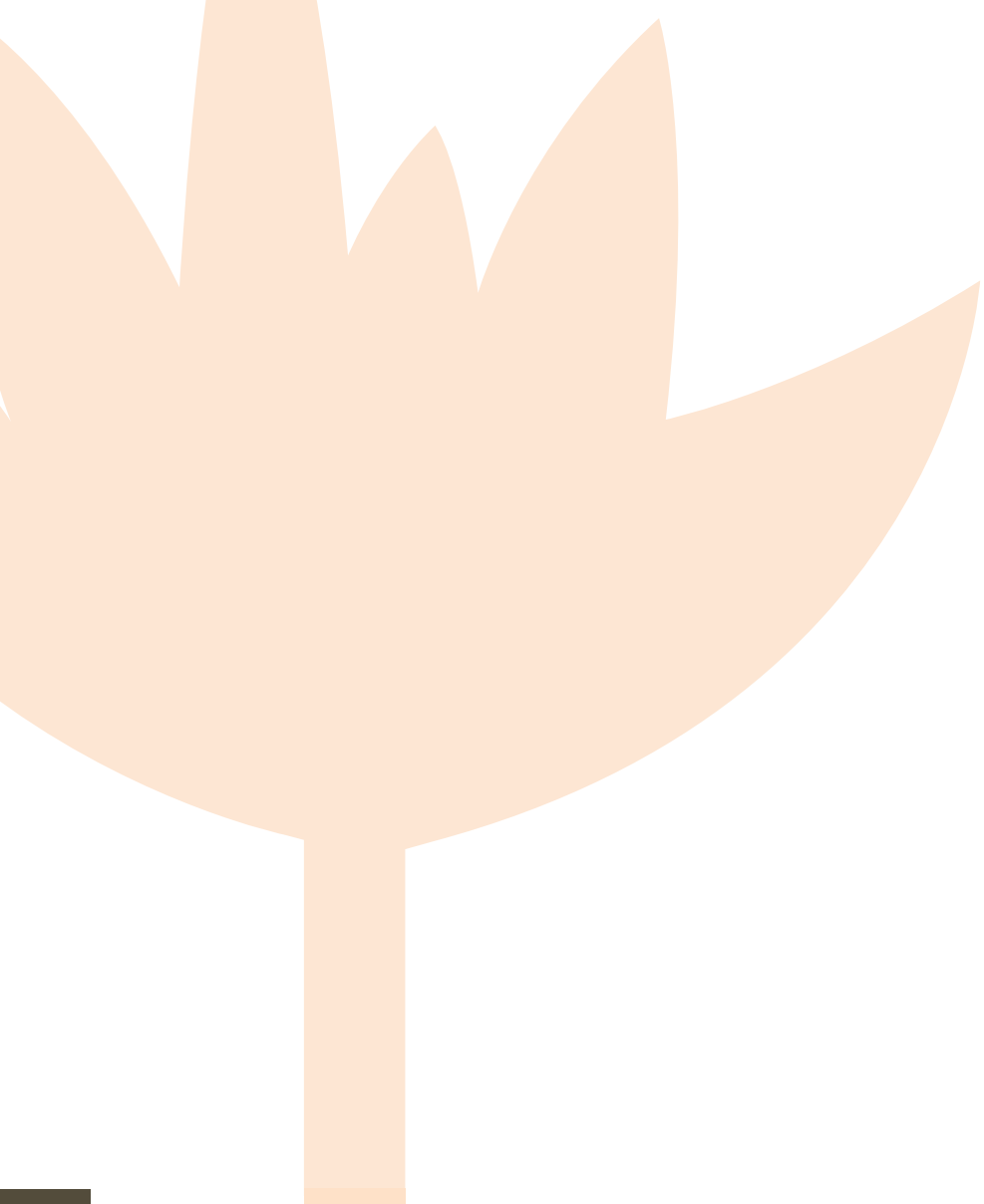


Work plan / gantt chart

Outline the time schedule for the completion of the study. It should include the **activities, outputs, deliverables, monitoring indicators and key meetings (e.g. Steering committee, etc...)**. See appendix 3.

Global list of the outputs & deliverables.

Please, indicate here the outputs of deliverables of the research project.



APPENDIX 1. Stakeholder and partnership analysis tools

Stakeholder analysis

Initial questions that can be asked are:
(source: Measure/DDRN)

- Who needs to use the data, and what questions are they seeking to answer?
- Who has influence and resources that can be brought to bear to aid this project?
- Who will be directly or indirectly affected by the outcome of this initiative?
- Who will support the plan? Who will oppose it? Why? How do we deal with it?
- What each of these individuals contribute to the process?

Stakeholders vs beneficiaries

Stakeholders are individuals or groups who can influence or will be affected by the project, negatively or positively. These can include target groups, beneficiaries, project partners and internal project management team members. For example, the ACF advocacy team is a stakeholder in ACF research projects.

Beneficiaries are those who benefit in whatever way, directly or indirectly, in the short or long-term, from the implementation of the project.



a. Stakeholder analysis matrix template

Stakeholder (name, organization, group – international, national, regional, or local?)	Expectations and how affected by the problem	Benefits from project	Available resources /capacity and motivation (staff, volunteers, money, technology, in- formation, influence...)	Brakes (Limitations: need funds to participate, lack of personnel, political or other barriers)	Engagement strategy (How will the stake- holder be engaged in the activity ?)	Follow-up strategy (plans for feedback or continued invol- vement)
INTERNAL						
EXTERNAL						

b. Partnership analysis matrix

Partnership (name, organization, group – international, national, regional, or local?)	Description (vocation, status, global strategy of the organism)	Justification of their involvement in the project	Engagement strategy	Available resources / capacity (staff, volunteer- rs, money, technology, information,...)	Follow-up strategy (plans for feedback or continued invol- vement)

APPENDIX 2. Global budget worksheet

[illegible]

APPENDIX 4. Bibliography

List the references cited in the research protocol, in alphabetical order

Annex 4 : Consent Form Model

Title of Project: xxx

Names of Researchers:xxx

1. I confirm that I have read and understood the information sheet dated xxx for the above study and have had opportunity to ask questions.

☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and that this will not affect my xxx rights in any way.

☐
3. I agree for data from this study to be used in reports, presentations or other publications of the organisation.

☐
4. I agree to take part in the above study.

☐

(Name of participant)

(Date)

(Signature)

(Researcher)

(Date)

(Signature)

1 for participant; 1 for researcher



Annex 5 : Participant Information Sheet Model

Title of Project:

Before you decide whether or not to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

Why have I been asked to take part?

We are asking you whether you would like to participate because you are...xxx It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time or a decision not to take part will not affect any aspect of...xxx All data collected from the study will be analysed by an independent researcher in ...xxx.

What is the purpose of the study?

The focus of this study is to ...xxx.

What will happen to me if I take part?

You will be asked to ...xxx...then to...xxx.

Are there any benefits or disadvantages to taking part?

There are no direct personal benefits from taking part, however we hope that the information from you and your peers can be used to develop...xxx. Also, there are no risks involved in this study since...xxx
If you have any concerns please contact...xxx.

Will my taking part in this study be kept confidential?

All information which is collected about you and your experiences during the course of the research will be kept strictly confidential. Apart from the consent form, your name and details will be removed from any other information you supply to us. The consent forms will be kept separately from the study data. The data will be securely stored for at least five years and will then be destroyed.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

What will happen to the results of the research study?

We anticipate that the findings of this study will be disseminated within the organisation and also outside of the organisation at international conferences and in international journals.

Who has reviewed the study?

XXX research ethics committee has reviewed the study. The study is funded by xxx.

Who can I contact if I have a complaint or question?

Complaints or questions should be addressed to...xxx



Annex 6.

STANDARD CLAUSES - MODEL

Intellectual Property Right – Publications (Partnership agreement)

Title to any Intellectual Property Rights, including Patent Rights, which could apply partly or wholly to the Research Results, shall vest jointly in ACF and XXX.

I. PUBLICATIONS

The Research Results cannot be given, sold or shared to any third party unless the other Party agrees in writing to it, and proper acknowledgement is guaranteed.

The Party who wants to publish the Research Results will furnish copies of any proposed publication to the other party at least thirty (30) days in advance of the date contemplated for submission for the proposed publication or public disclosure.

The latter Party may, upon receipt of such notification and delivery and at least fifteen (15) days prior to the planned submission, object by notice in writing to the former Party on the ground that the proposed publication contains an inadvertent disclosure of Confidential Information, in which case any such Confidential Information shall be deleted therefore before being published; or an information that is not correct, libelous or not acceptable to the other Party; in which case modification should be brought before being published.

Both Parties agree that any publication in a scientific or academic journal shall give due acknowledgement to the other Party in accordance with standard scientific practice.

II. EXPLOITATION OF INTELLECTUAL PROPERTY RIGHTS

As soon as a Party discovers or conceives any Intellectual Property Right, it shall provide a complete written disclosure to the other Party of this potentiality.

Each party shall possess an undivided one-half interest in such Joint Intellectual Property Rights, including Patent Rights.

However, considering the humanitarian scope of the Research Project, both Parties commit in advance to ensure a free access to the Research Results for the largest number of people and not to make any use of the jointly owned Intellectual Property Right that would prevent it.

Intellectual Property Right (Sub-contracting)

Both Parties agree that upon payment in full of the fees associated with the performance of the Services, title to any Intellectual Property Rights, including Patent Rights, which could apply partly or wholly to the Services, shall vest exclusively in ACF.

Confidentiality

In the performance of the Services under this Agreement, it may be necessary that the Contractor have access to certain confidential information (hereinafter called the "Confidential Information") in the possession of ACF.

Confidential Information means any written or oral information supplied by ACF which is designated as confidential or which, if transmitted orally, is reduced to writing, designated as confidential and so communicated to the Contractor, and also includes all documents prepared by the Contractor in the performance of this Agreement which incorporates such Confidential Information.

Confidential Information shall be held in confidence by the Contractor and shall not be disclosed to others without the prior written consent of ACF for a period of five (5) years from the date of this Agreement.

The provisions of this Article shall not apply to information within any of the following categories or any combination thereof:

- (a) Information which the Contractor can show was in its possession prior to receipt thereof from ACF,
- (b) Information received by the Contractor from a third party having no obligation of secrecy with respect thereto,
- (c) information which was in the public domain prior to the Contractor's receipt thereof from ACF or which subsequently becomes a part of the public domain by publication or otherwise except by the Contractor's wrongful act.

Ethics

The Contractor has read and accepts ACF ethical guidelines, attached as Annex XXX to this contract. The Contractor commits to respect these ethical guidelines while implementing the Research Project and further guarantees that all of its employees will comply with this obligation.



ANNEX 7 : ACF Research ethics guidelines

Corporate Evaluation Overview

VETTING PROCESS OF A POSSIBLE FOR-PROFIT COMPANY AS A SUB-CONTRACTOR

Recognizing the highly competitive environment for corporate charitable support, ACF's vetting process provides for the timely review of a proposed involvement of a for-profit company in a transparent, professional manner that upholds ACF's core values.

The vetting process of a for-profit company will lead us to group the prospective companies into one of three broad categories. The categories include:

A] INHERENTLY HARMFUL INDUSTRIES – STRICTLY FORBIDDEN

ACF will not accept funds from for profit companies whose principal activities are related to Weapons/Armaments, sex/pornography, or to the production, marketing, or distribution of Tobacco products.¹

B] INDUSTRIES REQUIRING MANDATORY REVIEW- FORMAL REVIEW

Though ACF welcomes support from a wide range of industries, including from many companies associated with the following businesses, a mandatory review by the Executive Committee of the HQ leading the research is triggered whenever a proposed gift comes from a company whose principal activities are related to one of the following industries:

- Alcoholic beverage
- Pharmaceuticals
- Natural resource extraction
- Food, Water & Agriculture
- Commodity Trading
- Gambling
- Nuclear energy

C] ALL OTHER INDUSTRIES – NO FORMAL REVIEW

Funding by companies whose principal activities do not fall into either of the two previous categories may be accepted without formal review by the Executive Committee of the HQ leading the research. Nonetheless, it is expected to apply the same standards detailed in the full review process. If for any reason there appears to be potential for conflict or controversy, the funding or sub-contracting may be reviewed by the Executive Committee of the HQ leading the research.

¹If a prospective donor corporation is part of a larger conglomerate with units classified as “Inherently Harmful,” but the prospective donor corporation does not otherwise fall into that precluded category, the proposed gift may be accepted—assuming it meets all other review criteria detailed in this policy.

Review standards

Ethics, brand and mission fit: Are the long-term effects of the company's products/business contrary to our goals of preventing malnutrition and hunger? Will a relationship with the company enhance or detract from the ACF brand? How well does the company's product line/services/core business fit with ACF core values and mission? How will the gift support our mission? What supplemental benefits might ACF derive from partnering with the company (e.g., engaging employees, exposure to client/customer base, leveraging in-kind products or services)?

Reputation: Are the company's practices potentially damaging to ACF's reputation or brand? Has the company been involved in significant controversies or major legal proceedings over the past two years? If so, what was the nature of the controversy/legal proceeding? What was the outcome? Is it relevant to the proposed partnership/gift? If the company operates where ACF runs programs, are there any particular concerns in these countries?

Resource impact: If the gift is other than an unrestricted gift of cash, will it present an operational burden to ACF? What is the potential cost/benefit? If the gift has restrictions or funds a special project, does it include adequate funding for indirect costs? Are the reporting and publicity requirements clear and reasonable?

Conflicts of interest: Are there any potential conflicts of interest with ACF board members, leadership, or senior staff? Are there strong links to political or religious organizations whose agendas are in conflict with ACF's mission and values? Would accepting funds or partnering with this company conflict with any of ACF's existing partners? Does the company comply with the World Health Assembly's International Code of Marketing of Breastmilk Substitutes?

1.

Does ACF have an existing relationship with the company?
If yes, please elaborate:

☐ yes ☐ no
2.

Did the company initiate the relationship with ACF?

☐ yes ☐ no
3.

Describe the proposed relationship, along with the markets/territories directly affected by the partnership.
4.

If the gift is restricted or otherwise designated for a special project, detail the implementation costs and indicate how much funding may be allocated to cover indirect costs.
5.

Are you aware of any controversial activity by the company?
If yes, please elaborate and attach any relevant supporting documents

☐ yes ☐ no
6.

Is the company part of a conglomerate engaged in the
Weapons/Armaments or Pornography industries?
If yes, provide evidence that the company does not engage in either of these industries:

☐ yes ☐ no
7.

List up to five charities, including individual ACF HQs, that accept donations from this company:



8. What public recognition, if any, does the company expect in recognition of their gift/involvement?
9. List any ACF board members, executive officers, or senior managers known to have a relationship with the prospective company that is or may be perceived of as a conflict of interest:

RECOMMENDATION

- ☐ accept gift without reservation ☐ accept if corporate partner mitigates reputational risk factors
- ☐ proceed with cultivation & reevaluate once gift details are finalized

AFFIRMATION & SIGNATURE

By signing this document, I affirm that to the best of my knowledge this prospective corporate partner does not pose a serious risk of damaging ACF's reputation, nor is the company engaged in practices that are in conflict with ACF's mission or core values.

signature name/title DATE



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