

**Science Council Commentary on the Report:
"Research Ethics and the CGIAR"**

Summary

The Science Council confirms the major finding of the Report that there is a need for the CGIAR at the System level to develop and adopt a uniform policy on ethical issues for the CGIAR. The guidelines and processes should follow international conventions. The Science Council believes that the development of such guidelines is a System-wide process, which should be led by the Alliance Executive/Alliance Board, in order to develop a common "Ethics codex". Guidance on the content of such guidelines, and models for the component parts, are provided in the Report and reviewed in this Commentary. The approach should also include recommendations for dealing with cases of serious misconduct. Subsequently, the specifics of implementation would be left to the Centers according to their particular needs and contexts, with due reference to host and partner country norms and requirements of funding agencies. The Science Council will subsequently review and endorse to ExCo the CGIAR Systemwide policy on Ethics developed by the Alliance.

A. Background

At SC2 in Rome, in September 2004, the Science Council received a report from Professor Peter Sandoe on "How should the CGIAR Handle Ethical Challenges? Issues and Proposal for a Strategic Study". The report made a recommendation for two further studies, the first to consider "Research Ethics and the CGIAR" and a second on "Ethics and the CGIAR Mission". The Science Council determined that it would be best to develop the studies consecutively, and so draft Terms of Reference for the study "*Research Ethics and the CGIAR*" were developed first, and these specified that the study should address the following topics:

1. The principles and guidelines of the System and the individual Centers, which should draw on extant international legal requirements and research ethics protocols in force at advanced research institutions (ARIs) around the world.
2. The extent to which Centers should adapt or extend prevailing Institutional Review Board approaches extant within ARIs.
3. Procedures for Institutional Review Boards at Centers, including guidelines for committee composition.
4. Consideration of whether System-wide level oversight is needed on matters of research ethics and, if so, how to operationalize such oversight.
5. Procedures and guidelines for identifying which research protocols need to undergo ethical review and which can be exempt.
6. Guidelines for when funding by or within the CGIAR should be awarded exclusively on a competitive basis.
7. System and Center policies and procedures for individual declarations of interest to prevent conflicts of interest in professional activities.
8. Whether the research ethics protocols of the Centers can or must be integrated with those of either local or national partners who might not have comparable protocols.
9. Plans and possibilities for research ethics training course(s) for CGIAR scientists.

A panel was formed under the chairmanship of Professor Sandoe. The report was presented to SC5 at WARDA in spring 2006 by Professor Sandoe who noted that Centers and the

System need to embrace ethics and ethical guidelines both because it is inherently correct to do so and because of the potential liability Centers face without them. The report covers participation and communication with stakeholders, dissemination, research on human subjects, research on animals, IPRs, Biodiversity, Biosafety and Risks, Good Scientific Practice, and Handling and Receiving Funding.

A final version of the report was delivered on the 30th of June 2006. The report lays out the principles for the ethical review of CGIAR Research and includes reference to existing CGIAR ethical guidelines and CGIAR policies regarding IPR, biodiversity and biosafety.

A further study on the subject of "*Ethics and the CGIAR Mission*" will be commissioned to address issues such as the trade offs in doing international public goods research, intergenerational benefits versus needs for short term impacts, and biodiversity.

B. Major recommendations of the Panel's report

The report's major recommendations include the following:

- That the CGIAR develop and adopt common policy/guidelines for the implementation of the ethical review of research projects in relation to how these fit the CGIAR mission and affect those involved in the research, as well as for dealing with scientific misconduct and conflicts of interests.
- That the CGIAR set up an institutional framework at system and/or Center levels to carry out the ethical review of research and to handle complaints about serious scientific misconduct.

A more detailed list of recommendations mentioned in the report is attached as Annex I to this Commentary.

C. General comments about the report

- The report presents an authoritative discussion of ethical issues and is based on state-of-the-art ethical principles and a number of internationally recognized conventions.
- The report's presentation and critique of current practices of ethical review of the CGIAR makes a compelling case for recommending guidelines and new structures and procedures. Despite some advances in particular Centers, the ethical review of CGIAR research processes is deficient in many instances. In particular, the ethical review of research involving human subjects and surveys or the use of data with personal identifiers should be implemented in all Centers conducting such research. Deficiencies in ethical review leave the CGIAR vulnerable to considerable liability and leave a gap that must be addressed as a System-wide issue.
- The report describes generally the process of ethical review in the CGIAR and makes recommendations for filling the considerable gaps. However, the report stops short of developing a full set of policies and guidelines to be adopted by the CGIAR. The authors feel that the Centers themselves need to be involved in defining and implementing the review process and that "an important part of the exercise lies ahead".

- The Science Council strongly endorses the *general* recommendations that guidelines and institutional structures for ethical reviews be developed as soon as possible.
- The Science Council agrees with the advice of the Panel in relation to Research on human subjects, Research on animals, IPR, Biosafety and Risks, Good scientific practice, Handling and receiving funding, and, Dissemination.
- The Science Council further agrees with the Report that CGIAR Guidelines should include clear ethical principles on Biodiversity and Participation and communication with stakeholders. Several of the Panel’s advisory statements on these subjects should be taken into account in the formulation of such guidelines. However, the Science Council recognizes that the development of guidelines will require a careful review of the implications and feasibility for implementation of each of the recommendations. Specifically, the Science Council demurs from three of the Report’s suggestions (identified below and in Annex 1), as it considers that their implementation, whilst desirable in principle, is beyond the CGIAR’s practical responsibility.

Specific considerations: The Science Council is pleased to endorse in principle the general advice provided by the report. It is important that the Alliance moves swiftly and thoughtfully to undertake the definition of guidelines and feasible implementation steps.

In the formulation of such guidelines, the Science Council only demurs from the advice in the Panel Report’s in three cases:

(i) In relation to Biosafety and Risks, the Report suggests that the CGIAR should:
“Engage in dialogue with expert organizations on equity, gender, conservation, sustainability, and nature protection issues with an aim to form partnerships and to integrate their concerns in research on genetic resources.”

The Science Council confirms the advantage of broad consultation in the formulation of research and policy on genetic resources. The Science Council notes the desirability of partnerships on specific issues and that balanced decision making in this area is required in line with the mandate and mission of the CGIAR, rather than the necessary integration of all contrasting view points.

(ii) In relation to Participation and Communication with Stakeholders, the Panel suggests that the CGIAR should:
“Develop policies for empowerment of local communities, particularly in the decision-making process”.

The Science Council notes that it is necessary for the CGIAR to provide information to stakeholders prior to, during and subsequent to research directly impinging on human subjects and communities. However, the generalized empowerment of local communities over and above those aspects accruing from research is beyond the remit of the CGIAR.

(iii) In relation to Participation and Communication with Stakeholders, the Panel also suggests that the CGIAR should:

“Strike a balance between pursuit of CGIAR objectives and local autonomy/empowerment”

The Science Council notes that the planning of CGIAR research should take into account the beneficial and potential adverse effects of its research on its immediate stakeholders and to share research-related knowledge, but that further influence over the empowerment of local communities is beyond the research remit of the CGIAR. Similarly, beyond pointing out any redistributive risks arising from the differential adoption of new technologies, the CGIAR cannot be held responsible for changes in local autonomy.

The Science Council stands ready to provide technical assistance, including through the continued discussion on the ethical roles and duties of the Centers and through the suggested implementation steps summarized in the study report and below.

D. System-wide implementation steps

- The Science Council agrees that there is a need for the CGIAR at the System level to develop/adopt a uniform policy on ethical issues for the CGIAR.

This might include issues related to:

- Transparency;
- Dealing with human research participants;
- Animal experiments;
- IPG-oriented IPR protection;
- Genetic resources in agriculture;
- Biosafety;
- Dialogue/partnership with expert organizations and stakeholders on relevant ethical issues;
- Good scientific practice (research protocols, data documentation/storage, interpretation, presentation, publication, dissemination); and
- Funding and dealing with conflicts of interest (disclosures and evaluation).

In some cases, it might be possible to consider and adopt existing documents with little change - such as ILRI's "Standard Operating Procedures for Animal Experimentation". In other cases, a more extensive review of internationally accepted guidelines might be necessary. (A list of such models and examples mentioned in the report are collected at the end of this Commentary as Annex II).

The Science Council believes that this is a System-wide process, which should be led by the Alliance Executive/Alliance Board (including Challenge Program Coordinators or Directors), in order to develop a common "Ethics codex". Subsequently, the specifics of implementation would be left to the Centers according to their particular needs and contexts. The Science Council will subsequently review and endorse to

ExCo the CGIAR Systemwide policy on Ethics developed by the Alliance.

- The Science Council suggests that there is also a need for guidelines for setting up an Ethics Committee in each Center. The Ethics Committee would possibly have the following tasks mentioned by the report:
 - Review, approve, oversee research projects from early stages and as necessary, with special focus on: long-term implications on other stakeholders; projects involving human subjects (clinical trials and surveys); and projects involving animal experiments.
 - Handle complaints about serious scientific misconduct
 - Oversee and evaluate possible conflict of interests
- The Science Council agrees that mechanisms for in-house training in ethics and research are needed. Guidelines are needed on who should be trained and certified. One suggestion is to use or develop on-line training material, with certification issued after passing a test.
- The report appears to call for a standing committee within the Science Council to be set up at System level to act as “a formal system to which complaints about serious scientific misconduct can be lodged for investigation and judgment”. While the need for mechanisms of review is clear, the Science Council is not the most appropriate existing body for this purpose. The Science Council notes that, normally, responsibility for staff issues is ultimately vested in the Boards of the Centers that employ them. The Science Council suggests that potential processes to meet the scientific and legal demand for review of cases of serious scientific misconduct be considered and proposed during the deliberations of the Alliance.

E. Steps at the level of Centers and Challenge Programs

- Each Center and Challenge Program would be responsible for participating in the development and approval of the Ethics Codex, as well as in its implementation at the Center or Challenge Program level.
- The Science Council suggests that **each Center/Challenge Program** would develop a detailed guideline on ethics and a framework through which the Ethics committee could conduct its work on ethical issues relating to research, including those mentioned in Section D, above.
- The Ethics committee could draw upon external expertise and/or set up sub-committees as necessary according to the nature of the research or question being addressed.

F. Next steps

- The Ethics Panel Report recommends that the Alliance takes the lead in developing the guidelines and the implementation plan and that these are approved by the Science Council. The Science Council endorses this recommendation and urges the Alliance to act on this recommendation without delay.

ANNEX I: Summary of detailed advice in the study “Research Ethics and the CGIAR”

This Annex provides, in summary form, the advice contained in the Panel’s report relating to ethical considerations in the conduct of CGIAR research. These are excerpts from the Study and are therefore the suggestions made by the authors of the Study. It should be noted that whilst the advice is largely endorsed by the Science Council, caveats are proposed in the Commentary of this text in relation to three aspects (marked with §). Thus each aspect of advice still requires careful consideration of how it should be implemented, and not all advice would necessarily lead to specific activities.

As a guide, this Annex to the Commentary further indicates the means (e.g. setting policies or establishing committees) that might be used for addressing the requirements and the level (Center or System) at which the policy or processes might be established. Suitable precedents and guidelines for the establishment of these processes are listed in Annex II.

(PO: policy; TR: transparency; CO: committee; ED: education)

(S: system-wide level; C: centre-level)

<i>Advice</i>	<i>Means</i>	<i>Level</i>
Research on Human Subjects		
<ul style="list-style-type: none"> Establishment of ethical committee or Institutional Review Board (ideally for each centre, or by establishing agreement with local committees) who will review and approve projects involving human subjects 	CO	C
<ul style="list-style-type: none"> Each institution conducting human subjects research should have a written, publicly available statement of its principles, policies and procedures for the protection of human research participants 	PO CO	S / C
<ul style="list-style-type: none"> Institutions should have a policy and a means to provide for education in the ethical conduct of human subjects research for all personnel who may be involved in such research 	PO ED	S / C
Research on Animals		
<ul style="list-style-type: none"> Animal experiments must be regulated by governmental authority set up for the purpose or within an Animal Care and Use Program 	PO	S / C
<ul style="list-style-type: none"> An Institutional Animal Care and Use Committee that reviews all proposed uses of animals and has the responsibility for oversight and evaluation 	CO	C
<ul style="list-style-type: none"> All members of the Institutional Animal Care and Use Committee, all researchers responsible for animal experimentation, and all staff directly involved in handling and care of the animals should receive proper education and training 	ED	C
<ul style="list-style-type: none"> At every facility where animal experimentation takes place there must be a veterinarian who has the authority to oversee key components of the Animal Care and Use program 	PO	C
IPR		
<ul style="list-style-type: none"> Ensure that intellectual property of research products is protected in order to pursue the IPG nature of research products, rather than for securing financial returns. 	PO	S / C

<ul style="list-style-type: none"> Actively negotiate with the private sector, universities, advanced research institutes, NARS, etc. to minimize any restrictions of third party IP for innovative technology associated with its mission. 	PO	S / C
Biodiversity		
<ul style="list-style-type: none"> Introduce measures to protect IPR in order to pursue the IPG nature of research products 	PO	S / C
<ul style="list-style-type: none"> Promote ready access to breeding materials for breeding and research activities, including GM varieties 	PO	C
<ul style="list-style-type: none"> § Engage in dialogue with expert organizations on equity, gender, conservation, sustainability, and nature protection issues with an aim to form partnerships and to integrate their concerns in research on genetic resources 	PO	S / C
Biosafety and Risks		
<ul style="list-style-type: none"> Handle any biosafety-related issues through dialogue with the relevant stakeholders, particularly when the balancing is needed between the concern for biosafety and the duty to benefit the poor 	PO	S / C
Good scientific practice		
<ul style="list-style-type: none"> State and enforce clear policies on good scientific practice by CGIAR formulating common policies on the presentation of research protocols, data documentation and data storage, and interpretation, presentation and publication of results. 	PO	S / C
<ul style="list-style-type: none"> Center staff to go through training courses on good scientific practice 	ED	C
<ul style="list-style-type: none"> Center supervisors to ensure that the norms of good scientific practice are known and adhered to by the entire staff 	ED	C
<ul style="list-style-type: none"> CGIAR to adopt the Vancouver rules as its standard for good scientific practice 	TR	C
<ul style="list-style-type: none"> Ensure that all members of the research team, including local and external scientists and non-research partners be appropriately credited. 	TR	C
<ul style="list-style-type: none"> CGIAR to have a formal system to which complaints about serious scientific misconduct can be lodged for investigation and judgment. 	CO	S
Handling and receiving funding		
<ul style="list-style-type: none"> Centers to maintain and enforce a written policy on conflict of interest, which establishes requirements for disclosures and evaluation. 	PO	S / C
<ul style="list-style-type: none"> Institutional review boards or ethics committees to evaluate conflict of interest 	CO	C
<ul style="list-style-type: none"> Ensure that collaborations with the private sector is done only if they complement and enhance a Center's ability to achieve its mandate (using guidelines developed by Future Harvest Centers) 	PO	S / C
<ul style="list-style-type: none"> Staff within the CGIAR system with conflict interests to voluntarily withdraw from decisions on funding 	PO	S / C
<ul style="list-style-type: none"> Preferably, allocate funding through open competition and review quality, i.e. through peer review. 	TR	S / C

<ul style="list-style-type: none"> • Maintain transparency about the conflict of interests and how the balance was struck. 	TR	S / C
Participation and Communication with Stakeholders		
<ul style="list-style-type: none"> • Ensure a clear link to the end-beneficiaries 	PO	S
<ul style="list-style-type: none"> • Transparency in how the research is directed 	TR	S / C
<ul style="list-style-type: none"> • Decide level of actual involvement of local stakeholders 	PO	C
<ul style="list-style-type: none"> • Seek procedures for involvement that balance the costs and the added value 	PO	C
<ul style="list-style-type: none"> • § Develop policies for empowerment of local communities, particularly in the decision-making process 	PO	S / C
<ul style="list-style-type: none"> • § Strike a balance between pursuit of CGIAR objectives and local autonomy/empowerment 	PO	C
<ul style="list-style-type: none"> • Research projects should be reviewed for their lifetime implications on other stakeholders, and the issues requiring dialogue with other stakeholders, at the early planning stage 	CO	C
<ul style="list-style-type: none"> • Normative and factual premises underlying advocacy of the use of certain technologies, or the pursuit of certain policies must be presented clearly 	TR	C
Dissemination		
<ul style="list-style-type: none"> • Dissemination of research results to the scientific community should follow internationally agreed principles and guidelines (Vancouver rules) 	TR	C
<ul style="list-style-type: none"> • Partnering directly with individuals who have more expertise in communication 	PO	S / C
<ul style="list-style-type: none"> • Develop content and modes of communication to maximize accessibility and comprehension for all stakeholders 	PO	C
<ul style="list-style-type: none"> • Consider development of public education tools that are not reliant solely on text 	PO	C

ANNEX II: Example of useful documents (includes both documents mentioned in the study “*Research Ethics and the CGIAR*” and additional recommended documents)

Focus on Poverty

- CGIAR Charter, November 2004

Participation and Communication with Stakeholders

- CGIAR Charter, November 2004
- Universal Declaration of Human Rights,
- UN Declaration on the Right to Development
- International Covenant on Civil and Political Rights
- Convention on the Elimination of All Forms of Discrimination Against Women
- African Charter for Popular Participation in Development
- CIAT Code of Ethics, 2005

Dissemination

- A Food Secure World for All: Toward a New Vision and Strategy for the CGIAR. TAC Secretariat, Food and Agricultural Organization of the United Nations, October 2002
- CIAT Code of Ethics, 2005
- Data Management Policy (Draft-1), ILRI
- Vancouver rules: Uniform Requirements for Manuscripts Submitted to Biomedical Journals <http://www.ICMJE.org>

Research on Human Subjects

- The Nuremberg Code
http://www.ushmm.org/research/doctors/Nuremberg_Code.htm
- The Declaration of Helsinki. <http://www.wma.net/e/policy/b3.htm>
- The Belmont Report <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- International Conference on Harmonisation *Guideline for Good Clinical Practice*
http://www.ich.org/MediaServer.jsr?@_ID=482&@_MODE=GLB
- Council for International Organizations of Medical Sciences *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002)
http://www.cioms.ch/frame_guidelines_nov_2002.htm
- Principles, Policies and Procedures for the Protection of Human research Subjects at the International Food Policy Research Institute. Assurance of Compliance with Federal Regulations for the Protection of Research Subjects. IFPRI 2003.
- Research Ethics, ICRAF Policy Guidelines Series, 2004.
- CIAT Code of Ethics, 2005
- Core International Human Rights Instruments are available at:
- <http://www.ohchr.org/english/law/>
- Office for Human Research Protections, US Department of Health and Human Services (2005) *International Compilation of Human Subject Research Protections*.
<http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>
- "Guide for Establishing Ethics Committees", Division of Ethics of Science and Technology of United Nations Educational, Scientific and Cultural Organization (2005). <http://unesdoc.unesco.org/images/0013/001393/139309e.pdf>

- Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects, Revised June 23, 2005. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- Health International, Research Ethics Training Curriculum for international scientists. <http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/index.htm>

Research on Animals

- Bayne, K & de Greeve, P: An Overview of Global Legislation, Regulation, and Policies on the Use of Animals for Scientific Research, Testing, or Education, in Hau, J & Van Hoosier, GL (eds.) *Handbook of Laboratory Animal Science, Second Edition: Essential Principles and Practices*, Vol. I, Chapter 2, pp 13-31, 2002: CRC Press LLC, USA.
- Animal Procedures Committee (2003). *Review of cost-benefit assessment in the use of animals in research*. Home Office, Communication Directorate: London. www.apc.gov.uk
- Standard Operating Procedures for Animal Experimentation, latest version by ILRI Institute Animal Care and Use Committee, 2004.
- Research Ethics, ICRAF Policy Guidelines Series, 2004.
- Russell, W.M.S. and Burch, R.L., *The Principles of Humane Experimental Technique*, London: Methuen, 1959.
- For more detailed descriptions of how to fill out the standards, reference should be made to one of the following guides:
- ARENA (Applied Research Ethics National Association) and OLAW (Office of Laboratory Animal Welfare), NIH (2002). *Institutional animal care and use committee guidebook*. Second edition. OLAW, NIH: Bethesda, MD. <ftp://ftp.grants.nih.gov/IACUC/GuideBook.pdf>
- Australian Government National Health and Medical Research Council (2004). *Australian code of practice for the care and use of animals in scientific procedures*. Australian Government. <http://www7.health.gov.au/nhmrc/publications/synopses/ea16syn.htm>
- New Zealand National Animal Ethics Advisory Committee (2002). *Good practice guide for the use of animals in research, testing and teaching*. MAF: Wellington. <http://www.biosecurity.govt.nz/animal-welfare/naeac/papers/guide-for-animals-use.pdf>

IPR

- Strategies for the CGIAR to Conduct Research and Deliver Technological Innovation that Benefit the Poor in a Context of Intellectual Property Rights., 2005.
- Policy of the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) on Intellectual property Rights (IPR). ILRI's Policy on Intellectual Property Rights, Biosafety and Bioethics, 2000. Assessment of Third Party Property related to the Challenge Program on Water and Food.
- ICRISAT *Guiding Principles on Management of Intellectual Property* Annex I, 2000. http://www.icrisat.org/ip_management/policy.htm

Biodiversity

- CGIAR's *Ethical Principles Relating to Genetic Resources*.
www.cgiar.org/corecollection/docs/sgrp_policy_booklet_2003.pdf
- *ICRISAT Guiding Principles on Management of Intellectual Property Annex I*, 2000.
http://www.icrisat.org/ip_management/policy.htm
- The FAO-CGIAR Agreement on Genetic Resources. The FAO International Undertaking of Plant Genetic Resources for Food and Agriculture.

Biosafety and Risks

- Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers
- CIAT Code of Ethics, 2005

Good scientific practice

- ICRAF: Scientific Fraud, Research Discussion Paper 1.
- CIAT Code of Ethics, 2005.
- Integrity and Misconduct in research: Report of the Commission on Research Integrity, <http://www.faseb.org/opar/cr.html>
- Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. <http://www.ICMJE.org>

Handing and receiving funding

- Policy on Partnerships in Research and Related Activities, ICLARM
- CIAT Code of Ethics, 2005.
- Alliance of Future Harvest Centers of the CGIAR: "Guidelines for center modes of collaboration with the private sector", May 2005, WorldFish Center, Penang, Malaysia

On setting up ethics committees (New Addition; not In Sandøe Panel Report)

- WHO (2000) Operational guidelines for ethics committees that review biomedical research. TDR/PRD/ETHICS/2000.1
<http://www.who.int/tdr/publications/publications/ethics.htm>
- WHO (2002) Surveying and evaluating ethical review practices. TDR/PRD/ETHICS/2002.1
<http://www.who.int/tdr/publications/publications/ethics2.htm>
- Report of a conference "Research Ethics Committees in Europe: facing the future together", Brussels, 27-28 January 2005
http://ec.europa.eu/research/conferences/2005/recs/index_en.htm
- UNESCO SHS (2006) Bioethics Committees at work: procedures and policies.
<http://www.unesco.org/ethics>
- World Commission on the Ethics of Scientific Knowledge and Technology (COMEST): Code of Conduct for Scientists (in process since 2004), UNESCO.
<http://www.unesco.org/shs/est>

Research Ethics and the CGIAR

Prepared by an independent panel consisting of **Linda Adair, Clarence Dias and Peter Sandøe** (chair)
with the assistance of Karsten Klint Jensen and Peter Gardiner

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Summary of Future Tasks for the CGIAR Concerning Research Ethics

The CGIAR has already issued statements and advice to Centers on Intellectual Property Rights and guidelines for the use of Genetic Resources. The Science Council has endorsed the recommendations from a study on biosafety. The Centers have developed guidelines for selected specific areas. The CIAT Code of Ethics covers a wide range of ethical issues.

The panel acknowledges these existing guidelines and advisory statements, which on their own terms appear very reasonable, balanced and thoughtful. However, the Alliance as a whole still has a long way to go in order to reach a common policy on research ethics which systematically covers all important areas. Hence, the most important task for the Alliance in the areas covered by the mentioned guidelines and advice is to clarify and systematize them and to complement them where necessary. Similarly, the individual Centers need to complement their guidelines and policies on research ethics related issues.

The panel thus recommends the following development of common guidelines for the Alliance to ensure that scientific research and research related activities are in accordance internationally recognized ethical standards:

- 1) Development of common guidelines for and implementation of ethical review of research projects within the CGIAR regarding relation of the research to the CGIAR mission. This involves:
 - a) Potential for contributing to the overall objective of the CGIAR (cf. section 1-2)
 - b) Potential links to implementation for end beneficiaries (cf. section 2)
 - c) Lifetime implications for stakeholders and plan for consultation, dialogue and involvement (cf. section 2)
 - d) Plan for dissemination (cf. section 3).
- 2) Development of common guidelines for and implementation of ethical review of research projects within the CGIAR on how the research affects other parties. This involves:
 - a) Research on human or animal subjects (cf. sections 4-5)
 - b) Biosafety issues and risk analysis (cf. section 8)
 - c) Participation of vulnerable groups (cf. section 8)
 - d) Bioethical issues (cf. section 8)
- 3) Development of common guidelines for and implementation of systems for dealing with scientific misconduct and conflicts of interest regarding funding (cf. sections 9-10).

The panel furthermore recommends the set up of the following set of frameworks:

- 4) Each Center should set up an institutional framework for ethical reviews. A possible framework would be a Standing Ethics Committee which has at least half of its members drawn from stakeholder bodies outside the Centre, and reports directly to the Centre Director General. Apart from the ethical reviews described in 1 and 2 above, a Standing Ethics Committee could also systematize and further develop advice and policies concerning
 - a) issues concerning IP (cf. section 6),
 - b) biodiversity (cf. section 7),
 - c) good scientific practice (cf. section 9),
 - d) funding (cf. section 10) and
 - e) other ethics related issues for the centre.

- 5) In case the research involves human or animal subjects (according to the definitions in sections 4-5), the research protocol has furthermore to be reviewed by an appropriate review board.
 - a) In case the Center conducts significant amounts of research on human subjects, it should have an Institutional Review Board like IFPRI; in other cases, it should find a suitable External Review Board.
 - b) Similarly, for research on animals: in the case the Center does a lot of research on animals, it should have an Institutional Animal Care and Use Committee, like ILRI; in other cases, it should find a suitable external committee.
- 6) The CGIAR should set up a framework for handling complaints about serious scientific misconduct (cf. section 9).

The panel finally suggests a process leading up to fulfilment of these recommendations along the following lines:

- A. This report is passed on to the Alliance with the following annexes:
 - a. Existing CGIAR guidelines
 - b. CGIAR policy statements regarding IPR, biodiversity and biosafety
- B. The Alliance works out guidelines and a plan for implementation
- C. The guidelines and plan are approved by the Science Council.

Introduction

The present document aims to carry through one of the proposals made in an earlier Science Council-commissioned report: “How should the CGIAR handle ethical challenges? - Issues and proposal for a strategic study”¹. That report proposed (pp. 19-21) that the CGIAR should launch two separate studies of ethical issues of relevance for the CGIAR, one about “Research Ethics and the CGIAR”, and another on “Ethics and the CGIAR Mission”. The reason for treating the ethical issues in two separate studies stems roughly from the ethical distinction between ultimate goals and the process leading to these goals.

The proposed study about the CGIAR mission is envisaged to be concerned with the challenges and possibly conflicting ethical considerations involved in the *ultimate goal* of the CGIAR mission – to achieve food security and reduce poverty in developing countries. The issues center on how to balance cost efficiency in achieving food security and reducing poverty against the need to help the very poor, how to balance concern for the people living now and in the near future against concern for future generations, how to protect parts of nature that are production resources but at the same time may possess intrinsic value and how to develop capabilities, political rights, self esteem and initiative among the least privileged groups.

The present study is concerned with ethical issues relating to the *process* involved in the CGIAR mission – scientific research and research-related activities. Roughly, these ethical issues can be divided into three different categories:

¹ “How should the CGIAR handle ethical challenges? - Issues and proposal for a strategic study”, prepared by Karsten Klint Jensen & Peter Sandøe for the SC of the CGIAR.

The *first* is about the implications of the CGIAR's overall objective for the way the research activities are conducted, i.e. the requirements of ensuring that the end beneficiaries of the research actually are benefited through dissemination of research results, through empowerment and through participation in relevant parts of the research process. Another implication is the requirement of ensuring a stable and transparent research process through dialogue and communication with the relevant stakeholders.

A *second* type of ethical issue is that relating to the parties affected by the research activities. These are, among others, human or animal research subjects, the environment and the general public. Important issues are concerned with ensuring that research results remain a public good and how to deal with intellectual property (IP) issues. Other important issues are biodiversity protection and biosafety.

The *third* types of issue relate to the ethical requirements internal to the conduct of research activities. These requirements include norms of good scientific practice and norms concerning the handling of funding.

Research ethics is important for the CGIAR not only because of the duty to act rightfully but also because misconduct – be it e.g. in the form of scientific fraud or of unrightful treatment of human or animal subjects – is very likely to attract negative attention internationally. Increasingly, donors and other stakeholder will expect that the CGIAR is able to document how it handles research ethical questions and conflicts.

The aim of the present document is to provide a review for the CGIAR on the ethical issues relating to the research process. Each section, except the first, is structured in three sub-sections. First, the background is presented, that is, a description of the issues of concern. Also, reference is made to relevant documents, comprising a review of CGIAR documents relating to the issues and reference to relevant international guidelines where they exist. Next, the fundamental values and principles are outlined, and potentially conflicting considerations are discussed. Then some more specific advice is derived from these principles. In some cases, the advice is to further develop existing CGIAR policies; in other cases, the advice is to adopt widely recognised international standards. Finally, in some cases, the advice is to develop new policies or structures, either individually as Centers or jointly. The report concludes in a summary (placed at the beginning) on recommendations and future tasks for the CGIAR concerning research ethics; particularly, an overview of the recommendations about ethical review of research projects is provided.

The purpose of this review therefore is to sharpen the CGIAR's attention to ethical considerations. The panel hopes to inspire Centers to develop more specific policies, either individually or jointly. The panel has not seen it as its task to develop a full set of policies and guidelines to be adopted by Alliance and the Centers. Guidelines should express the ethical views actually held within the Alliance. Hence, it is the conviction of the panel members that detailed ethical guidelines only makes sense if they are worked through and stated by the Alliance or the Centers themselves. Hence, an important part of the exercise still lies ahead for the Alliance and the Centers.

A. IMPLICATIONS OF THE CGIAR'S OVERALL MISSION

1. The Focus on Poverty

*The mission of the CGIAR is to achieve sustainable food security and reduce poverty in developing countries through scientific research and research-related activities in the fields of agriculture, livestock, forestry, fisheries, policy and natural resources management.*²

Values and Principles

The most fundamental requirement is that the research is constructed to meet the avowed CGIAR goals in as efficient a way as possible. In other words, the research of the CGIAR should be relevant for the objective of achieving sustainable food security and reducing poverty in developing countries. Clearly, this requirement has a number of implications for the research process. Most importantly, there is a need to choose research topics of relevance for achieving the overall objective. This raises many questions of how to understand the objective in operational detail. For instance, how should poverty be defined and how should the poor be identified? How precisely is research in the fields of agriculture, livestock, forestry, fisheries, policy and natural resources management most effective in ensuring sustainable food security and reducing poverty for the poorest? However, we believe that these questions about the content of the research are so closely related to the ethics of the mission itself that we want to leave them for the second study. In the remaining part of the first section, we shall deal with other more formal requirements of the research process that derive from the overall objective of the CGIAR.

2. Participation and Communication with Stakeholders

Background

The CGIAR charter defines *stakeholders* as “the broadest possible group of individuals and organizations that have a stake in agricultural research for development”.³ We should like to stress that, from an ethical point of view, stakeholders should be understood as the groups of individuals or organizations who affect, and/or are affected by CGIAR research and related activities. A rough outline of stakeholders includes members, partners and challenge program participants, donor organizations and donor countries, the end beneficiaries, local governments and local communities, national and international NGOs, national and international scientific communities within the fields of agriculture and development, private national and international enterprises or corporations, and national and international press.

In pursuing the objective of reducing poverty, hunger and malnutrition, the CGIAR Centers inevitably will be involved with controversial issues. One example could be research in, or even advocacy of using technologies, such as GM crops, that are perceived as controversial by some constituencies. Another example could be advocacy of policies with effects on traditional ways of life, such as local power relations or gender relations. In such cases, dialogue with local or international stakeholders on the choice of research areas or development of policies derived from the overall objective of the CGIAR system might be mutually beneficial.

In principle, all affected parties have a moral right of participation in the decision-making process. In this broad sense, ‘participation’ means having one’s interests considered. In some cases, there is a legal right of participation in a more formal sense as a right of being heard, or even a right to participate in meetings where decisions are made. In most cases, it is prudent to involve the affected parties in the decision-making process, because it increases the chance of decisions being robust and sustainable. However, it should be acknowledged that it is time-consuming and financially costly to involve others in the decision-making, and it could lead the decisions to vary from the overall objective of the research or impair efficiency. The

² CGIAR Charter, November 2004

³ CGIAR Charter, November 2004, p. iv.

problem is therefore: who should be involved, what should they be involved in, and how should they be involved?⁴

The CIAT Code of Ethics contains guidelines on public communication.⁵ It also has guidelines on research planning, implementation and dissemination. In planning and implementing research, it says, the ethical acceptability of the research should be reviewed according to the Code.

Principles

The general principle is that pursuit of the overall beneficial objective of the CGIAR should be constrained by choice of ethically acceptable means. Most important here is respect for the interests of the persons affected by the choice of means. This implies that the affected parties have the opportunity to give their consent to the means chosen in pursuit of the overall objective. Hence, there is a general duty to engage in open dialogue with the relevant stakeholders.

The main objective of the CGIAR Centers is to produce research results that will benefit the poor by reducing poverty, hunger and malnutrition sustainably, i.e., without increasing the risks that future generations will face poverty, hunger and malnutrition. Most important in relation to this goal are the potential beneficiaries. Firstly, there is the moral right of beneficiaries to participate effectively in decisions which affect their lives. The primary duty of the CGIAR is to benefit the poor through research; however, a secondary duty is to respect and possibly strengthen local autonomy through the implementation of research. The poor should, as far as possible, decide for themselves how their problems are to be solved. Secondly, involvement of the beneficiaries is clearly instrumental to achieve sustainable results of the research in relation to the goal of reducing poverty, hunger and malnutrition. A necessary condition for the research results to be effective is that the beneficiaries actually find such results relevant and useful and are willing to expend social energy in their implementation. Their interests should be taken into account throughout the agenda-setting, the decision-making processes and dissemination of knowledge.

Advice

From the initial planning phase, to the dissemination of research findings and implementation of practices informed by research results, there is a duty to make sure that there is a clear link to the end-beneficiaries and their needs and wants. Early in the planning phase, it should be transparent how the research is directed towards the goal of contributing to the reduction of poverty, hunger and malnutrition in one way or another. Reasonable scenarios for the implementation of the results should be considered so as to maintain the link to the beneficiaries. Deciding the level of actual involvement, e.g. by local beneficiaries or relevant NGOs, is a matter of balancing the duty to respect the right to participation, and the potential benefits of doing so, against the duty to respect the integrity of science and not to make decision-making unduly time consuming or financially costly. It is the responsibility of the centre management to strike this balance in a fair way. The guiding principles should be to ensure that involvement takes place where it adds important value – as compared with considering the affected parties' interest; and furthermore, to seek out procedures for involvement that keep the costs of involvement in reasonable proportion to the added value.

⁴ Relevant documents on participation include: The Universal Declaration of Human Rights, UN Declaration on the Right to Development, the International Covenant on Civil and Political Rights, the Convention on the Elimination of All Forms of Discrimination Against Women, and the African Charter for Popular Participation in Development

⁵ CIAT Code of Ethics, 2005.

Locally, it will be necessary to involve the beneficiaries in the decision making process. Local communities should be educated to ensure the necessary understanding of a policy and its implications. The Centers should develop policies for empowerment of local communities to ensure that every contact with local communities is governed by a thoroughly considered plan for how to respect and strengthen the beneficiaries' autonomy.

In some cases, there will be conflict between pursuing the beneficial objective of the CGIAR most efficiently in the short term and perhaps costly and time-consuming procedures of respecting autonomy or setting up education schemes in order to ensure effective dissemination. In these cases, a reasonable balance has to be found. However, in striking this balance, the long term effects of autonomy and empowerment are likely to be helpful in relation to achieving the overall goal, and this should be taken into account.

Very early in the planning stages, research projects should be reviewed for their lifetime implications on other stakeholders, and the issues requiring dialogue with other stakeholders should be identified. Each CGIAR Center needs to develop policies for running an open dialogue with relevant stakeholders during the lifetime of a research project. This implies setting up routines for identifying relevant stakeholders, locally, as well as internationally. It also implies developing ways and channels to engage in dialogue with different types of relevant stakeholders.

In advocating the use of certain technologies, or the pursuit of certain policies, the Centers should always be transparent. This means that the normative and factual premises underlying the advocacy should be presented for all relevant stakeholders in a clear way. Particularly, the relation to the overall beneficial objective of reducing poverty, hunger and malnutrition should be apparent. In case some technology or policy advocated for by a centre involves heavy burdens on some group, there is a duty to ensure that this burden is distributed and shared in an equitable way.

3. Dissemination

Background

It follows clearly from the CGIAR's overall mission that research results, in order to be efficient, should be effectively disseminated to the potential end beneficiaries. Moreover, one of the seven planks that define the vision and strategy of the CGIAR, is that the CGIAR should strengthen its role as a "catalyst, integrator, and disseminator of knowledge within the overall global agricultural research system".⁶ Attainment of these goals requires effective communication of research results to a wide range of audiences.

ILRI has developed a data management policy⁷ with the purpose of archiving data in a form so they can be shared with other research groups and collaborating partners and be made available for integrated studies, long term studies, different sorts of publications, and for the scientific community and the general public. This could serve as a model for other CGIAR Centers. Also, the CIAT Code of Ethics contains guidelines on data sharing, on confidentiality and on dissemination.⁸

⁶ A Food Secure World for All: Toward a New Vision and Strategy for the CGIAR. TAC Secretariat, Food and Agricultural Organization of the United Nations, October 2002

⁷ Data Management Policy (Draft-1), ILRI.

⁸ CIAT Code of Ethics, 2005.

Principles

As members of an organization with the goal of producing publically available research within the fields of agriculture, livestock, forestry, fisheries, policy and natural resources management, the CGIAR Centers have a duty to disclose all findings that might benefit the poor by reducing poverty, hunger and malnutrition, in a manner that reflects honesty and transparency in research goals and findings. The dissemination of knowledge should focus on, and be tailored to the following audiences, under the principle that all have the right to know:

1. *The scientific community.* Research results and technical information should be communicated through scholarly, peer reviewed publication in order to provide an evidence-base for actions and policies, and a foundation for further research within the Center and by other scientists. Peer reviewed publication also serves as a basis for projected impact assessments, and as a source for evaluation and accountability of center activities. Collaboration in the preparation of research papers for publication is also important for building local research capacity.

In addition, with adequate protection of privacy and confidentiality, data and documentation should be shared in a timely manner so that it is available for other researchers and the general public.

2. *Governments, private enterprises and NGOs.* These are the groups most likely to be able to act on research findings and thereby contribute to the goals of alleviating poverty and malnutrition in developing country contexts. While scholarly publications can be used for this purpose, a deliberate attempt to translate research findings into a more accessible format such as policy briefs and reports, is likely to be more effective.

3. *Potential beneficiaries of the research,* which may include communities and individuals. Local organizations, communities, and individuals need information to inform practices that may lead to outcomes such as improved agricultural or economic productivity. Hence, there should be a focus on translation of scientific information into practical messages and communication in multiple modalities.

Advice

Dissemination of research results to the scientific community should follow the principles (though not necessarily the details for manuscript preparation, formatting, and submission) articulated in the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*,⁹ also known as the "Vancouver Rules", see Section 9. Decisions about when to disseminate information should balance urgency with careful evaluation of the scientific evidence.

Though peer-reviewed publication is necessary, it is not sufficient for achieving the CGIAR's goal. The translation of scientific results and their communication to policy makers and the public is a responsibility as well as an important challenge. Researchers should consider partnering directly with individuals who have more expertise in communication with these groups. Special efforts should be made to develop content and modes of communication to maximize accessibility and comprehension for all stakeholders. Consideration should be given to the development of public education tools that are not reliant solely on text.

⁹ Uniform Requirements for Manuscripts Submitted to Biomedical Journals <http://www.ICMJE.org>

B. PARTIES AFFECTED BY THE RESEARCH ACTIVITIES

4. Research on human subjects

Background

The Nuremberg trials at the end of World War II brought to light the horrors of experimentation on prisoners conducted by Nazi doctors and scientists, and identified an urgent need for standards to guide the ethical conduct of research involving human subjects. The *Nuremberg Code*¹⁰ established a legal standard for such research. In 1964, the World Medical Association reinterpreted and expanded the Code to include medical research with a therapeutic intent. This new code of research ethics came to be known as the *Declaration of Helsinki*.¹¹ In the United States, the National Research Act of 1974 established a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which, in the *Belmont Report*,¹² articulated basic ethical principles and guidelines for the ethical conduct of research with human subjects. Federal regulations were implemented in the US to insure the protection of human subjects of biomedical and behavioral research. Similar national statutes guide the conduct of human subjects research in other countries, but not all countries have appropriate statutes.

Several organizations have addressed the need for international guidelines. Representatives from regulatory agencies and industry associations of the United States, Japan and Europe formed the International Conference on Harmonisation (ICH), to standardize the process by which new drugs are developed, tested and brought to market. Their *Guideline for Good Clinical Practice*¹³ establishes an “international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human subjects.” Many pharmaceutical companies have voluntarily adopted these guidelines as the standard for conducting clinical trials. The Council for International Organizations of Medical Sciences (CIOMS), a non-government organization officially related to the World Health Organization and UNESCO has focused on the application of guidelines in developing countries. They have published *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.¹⁴

The CIOMS guidelines identify a challenge of particular importance to the CGIAR. This is to “apply universal ethical principles ... in a multicultural world”. The guidelines take the position that human subject research must not violate any universally applicable ethical standards, but that the application of principles needs to take account of cultural values while respecting the absolute ethical principles. The guidelines emphasize the need for research conducted in developing countries to take account of factors which make the country or specific communities especially vulnerable to harm or exploitation from external scientific research. These include economic disparity, authoritative or corrupt political systems, lack of protection of human rights, lack of individual autonomy and lack of infrastructure for scientific/ethical review. Those who are involved in international research should therefore have some understanding of and sensitivity to the social, economic, and political milieu that frames the context in which their research is taking place.

¹⁰ The Nuremberg Code http://www.ushmm.org/research/doctors/Nuremberg_Code.htm

¹¹ The Declaration of Helsinki. <http://www.wma.net/e/policy/b3.htm>

¹² The Belmont Report <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

¹³ International Conference on Harmonisation *Guideline for Good Clinical Practice*
http://www.ich.org/MediaServer.jserv?@_ID=482&@_MODE=GLB

¹⁴ Council for International Organizations of Medical Sciences *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002) http://www.cioms.ch/frame_guidelines_nov_2002.htm

IFPRI has a document on the protection of human research subjects.¹⁵ The document states that the institute is guided by the ethical principles set forth in the Belmont Report. It is part of the institutional policy to have an Institutional Review Board. ICRAF has made policy guidelines on research ethics.¹⁶ Also these refer to the Belmont Report; however, they do not go into detail about ethical review of research. Also, the CIAT Code of Ethics¹⁷ contains guidelines for informed consent in research. Though the importance of an Institutional review Board or a similar body is mentioned, the guidelines does not set up standards for such a Board.

The present document presents standards that can provide for equivalent protections, while respecting local differences.

Definitions: A working definition of human subjects research is needed to enable organizations to make judgments about activities to which the guidelines may apply. According to the Belmont Report, *research* is an “activity designed to test an hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge (expressed, for example in theories, principles and statements of relationships).” Research is described in a formal protocol that sets out objectives and procedures. *Human subjects* are living individuals about whom an investigator obtains data through intervention or interaction with the individual, or identifiable private information.

In ordinary circumstances, the CGIAR is not involved in clinical research on patients. A typical kind of research that involves human subjects would be nutritional trials of biofortified staples produced by either conventional breeding or genetic engineering. Any negative impacts on health resulting from such trials would constitute a violation of that person’s right to health under the Universal Declaration on Human Rights and the International Covenant on Economic, Social and Cultural Rights. Another typical kind of research would be social science research with questionnaires involving identifiable private information.

Principles

All research involving the participation of human subjects should be guided by the following ethical principles:

Respect for persons: This requires an acknowledgment of autonomy, or the individual’s freedom to choose whether or not to take part in research, in the absence of coercion. Respect for the human person mandates informed consent, a process for ensuring voluntary participation in research after being fully informed and comprehending all procedures, risks, and benefits. Respect for the human person also demands protection of individuals with diminished autonomy and for individuals who are cognitively, or otherwise impaired.

Beneficence: Research should maximize benefits and minimize harm to participants.

¹⁵ Principles, Policies and Procedures for the Protection of Human research Subjects at the International Food Policy Research Institute. Assurance of Compliance with Federal Regulations for the Protection of Reseach Subjects. IFPRI 2003.

¹⁶ Research Ethics, ICRAF Policy Guidelines Series, 2004.

¹⁷ CIAT Code of Ethics, 2005.

Justice: There should be equal sharing of the burdens and the benefits of research. The principle of justice has important implications for the selection of research subjects, with special care taken to avoid the exploitation of poor communities.

Advice

Standards

- 1) *All research involving human subjects should be reviewed by a properly constituted ethical committee or Institutional Review Board and be approved by the committee before the research begins.*
 - a) The IRB/ethics committee should be comprised of a diverse group of individuals who possess expertise which allows them to understand the scientific merit as well as the ethical issues surrounding the research questions being addressed. Committee members should be familiar with the customs and traditions of the community in which the research is carried out. The committee members should be free from conflicts of interest, being independent of the investigator, the sponsor or any other undue influence. The committee should be in conformity with international law¹⁸, and the laws of the country in which it is operating.

*An International Compilation of Human Subject Research Protections*¹⁹ developed by the Office for Human Research Protections of the US Department of Health and Human Services identifies country-specific sources of information about laws, regulations, or guidelines pertaining to human subjects research.
 - b) The IRB/ethics committee should conduct careful reviews of all protocols for human subjects research to determine that:
 - risks to participants are minimized and are reasonable in relation to benefits
 - there are adequate provisions for obtaining the informed consent of each individual research participant
 - participation is voluntary and free from coercion
 - there are adequate protections to maintain participants' privacy and the confidentiality of information they provide
 - there are adequate protections for vulnerable individuals and populations (children, pregnant women, cognitively or otherwise impaired individuals, prisoners, members of disadvantaged communities)
 - there is an equitable distribution of burdens and benefits of research.
 - c) Whenever possible, the IRB/ethics committee should be local to the research so that the views of persons knowledgeable about the prevailing community culture and norms can be taken into account. Ideally, each CGIAR constituent organization would have its own IRB/ethics committee or would establish an agreement with a local university or government committee. The committee should have expertise related to the range of research represented by the activities of the organization, be it clinical trials, or community based behavioral research.

¹⁸ Core International Human Rights Instruments are available at:

<http://www.ohchr.org/english/law/>

¹⁹ Office for Human Research Protections, US Department of Health and Human Services (2005) **International Compilation of Human Subject Research Protections**
<http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>

- d) For organizations wishing to develop their own committees, the Division of Ethics of Science and Technology of United Nations Educational, Scientific and Cultural Organization (UNESCO) has published a *Guide for Establishing Ethics Committees*²⁰.
- 2) *Research should be conducted with a high level of vigilance and high standards of institutional accountability.* Each institution conducting human subjects research should have a written, publicly available statement of its principles, policies and procedures for the protection of human research participants. Whenever research is conducted in collaboration with, or funded by a sponsor external to the performance site, the research should adhere to local laws as well as the procedures mandated by the sponsor's country. Investigators from institutions outside of the country where research takes place must respect the ethical standards of their own countries and the cultural expectations of the societies in which studies are undertaken, unless this violates basic ethical principles. For example, research conducted in collaboration with, or funded by, the US must conform to 45 CFR 46, the Code of Federal Regulations²¹ that governs federally funded human subjects research.
- 3) *Institutions should have a policy and a means to provide for education in the ethical conduct of human subjects research for all personnel who may be involved in such research.* Educational resources in several different languages are available. For example, many international organizations make reference to Family Health International's Research Ethics Training Curriculum for international scientists.^{22 23}

It should be noted that very poor people are particularly vulnerable and therefore require stronger protection. It is important to be aware of cases where there is doubt about whether consent is fully informed, e.g. due to illiteracy, or whether it is fully voluntary, e.g. because compensation for participation may imply that there is no free choice. In such cases, guardians should be appointed.

5. Research on Animals

Background

Contemporary research in the life sciences involves experimentation on live animals. This research is considered an important tool in the progress of science. Within the CGIAR system and affiliated institutions animal experimentation is primarily used in studies relating to human nutrition, in studies concerning biosafety of products and in studies relating to livestock production and health.

However, dating back to the nineteenth century the use of live animals for experimentation has given rise to controversies relating to an underlying ethical problem: Animals are used as tools with the aim of protecting humans against illness or to improve their wealth or quality of life. In the process animals may in various ways be harmed. Thus it seems that we allow animals to be harmed with the aim of making life

²⁰ "Guide for Establishing Ethics Committees", Division of Ethics of Science and Technology of United Nations Educational, Scientific and Cultural Organization (2005).

<http://unesdoc.unesco.org/images/0013/001393/139309e.pdf>

²¹ Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects, Revised June 23, 2005. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

²² Versions are currently available in English, French, Spanish, and Portuguese
<http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/index.htm>.

²³ Web addresses and documents are cited as these are most easily accessed. In many cases, the cited documents are publicly available on many websites such as the CODEX Rules and Guidelines for Research http://www.codex.vr.se/codex_eng/codex/ and the US Office for Human Research Protections <http://www.hhs.gov/ohrp/>

better for humans. Even though the end may be good, it may be debated from an ethical point of view whether the end justifies the means.

In Europe, Northern America and Australasia the problem has been dealt with in the following way: Animal use is accepted, provided that care is taken to consider alternative means of achieving the same result, that care is taken to keep the animals under good conditions, and that great effort is put into designing experiments so that results can be achieved with no or a minimum of suffering for the animals. A parallel reason speaking in favour of good animal care is that lack of care leads to unreliable research results.

There are significant differences in legislation, regulations and policies across the continents. In Europe there is a system with binding rules enforced by governments, whereas in the US there is a more flexible system based on the idea of local Animal Care and Use Program that should be complied with by every individual and institution involved in animal experimentation.²⁴

ILRI has an Institute Animal Care and Use Committee. The panel is not aware of the guidelines set up for this committee; however, the committee has produced a detailed manual for Standard Operating Procedures for Animal Experimentation²⁵ to ensure animal welfare. The ICRAF guidelines on research Ethics²⁶ refer to the standards and practices developed by ILRI to be used when research has animal welfare implications.

Principles

Animals should be respected as sentient beings. Animal experimentation is only acceptable when substantial human benefits are at stake and animal suffering is minimised. The three Rs proposed by Russell and Burch²⁷ – the replacement of existing experiments with animal-free alternatives, or reductions in the number of animals used, or refined methods that cause animals less suffering – should guide animal researchers to ensure that animal suffering is minimised.

Advice

Whenever animal experiments are conducted at CGIAR institutions or at other institutions financed by CGIAR funds, they must be regulated by governmental authority set up for the purpose or within an Animal Care and Use Program in accordance with the following standards.

Standards

An Animal Care and Use Program must cover at least the following elements:²⁸

²⁴ Relevant documents:

Bayne, K & deGreeve, P: An Overview of Global Legislation, Regulation, and Policies on the Use of Animals for Scientific Research, Testing, or Education, in Hau, J & Van Hoosier, GL (eds.) *Handbook of Laboratory Animal Science, Second Edition: Essential Principles and Practices*, Vol. I, Chapter 2, pp 13-31, 2002: CRC Press LLC, USA.

Animal Procedures Committee (2003). *Review of cost-benefit assessment in the use of animals in research*. Home Office, Communication Directorate: London. www.apc.gov.uk

²⁵ Standard Operating Procedures for Animal Experimentation, latest version by ILRI Institute Animal Care and Use Committee, 2004.

²⁶ Research Ethics, ICRAF Policy Guidelines Series, 2004.

²⁷ Russell, W.M.S. and Burch, R.L., *The Principles of Humane Experimental Technique*, London: Methuen, 1959.

²⁸ For more detailed descriptions of how to fill out the standards, reference should be made to one of the following guides:

An Institutional Animal Care and Use Committee. This committee should review all proposed uses of animals and has the responsibility for oversight and evaluation of the entire animal care and use program and facilities. The committee should consist of a minimum of five members. Of these at least one should be Doctor of Veterinary Medicine, at least one should be a practicing animal-research scientist, at least one should be a non-scientist; and at least one should not be affiliated with the institution in question. The committee should receive administrative support and should refer directly to the top management of the institute.

Education. All members of the Institutional Animal Care and Use Committee, all researchers responsible for animal experimentation, and all staff directly involved in handling and care of the animals should receive proper education and training. This should ensure that those responsible for animal experimentation are up to date with developments in experimental methodology, bearing in mind particularly the design of alternative methods. Those responsible for the housing and daily care of laboratory animals will ideally be equipped with a thorough understanding of the behavioural and physiological needs of the relevant animal species and know how to implement various form of environmental enrichment.

Adequate veterinary care. At every facility where animal experimentation takes place there must be a veterinarian who has the authority to oversee key components of the Animal Care and Use program.

6. Intellectual Property Rights

Background

The CGIAR mission demands that the Centers can operate freely and can produce research results as international public goods. However, the situation is becoming difficult as a result of new national IPR regimes, rising local private sector investment in developing countries, and increases in the export of agricultural products based on proprietary science. The increasing importance of intellectual property rights (IPR) and proprietary science is leading to greater investment by the private sector in agricultural research (especially in the applications of modern biotechnology), but also to the commercialisation of the processes and the commodification of the products of such research

Given the importance of IPR, it is not surprising that the CGIAR has developed detailed guiding principles. There has also been a study on IPR strategies.²⁹ In addition, several centers have made statements.³⁰ However, there are several versions of the CGIAR guidelines. The most complete version seems to be the

ARENA (Applied Research Ethics National Association) and OLAW (Office of Laboratory Animal Welfare), NIH (2002).

Institutional animal care and use committee guidebook. Second edition. OLAW, NIH: Bethesda, MD.

<ftp://ftp.grants.nih.gov/IACUC/GuideBook.pdf>

Australian Government National Health and Medical Research Council (2004). *Australian code of practice for the care and use of animals in scientific procedures.* Australian Government. <http://www7.health.gov.au/nhmrc/publications/synopses/ea16syn.htm>

New Zealand National Animal Ethics Advisory Committee (2002). *Good practice guide for the use of animals in research, testing and teaching.* MAF: Wellington. <http://www.biosecurity.govt.nz/animal-welfare/naeac/papers/guide-for-animals-use.pdf>

²⁹ Strategies for the CGIAR to Conduct Research and Deliver Technological Innovation that Benefit the Poor in a Context of Intellectual Property Rights., 2005.

³⁰ Policy of the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) on Intellectual property Rights (IPR). ILRI's Policy on Intellectual Property Rights, Biosafety and Bioethics, 2000. Assessment of Third Party Property related to the Challenge Program on Water and Food.

one quoted as an annex in the ICRISAT statement.³¹ The present panel confirms its support to the policy inherent in these guidelines. We shall quote some of the underlying values.

Principles

“The management of intellectual property by Centers will be guided by the CGIAR mission to contribute to food security and poverty eradication in developing countries through research, partnerships, capacity building and policy support. The Centers will manage intellectual property issues with integrity, equity, responsibility and accountability.”

Advice

- *The CGIAR does not view the protection of intellectual property as a mechanism for securing financial returns upon which it may depend. To the extent that such returns are generated, they will be used in support of specific tasks and projects fully compatible with the CGIAR mission and objectives.*
- *The CGIAR promotes ready access to breeding material for breeding and research activities. Subject to the paragraph below, the CGIAR regards any information, inventions, processes, biological material or other research products funded or developed by the CGIAR or the Centers (research products) as international public goods to be used in furtherance of its mission. Full and timely disclosure of research results and products in the public domain is the preferred strategy for preventing misappropriation by others.*
- *Recognizing there may be times when using intellectual property is a necessary or preferred means to pursue CGIAR and Center objectives, Centers may consider acquiring and managing intellectual property in research products developed or funded by the Center when to do so would*
 - a) *support public and private partnerships which pursue mission-based research or which develop and apply research results;*
 - b) *assure ready access by others to research products developed or funded by the Center;*
 - c) *ensure the Center’s ability to pursue its research, together with its partners, without undue hindrance;*
 - d) *facilitate the transfer of technology, research products and other benefits to the resource poor including, where appropriate, through commercialization or utilization of research products; and/or*
 - e) *facilitate the negotiation and conclusion of agreements for access to proprietary technologies of use to the Center’s research and in furtherance of its mission.*

The CGIAR has a duty to engage the private sector, universities, advanced research institutes, National Agricultural Research Systems, and other organizations to use the Centers’ research products in order to bring them to bear on the opportunities of poor people. The CGIAR should actively negotiate to minimize any restrictions of third party IP for innovative technology associated with its mission, and that which may benefit people in developing countries. Engagement with the private sector should follow the guidelines outlined in Section 10.

7. Biodiversity

Background

Perhaps no single input is as important to the work of the CGIAR as genetic resources. Hence, the CGIAR has been playing a leading role internationally, regarding plant and animal genetic resources and biodiversity.

³¹ ICRISAT Guiding Principles on Management of Intellectual Property Annex I, 2000.
http://www.icrisat.org/ip_management/policy.htm

Ethical issues relating to genetic resources and biodiversity include erosion and species loss; bio-prospecting; collection, characterization and conservation (both *in situ* and *ex situ*) of genetic resources; ownership and control of and access to plant genetic resources and to improvements; equitable access and sharing of the benefits deriving from plant genetic resources; and the patenting of plant genetic resources.

The issue of biodiversity is regulated by the *Convention on Biological Diversity*. The issue of genetic resources was the first area, in which the CGIAR made a statement on ethical principles.³² The CGIAR guidelines on IPR also covers the issue of genetic resources.³³

Principles

The guiding principle is the CGIAR's commitment to maintain genetic materials and bio-control agents in its collections in the public domain and to ensure access to, and free and equitable exchange of such materials. Designated germplasm is held in trust for the world community and the CGIAR is obliged to conserve, maintain, study, improve, and distribute germplasm world-wide for use in agricultural research and development. The CGIAR has a responsibility for safe and secure conservation of these In-Trust genetic materials for present and future generations, including their duplication in at least one other location for safety.

The CGIAR recognizes the contributions of farming and indigenous communities to the conservation and enhancement of local genetic resources. The CGIAR furthermore recognizes the right of these communities to benefit from these resources. However, the CGIAR is also committed by its duty to ensure equitable access to genetic resources and cannot, as a general rule, support exclusive rights for particular communities.

Utilizing local genetic resources sometimes conflicts with the duty to respect wildlife and to protect valuable non-cultivated areas. The CGIAR should encourage solutions that minimize such conflicts.

Advice

The CGIAR is in principle committed to regard any information, inventions, processes, biological material or other research products funded or developed by CGIAR as international public goods to be used in furtherance of its mission. To achieve this in practice some measures to protect intellectual property rights may be required to be put in place. The CGIAR should promote ready access to breeding materials for breeding and research activities; where appropriate this should include new genetically modified varieties that can be made available when they are off patent (and perhaps even when they are on patent by licensing at nominal rates). The CGIAR encourages germplasm donors to permit the designation of material in accordance with the 1994 agreements with FAO.³⁴

The CGIAR recognizes the expertise of many national and international NGOs on equity, gender, conservation, sustainability, and nature protection issues. The CGIAR therefore commits itself to engage in dialogue with these organisations according to the principles outlined in Section 2, and can, where appropriate, form partnerships with them to integrate these concerns in research on genetic resources.

³² CGIAR's *Ethical Principles Relating to Genetic Resources*. www.cgiar.org/corecollection/docs/sgrp_policy_booklet_2003.pdf

³³ ICRISAT *Guiding Principles on Management of Intellectual Property* Annex I, 2000. http://www.icrisat.org/ip_management/policy.htm

³⁴ The FAO-CGIAR Agreement on Genetic Resources. The FAO International Undertaking of Plant Genetic Resources for Food and Agriculture.

8. Biosafety and Risks

Background

Biosafety is an issue clearly important to the CGIAR. A panel on biosafety reported in 2002 to the SC of the CGIAR³⁵ and made 12 specific recommendations:

- *Enhance CGIAR Centre Biosafety Policies*
- *Enhance Capacity Building in National Biosafety Policies and Practices*
- *Strengthen Centre Capacity in Biosafety Practice and Research through Pro-active Approaches to Biosafety*
- *Develop an Integrated Approach to the Practice of Biosafety in the Centers*
- *Establish a CGIAR System Biosafety Network*
- *Increase Biosafety-related Research by the Centers*
- *Publish and Communicate Results of Biosafety Research*
- *Prepare for Forestry and Fisheries Biosafety Issues*
- *Undertake more Risk/benefit Analysis*
- *Develop Plans for Preparing Risk Assessment Dossiers for Product Approval*
- *Better Address Bioethical Issues*
- *Initiate a CGIAR System-wide Biosafety Workshop to Plan Implementation of the Biosafety Panel's Recommendations*

The present panel acknowledges the ongoing work in this area. Particularly, we note the panel recommended that the Centers should “better address bioethical issues”, and to this purpose, the panel further recommended that each centre maintain a standing ethical committee to give advice on biosafety. This report was endorsed in principle by the Science Council, but the means by which the CGIAR might proceed to implementation was qualified in an SC Commentary. Most importantly, the SC did not see any important ethical difference between Genetically Modified Organisms (GMOs) and organisms produced by traditional breeding. The present panel fully approves of the recommendations with this qualification added and it shall not add any further advice in this respect. However, it might be useful, in context of these guidelines, to clearly state the underlying values in the concern for biosafety.

An area of special concern is the risk of unintended effects of CGIAR research. Examples could be farmers' participation in participatory breeding or resource management experiments which alter the efficacy of former genetic or natural resource use by the participants involving risks of greater reliance on monocropping, unsustainable input levels and the like. Another example could be community management experiments involving a risk of gradual exclusion of people rather than inclusion. Even though such research does not, in the technical sense, involve human subjects, some of the same doubts about informed consent can arise here: Does the poor farmer understand the risk of participating? Is there a truly free choice?

We should also like to mention the CIAT Code of Ethics,³⁶ which states that “CIAT scientists takes steps to implement protections for the rights and welfare of research participants and other persons affected by the research” and “In planning and implementing research CIAT scientists consult those with expertise concerning any special population or agroecosystem under investigation or likely to be affected”.

Principles

³⁵ Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers

³⁶ CIAT Code of Ethics, 2005.

The general principle at stake here is that the duty to benefit the poor is constrained by the principle of respect for persons. Biosafety becomes an ethical issue for the CGIAR because a technology or a policy used in the pursuit of the objective of reducing poverty, hunger and malnutrition often to some degree involves risks of unwanted outcomes. It is wrong to sacrifice individuals in the pursuit of benefiting the poor. It is also wrong to expose others to serious risk of harm in the pursuit of benefiting the poor. Similarly, it is wrong to harm the environment or to expose the environment to serious risk of harm.

In the case of Genetically Modified Organisms (GMOs), these risks are often regulated, such that GMOs only can be approved in cases where a risk assessment has demonstrated that the risk of unwanted effects is acceptably low. However, as the SC rightly points out in its comments to the report on biosafety, there are biosafety issues, and thus ethical problems, also for traditional types of breeding, even though they are not regulated.

Another issue concerns uncertainty about how well a means will achieve the overall objective of reducing poverty, hunger and malnutrition. Thus, certain technologies or policies might involve serious risks, e.g. of an environmental catastrophe, and thereby endanger the long term achievement of the overall objective. Through its commitment to sustainable development, the CGIAR clearly has a duty to adopt a precautionary approach which seeks to find beneficial solutions that avoids unnecessary risk-taking in the short term and which obviates endangering future possibilities of reducing poverty, hunger and malnutrition.

The Precautionary Principle, as it is used in most contexts, is a principle allowing governments to enforce restrictions or bans on technologies or products not just in case of a scientifically documented harmful effects at an unacceptable level on human health or the environment, but also when there is a scientifically based worry of such harmful effects. What we mean by a precautionary approach, in this context, is an approach where the agent, when comparing relevant alternatives of action including doing nothing, seeks to avoid unjustified risks or unduly high stake risks. Clearly, in very poor countries, a continuation of the status quo is very likely to have serious harmful effects in terms of continued poverty, hunger or malnutrition. The risk of alternatives to the status quo should be judged in the light of this fact; however, there is still reason to be aware of risks and particularly to avoid high stake risks for future generations.

Advice

Biosafety issues should always be handled through dialogue with the relevant stakeholders as outlined in Section 2, in order to choose means where the risk of harm to others or to the environment is acceptably low for all affected parties. National regulation of risks should of course always be respected.

Ethically speaking, in the areas not regulated, there is no clear limit for how serious a risk of harm must be before it is wrong to expose others to it without their consent. Thus, in some cases there could be a dilemma, when the risk for others in question is considered low, and the consequence of avoiding running the risk is a serious constraint on achieving the objective of benefiting the poor. In such cases, the balancing between the concern for biosafety and the duty to benefit the poor should involve the affected stakeholders.

Research involving participation by vulnerable groups, e.g. very poor farmers, should be reviewed by an ethical review board, and guardians should be appointed where necessary.

C. THE INTERNAL SCIENTIFIC PROCESS

9. Good Scientific Practice

Background

Science has evolved from ideals such as truth, objectivity, openness and rationality. Scientists are brought up to respect these ideals of science throughout their education. However, massive structural changes pose challenges for maintaining the integrity of science. Scientists are involved in hard competition to get funding, and therefore they are under a strong pressure to present results. Scientists also have become increasingly specialised, and they are almost exclusively evaluated by their peer-reviewed international publications. Hence, an increasing number of scientists may be tempted to engage in dishonesty or even fraud in the production and presentation of scientific results in order to pursue their career interests. Problems with scientific dishonesty include practices such as fabrication of data, misleading or distorting interpretation or presentation of results, plagiarism and inappropriate credit for authorship.

ICRAF has produced a good discussion paper which makes it clear that scientific dishonesty is a possibility of which the CGIAR Centers have to be aware.³⁷ The CIAT Code of Ethics contains guidelines for a number of issues like scientific standards, competence, use and misuse of expertise, delegation and supervision, non-discrimination and non-exploitation, harassment, employment decisions, conflicts of interest.³⁸ The code also has guidelines for reporting of research, plagiarism, authorship credit, publication and review, and education and training.

Principles

The fundamental value at stake is the integrity of science. Ideally speaking, science is the search for the truth through rational and openly documented procedures, serving all mankind. If individual scientists seek to further personal interests through deceitful or fraudulent conduct, the integrity of science is threatened, because the scientific enterprise as a whole is called into question. The integrity of science builds on the fact that scientific results are open for public scrutiny. But it is also dependent on the integrity of scientists. Scientists must be reliable in their production and presentation of results. Hence, science as an institution needs to protect its integrity by fostering good scientific practice among scientists. Also, it needs to detect scientific dishonesty and seek to eliminate it from the scientific corpus.

Advice

The Centers need to state and enforce clear policies on good scientific practice. We recommend that the CGIAR formulate common policies on the presentation of research protocols, data documentation and data storage, and interpretation, presentation and publication of results. The *Ryan Commission Report on Research Integrity* provides guidelines on these issues.

In order to ensure adherence to the norms of good scientific practice throughout the CGIAR system, we suggest that the policies be taught in training courses for the staff. It is the responsibility of supervisors to ensure that the norms of good scientific practice are known and adhered to by the entire staff. This also implies that supervisors motivate staff by making sure they understand the context and reasons for the work. Unreasonable requests or work loads should not be imposed.

³⁷ ICRAF: Scientific Fraud, Research Discussion Paper 1.

³⁸ CIAT Code of Ethics, 2005.

³⁹ Integrity and Misconduct in research: Report of the Commission on Research Integrity, <http://www.faseb.org/opar/cri.html>

Concerning authorship and publication, we suggest the CGIAR adopt the Vancouver rules⁴⁰ as its standard for good scientific practice. While this guidance was developed for biomedical publications, the principles relating to ethical considerations in the conduct and reporting of research and aspects of publishing, and editorial issues related to publication are applicable to all scientific disciplines. In relation to authorship, the main point of these guidelines are:

Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.

It is particularly important that the contribution of all members of the research team, including local and external scientists and non-research partners be appropriately credited, either through authorship, contributorship or formal acknowledgement. An author shall have contributed substantially to the research process, s/he shall have contributed substantially to the preparation of the manuscript and s/he shall take responsibility for appropriate portions of the content. We recommend that a comprehensive *co-author statement* should be prepared and signed by all authors, describing precisely the nature and extent of each author's contribution without using stereotypical language

Also, the CGIAR should have a formal system to which complaints about serious scientific misconduct can be lodged for investigation and judgment. We recommend that the CGIAR set up common rules for the handling of scientific fraud. These rules should prescribe an independent committee, based within the Science Council, to which substantial doubts about the honesty or integrity of a work can be referred and appropriately pursued. The committee should conduct a full investigation and make a determination adhering to due process standards. The rules should also describe the relevant sanctions in the event of demonstrable fraudulent behaviour.

10. Handling and Receiving Funding

Background

Objectivity and integrity of researchers are essential values in scientific research, and form the basis for public trust. A conflict of interest arises when a researcher or employee of an organization has competing professional and personal obligations or financial interests that would make it difficult to fulfill his or her duties objectively.

Within the CGIAR, activities related to improvement of commodities, plant and animal genetics such as plant breeding for improved micronutrient content of foods have potential for economic gains and thus require careful scrutiny. Concerns are raised when financial considerations may compromise or have the appearance of compromising an investigator's professional judgment and independence in the design, conduct, or publication of research. As for receiving funding, a principal question is how to deal with such conflicts of interests.

The CGIAR's internal funding decisions concern the use to which funds are put, particularly prioritizing between research fields. The CGIAR also makes funding decisions when it choose between partners in Challenge Programs though running competitive tenders. We envisage two types of conflicts concerning

⁴⁰ *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication.*
<http://www.ICMJE.org>

the handling of funding within the CGIAR system. One is concerned with the cases where a scientist or Board of Trustee Member within the CGIAR is both a potential receiver of funding and member of a funding committee. The other is the conflict between funding allocated through open competition and funding allocated to special issues or to the benefit of special areas or the like. The general trend is that more and more funding is allocated through open competition, because open competition is believed to be the best guarantee for scientific quality and freedom from conflict of interest.

ICLARM (now the WorldFish Center) has a policy on partnerships⁴¹ which states guidelines for collaboration with partners such as government and non-government national institutions, advanced scientific institutions, regional and international organisations, research centers, individual scientists, the private sector and participating farmers or fishers. Similar guidelines would be useful for all Centers. The CIAT Code of Ethics⁴² contains guidelines on conflicts of interest and contractual and consulting services.

Principles

Is important to avoid not only actual conflicts of interest, but also apparent and potential conflicts in order to maintain the public's trust. Concerning receipt of funding, the guiding principle should be that the CGIAR only accepts such funding if it is compatible with the overall mission of the CGIAR and the duty to keep research a public good. In all cases of funding and collaboration, there should be transparent declaration of interests from the involved parties.

Funding decisions within the CGIAR system should be free from conflict of interest, and the process by which decisions are made should be transparent. Decisions about funding should consider the duties and responsibilities of the CGIAR to all of the communities that it serves. First and foremost, the CGIAR has the duty to do research that actually benefits the poor. Second, the CGIAR has a duty to do the best science possible and to strengthen the scientific capacity in local communities. Finally, the CGIAR has a duty to choose the most cost-effective means to benefit the poor through methodologically sound science.

Advice

Centers should maintain a written policy on conflict of interest which is enforced to protect the integrity of the scientific process, the missions of the institutions, the investment of stakeholders in institutions and public confidence in the integrity of research. This policy should establish requirements for disclosures of conflict of interest.

Evaluation of the potential for conflict of interest should be part of the review of research protocols conducted by institutional review boards or ethics committees, since the protection of human subjects requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. As for funding from the private sector, we believe the Alliance of Future Harvest Centers of the CGIAR has provided useful guidelines:⁴³

⁴¹ Policy on Partnerships in Research and Related Activities, ICLARM.

⁴² CIAT Code of Ethics, 2005.

⁴³ Alliance of Future Harvest Centers of the CGIAR: "Guidelines for center modes of collaboration with the private sector", May 2005, WorldFish Center, Penang, Malaysia.

As such, fund raising is not the focus for collaboration with the private sector but, rather, partnerships with the private sector will be entered into when they serve to enhance the capability of the Center to deliver to its stakeholders and collaborators the best quality science aimed at meeting the Center and CGIAR objectives and goals.

- The CGIAR policy on these matters is that we will enter into such arrangements only if they complement and enhance a Center's ability to achieve its mandate of service to the resource-poor and the environment. In simple terms, will a particular agreement help us to more quickly develop new, appropriate technologies and/or deliver them to beneficiaries in developing countries?*
- Wherever possible, the terms of the collaboration will be consistent with the International Public Good's basis of the Center's work and the use of its products. Where products of the partnership cannot be so protected, the Center will ensure that our target beneficiaries, the poor in developing countries, can gain from the products of the partnership.*
- As the nature of the CGIAR changes to include more research arrangements with advanced research institutes both public and private we believe that it is important that the best efforts should be exercised to ensure that the major partners are well informed of the arrangements with the private sector.*
- Private sector collaborations will be governed by appropriate, time-bound legal contracts and memoranda of agreement which will clearly define the Center's obligations and protect the Center from potential liabilities;*
- Where other major research partners have been directly involved in research and related activities of relevance to the private sector partnership, best efforts should be exercised to obtain the agreement of these partners before entering into arrangements with the private sector;*
- The Center will follow good business practices such as efficient use of resources, respect for legal contracts and confidentiality provisions. In the specific area of IP the Centers shall act in a manner fully consistent with national and international law in this area, while ensuring that issues such as exclusive licensing is only adopted when clearly consistent with the best interests of its beneficiaries as indicated in other provisions of these guidelines.*
- Centers will not accept funding from private companies that could reasonably create a conflict of interests or in any way compromise the objectivity of the results of work carried out.*

Staff within the CGIAR system participating in committees that allocate funding have a duty to declare any real or potential conflict of interest. Persons whose conflicting interests may raise questions about their ability to make fair decisions should withdraw from decisions about funding, on their own initiative.

In general, scientific quality is best served by allocating funding through open competition. However, there might be cases, where funding to an important and potentially beneficial topic cannot be allocated through open competition, because there is only one competent research group within the area. In these cases, it should be possible to allocate earmarked funding directly. However, it is important to note that all science – including science funded through earmarked money – should be reviewed for quality, i.e. through peer review from independent experts. Regardless of how this balancing plays out, it is important that the CGIAR is transparent about the conflicting values at stake and how the balance is struck in a particular instance.