RESEARCH ETHICS

OBJECTIVES IN RESEARCH ETHICS

1. The first and broadest objective is to protect human participants.

2. The second objective is to ensure that research is conducted in a way that serves interests of individuals, groups and/or society as a whole.

3. Finally, the third objective is to examine specific research activities and projects for their ethical soundness, looking at issues such as the management of risk, protection of confidentiality and the process of informed consent.

INTRODUCTION:

Research ethics involves the application of fundamental ethical principles to a variety of topics involving scientific research. The application of fundamental ethical principles to a topics like

1. The design and implementation of research involving human experimentation, animal experimentation

2. Various aspects of academic scandal, including scientific misconducts (such as fraud, fabrication of data and plagiarism),

3. Whistle blowing (wrongdoing within an organization to the public or to those in positions of authority); regulation of research, etc. Research ethics is most developed as a concept in all the scientific research.

4. Research in the social sciences presents a different set of issues than those in medical research.

The scientific research enterprise is built on a foundation of trust. Scientists trust that the results reported by others are valid. Society trusts that the results of research reflect an honest attempt by scientists to describe the world accurately and without bias. But this trust will endure only if the scientific community devotes itself to exemplifying and transmitting the values associated with ethical scientific conduct. There are many ethical issues to be taken into serious consideration for research. Sociologists need to be aware of having the responsibility to secure the actual permission and interests of all those involved in the study. They should not misuse any

of the information discovered, and there should be a certain moral responsibility maintained towards the participants. There is a duty to protect the rights of people in the study as well as their privacy and sensitivity. The confidentiality of those involved in the observation must be carried out, keeping their anonymity and privacy secure. As pointed out in the BSA for Sociology, all of these ethics must be honoured unless there are other overriding reasons to do so - for example, any illegal or terrorist activity. Most people learn ethical norms at home, at school, in temple, in church or in other social settings. Although most people acquire their sense of right and wrong during childhood, moral development occurs throughout life and human beings pass through different stages of growth as they mature. Ethical norms are so everywhere that one might be tempted to regard them as simple commonsense. On the other hand, if morality were nothing more than commonsense, then why are there so many ethical disputes and issues in our society? One reasonable explanation of these disagreements is that all people recognize some common ethical norms but different individuals interpret, apply, and balance these norms in different ways in light of their own values and life experiences. Most societies also have legal rules that govern behavior, but ethical norms tend to be broader and more informal than laws. Although most societies use laws to enforce widely accepted moral standards and ethical and legal rules use similar concepts, it is important to remember that ethics and law are not the same. An action may be legal but unethical or illegal but ethical. We can also use ethical concepts and principles to criticize, evaluate, propose, or interpret laws. Indeed, in the last century, many social reformers urged citizens to disobey laws in order to protest what they regarded as immoral or unjust laws. Peaceful civil disobedience is an ethical way of expressing political viewpoints. Another way of defining 'ethics' focuses on the disciplines that study standards of conduct, such as philosophy, theology, law, psychology, or sociology. For example, a "medical ethicist" is someone who studies ethical standards in medicine. One may also define ethics as a method, procedure, or perspective for deciding how to act and for analyzing complex problems and issues. For instance, in considering a complex issue like global warming, one may take an economic, ecological, political, or ethical perspective on the problem. While an economist might examine the cost and benefits of various policies related to global warming, an environmental ethicist could examine the ethical values and principles at stake. Many different disciplines, institutions, and professions have norms for behavior that suit their particular aims and goals. These norms also help members of the discipline to coordinate their actions or activities and to

establish the public's trust of the discipline. For instance, ethical norms govern conduct in medicine, law, engineering, and business. Ethical norms also serve the aims or goals of research and apply to people who conduct scientific research or other scholarly or creative activities. There is even a specialized discipline, research ethics, which studies these norms. There are several reasons why it is important to adhere to ethical norms in research. First, norms promote the aims of research, such as knowledge, truth, and avoidance of error. For example, prohibitions against fabricating, falsifying, or misrepresenting research data promote the truth and avoid error. Second, since research often involves a great deal of cooperation and coordination among many different people in different disciplines and institutions, ethical standards promote the values that are essential to collaborative work, such as trust, accountability, mutual respect, and fairness. For example, many ethical norms in research, such as guidelines for authorship, copyright and patenting policies, data sharing policies, and confidentiality rules in peer review, are designed to protect intellectual property interests while encouraging collaboration. Most researchers want to receive credit for their contributions and do not want to have their ideas stolen or disclosed prematurely. Third, many of the ethical norms help to ensure that researchers can be held accountable to the public. For instance, federal policies on research misconduct, conflicts of interest, the human subject protections, and animal care and use are necessary in order to make sure that researchers who are funded by public money can be held accountable to the public. Fourth, ethical norms in research also help to build public support for research. It is seen that people more likely to fund research project if they can trust the quality and integrity of research. Finally, many of the norms of research promote a variety of other important moral and social values, such as social responsibility, human rights, and animal welfare, compliance with the law, and health and safety. Ethical lapses in research can significantly harm human and animal subjects, students, and the public. For example, a researcher who fabricates data in a clinical trial may harm or even kill patients and a researcher who fails to abide by regulations and guidelines relating to radiation or biological safety may jeopardize his health and safety or the health and safety of staff and students.

CODES AND POLICIES FOR RESEARCH ETHICS

Given the importance of ethics for the conduct of research, it should come as no surprise that many different professional associations, government agencies, and universities have adopted

specific codes, rules, and policies relating to research ethics. Many government agencies, such as the National Institutes of Health (NIH), the National Science Foundation (NSF), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA) have ethics rules for funded researchers. Other influential research ethics policies include the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (International Committee of Medical Journal Editors), the Chemist's Code of Conduct (American Chemical Society), Code of Ethics (American Society for Clinical Laboratory Science) Ethical Principles of Psychologists (American Psychological Association), Statements on Ethics and Professional Responsibility (American Anthropological Association), Statement on Professional Ethics (American Association of University Professors), the Nuremberg Code and the Declaration of Helsinki (World Medical Association).

The following is a rough and general summary of some ethical principles that various codes address*:

1. Honesty: Strive for honesty in all scientific communications. Honestly report data, results, methods and procedures, and publication status. Do not fabricate, falsify, or misrepresent data. Do not deceive colleagues, granting agencies, or the public.

2. Objectivity: Strive to avoid bias in experimental design, data analysis, data interpretation, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research where objectivity is expected or required. Avoid or minimize bias or self-deception. Disclose personal or financial interests that may affect research.

3. Integrity: Keep your promises and agreements; act with sincerity; strive for consistency of thought and action.

4. Carefulness: Avoid careless errors and negligence; carefully and critically examine your own work and the work of your peers. Keep good records of research activities, such as data collection, research design, and correspondence with agencies or journals.

5. Openness: Share data, results, ideas, tools, resources. Be open to criticism and new ideas.

6. Respect for Intellectual Property: Honor patents, copyrights, and other forms of intellectual property. Do not use unpublished data, methods, or results without permission. Give credit where

credit is due. Give proper acknowledgement or credit for all contributions to research. Never plagiarize.

7. Confidentiality: Protect confidential communications, such as papers or grants submitted for publication, personnel records, trade or military secrets, and patient records.

8. Responsible Publication: Publish in order to advance research and scholarship, not to advance just your own career. Avoid wasteful and duplicative publication.

9. Responsible Mentoring: Help to educate, mentor, and advise students. Promote their welfare and allow them to make their own decisions.

10. Respect for colleagues: Respect your colleagues and treat them fairly.

11. Social Responsibility: Strive to promote social good and prevent or mitigate social harms through research, public education, and advocacy.

12. Non-Discrimination: Avoid discrimination against colleagues or students on the basis of sex, race, ethnicity, or other factors that are not related to their scientific competence and integrity.

13. Competence: Maintain and improve your own professional competence and expertise through lifelong education and learning; take steps to promote competence in science as a whole.

14. Legality: Know and obey relevant laws and institutional and governmental policies.

15. Animal Care: Show proper respect and care for animals when using them in research. Do not conduct unnecessary or poorly designed animal experiments.

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16. Human Subjects Protection: When conducting research on human subjects minimize harms and risks and maximize benefits; respect human dignity, privacy, and autonomy; take special precautions with vulnerable populations; and strive to distribute the benefits and burdens of research fairly.

17. There are many other activities that do not define as "misconduct" but which are still regarded by most researchers as unethical. These are called "other deviations" from acceptable research practices and include:

- Publishing the same paper in two different journals without telling the editors
- Submitting the same paper to different journals without telling the editors
- Not informing a collaborator of your intent to file a patent in order to make sure that you are the sole inventor
- Including a colleague as an author on a paper in return for a favor even though the colleague did not make a serious contribution to the paper
- Discussing with your colleagues confidential data from a paper that you are reviewing for a journal
- Trimming outliers from a data set without discussing your reasons in paper
- Using an inappropriate statistical technique in order to enhance the significance of your research
- Bypassing the peer review process and announcing your results through a press conference without giving peers adequate information to review your work
- Conducting a review of the literature that fails to acknowledge the contributions of other people in the field or relevant prior work
- Stretching the truth on a grant application in order to convince reviewers that your project will make a significant contribution to the field Stretching the truth on a job application or curriculum vita
- Giving the same research project to two graduate students in order to see who can do it the fastest
- Overworking, neglecting, or exploiting graduate or post-doctoral students
- Failing to keep good research records
- Failing to maintain research data for a reasonable period of time
- Making derogatory comments and personal attacks in your review of author's submission
- Promising a student a better grade for sexual favors
- Using a racist epithet in the laboratory
- Making significant deviations from the research protocol approved by your institution's
- Animal Care and Use Committee or Institutional Review Board for Human Subjects Research without telling the committee or the board Not reporting an adverse event in a human research experiment

- Wasting animals in research
- Exposing students and staff to biological risks in violation of your institution's biosafety rule
- Rejecting a manuscript for publication without even reading it Sabotaging someone's work
- Stealing supplies, books, or data• Rigging an experiment so you know how it will turn out
- Making unauthorized copies of data, papers, or computer programs
- Deliberately overestimating the clinical significance of a new drug in order to obtain economic benefits

These actions would be regarded as unethical by most scientists and some might even be illegal. Most of these would also violate different professional ethics codes or institutional policies.

PROMOTING ETHICAL CONDUCT IN SCIENCE

Many of you may be wondering why you are required to have training in research ethics. You may believe that you are highly ethical and know the difference between right and wrong. You would never fabricate or falsify data or plagiarize. Indeed, you also may believe that most of your colleagues are highly ethical and that there is no ethics problem in research.

If you feel this way, relax. No one is accusing you of acting unethically. Indeed, the best evidence we have shows that misconduct is a very rare occurrence in research, although there is considerable variation among various estimates. The rate of misconduct has been estimated to be as low as 0.01% of researchers per year (based on confirmed cases of misconduct in federally funded research) to as high as 1% of researchers per year (based on self-reports of misconduct on anonymous surveys).

Clearly, it would be useful to have more data on this topic, but so far there is no evidence that science has become ethically corrupt. However, even if misconduct is rare, it can have a tremendous impact on research. Consider an analogy with crime: it does not take

many murders or rapes in a town to erode the community's sense of trust and increase the community's fear and paranoia. The same is true with the most serious crimes in science, i.e. fabrication, falsification, and plagiarism. However, most of the crimes committed in science probably are not tantamount to murder or rape, but ethically significant misdeeds that are classified by the government as 'deviations.' Moreover, there are many situations in research that pose genuine ethical dilemmas.

Will training and education in research ethics help reduce the rate of misconduct in science? It is too early to tell. The answer to this question depends, in part, on how one understands the causes of misconduct. There are two main theories about why researchers commit misconduct. According to the "bad apple" theory, most scientists are highly ethical. Only researchers who are morally corrupt, economically desperate, or psychologically disturbed commit misconduct. Moreover, only a fool would commit misconduct because science's peer review system and self-correcting mechanisms will eventually catch those who try to cheat the system. In any case, a course in research ethics will have little impact on "bad apples," one might argue. According to the "stressful" or "imperfect" environment theory, misconduct occurs because various institutional pressures, incentives, and constraints encourage people to commit misconduct, such as pressures to publish or obtain grants or contracts, career ambitions, the pursuit of profit or fame, poor supervision of students and trainees, and poor oversight of researchers. Moreover, defenders of the stressful environment theory point out that science's peer review system is far from perfect and that it is relatively easy to cheat the system. Erroneous or fraudulent research often enters the public record without being detected for years. To the extent that research environment is an important factor in misconduct, a course in research ethics is likely to help people get a better understanding of these stresses, sensitize people to ethical concerns, and improve ethical judgment and decision making.

Misconduct probably results from environmental and individual causes, i.e. when people who are morally weak, ignorant, or insensitive are placed in stressful or imperfect environments. In any case, a course in research ethics is useful in helping to prevent deviations from norms even if it does not prevent misconduct. Many of the deviations that occur in research may occur because researchers simple do not know or have never

thought seriously about some of the ethical norms of research. For example, some unethical authorships practices probably reflect years of tradition in the research community that has not been questioned seriously until recently. If the director of a lab is named as an author on every paper that comes from his lab, even if he does not make a significant contribution, what could be wrong with that? That's just the way it's done, one might argue. If a drug company uses ghostwriters to write papers "authored" by its physician-employees, what's wrong about this practice? Ghost writers help write all sorts of books these days, so what's wrong with using ghostwriters in research?

Another example where there may be some ignorance or mistaken traditions is conflicts of interest in research. A researcher may think that a "normal" or "traditional" financial relationship, such as accepting stock or a consulting fee from a drug company that sponsors her research, raises no serious ethical issues. Or perhaps a university administrator sees no ethical problem in taking a large gift with strings attached from a pharmaceutical company. Maybe a physician thinks that it is perfectly appropriate to receive a $300 finder‟s fee for referring patients into a clinical trial.

If "deviations" from ethical conduct occur in research as a result of ignorance or a failure to reflect critically on problematic traditions, then a course in research ethics may help reduce the rate of serious deviations by improving the researcher's understanding of ethics and by sensitizing him or her to the issues.

Finally, training in research ethics should be able to help researchers grapple with ethical dilemmas by introducing researchers to important concepts, tools, principles, and methods that can be useful in resolving these dilemmas. In fact, the issues have become so important that the NIH and NSF have mandated training in research ethics for graduate students

ANIMAL USED IN RESEARCH

Animals play a significant role in research. They are used in a variety of ways by researchers, such as for testing new pharmaceuticals, as teaching tools for medical students and as experimental subjects for new surgical procedures. Research with animals is necessary and vital to biomedical research because animal research is frequently a

necessary first step towards research involving new medical treatments and pharmaceuticals intended for human use.

Many dedicated organizations and individuals are interested in protecting and safeguarding animal subjects as regards their use in research. Some organizations are interested in eliminating the use of animals in research. Others consider research with animals a necessary evil to the advancement of medicine, but still aim to eliminate unnecessary suffering, pain and poor facility conditions for animal subjects.

To protect animals, research projects that use animals have to be reviewed. These review processes assess the risks and benefits of using animals in research. This can prove difficult for project reviewers and often makes for intense debates and arguments about the appropriate use of animal subjects, particularly because the animal subjects usually bear all the risks while human beings realize all the benefits. Debates also center on judging how much pain is too much, whether or not animals experience pain in the same way that humans do and whether or not these ideas should even factor into the debate at all.

To assure that research with animals is conducted ethically and responsibly, the government has created regulations involving the use and care of animals involved in teaching, testing, and research.

Animals are used for many purposes within schools, universities and research establishments. Others are studied within their natural habitats. The purposes for which they are used and the impact on these animals themselves varies considerably. In all cases, it is essential that the individual animal is treated in humane and considerate manner.

Regulation and Controls Research and teaching using animals may only be performed when they are essential:

- To obtain and establish significant information relevant to the understanding of humans and/or animals;•
- For the maintenance and improvement of human and/or animal health and welfare;•
- For the improvement of animal management or production;•

- To obtain and establish significant information relevant to the understanding, maintenance or• improvement of the natural environment; or
- For the achievement of educational objectives.•

Projects using animals may only be performed after a decision has been made that they are justified, weighing the predicted scientific or educational value of the research against the potential effects on the welfare of the animals.

Investigators and teachers must submit a written proposal to an Animal Ethics Committee for all animal projects which must take into account the expected value of the knowledge to be gained, the justification for the project and all ethical and animal welfare aspects taking into account the 3RS - Replacement, Reduction and Refinement as outlined in the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes.

In South Australia compliance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (the Code) is mandatory and a legal requirement. Breaches of the Code can incur penalties under the Animal Welfare Act 1985. The purpose of the Code is to ensure the ethical and humane care and use of animals in research and teaching. The principles set out in the Code are for guidance of investigators, teachers, institutions, Animal Ethics Committees (AECs) and all people involved in the care and use of animals for scientific purposes.

The Code emphasizes the responsibilities of investigators, teachers and institutions using animals to ensure that the use of animals is justified, that the welfare of the animals is always considered, to promote the development of techniques that replace the use of animals, to minimise the numbers of animals used and to refine procedures to avoid pain or distress in animals.

The 3 Rs: Replacement, Reduction and Refinement Encapsulated in the code of practice for the care and use of animals for scientific purposes is the requirement for scientific and teaching activities to consider

The 3Rs.

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

2. Reduction: Each project must use no more than the minimum number of animals necessary to ensure scientific and statistical validity. The principle of reducing the number of animals used should not be implemented at the expense of greater suffering of individual animals. Scientific and teaching activities involving the use of animals must not be repeated unless essential for the purpose or design of the project. Teaching activities must involve no more than the minimum number of animals required to reach the educational objectives. Overproduction of animals bred for scientific purposes should be avoided so that the need to kill healthy animals is minimized.

3. Refinement: Animals must be suitable for the scientific purpose taking into account their biological characteristics including behaviour, genetic attributes and nutritional, microbiological and general health status. The design and management of animal accommodation should meet with species-specific needs. Special consideration is required where this is precluded by the requirements of the project. Animals should be transported, housed, fed, watered, handled and used under conditions that meet species-specific needs

The welfare of the animals must be a primary consideration in the provision of care, which should be based on behavioural and biological needs. Wildlife should not be taken from natural habitats unless animals bred in captivity are not available or are not suitable for the specific scientific purpose. Investigators and teachers who use animals for scientific purposes must employ the best available scientific and educational techniques and be competent in the procedures they perform or must be under the direct supervision of a person competent in the procedure.

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Projects should be designed to avoid both pain and distress in animals. If this is not possible, pain or distress must be minimized. Pain and distress cannot be evaluated easily in animals and therefore investigators and teachers must assume that animals experience these in a manner similar to humans unless there is evidence to the contrary. Decisions regarding the animals' welfare must be based on this assumption. An animal with signs of pain or distress not predicted in the proposal must have the pain or distress alleviated promptly. Alleviation of such pain or distress must take precedence over completing the project. If this is not possible the animal must be euthanized without delay.

Scientific and teaching activities that may cause pain or distress of a kind or degree for which anesthesia would normally be used in medical or veterinary practice must be carried out using anesthesia appropriate to the species and the procedure. Pain management appropriate to the species, the procedure and the circumstances must be provided. The use of local or general anesthetic, analgesic or tranquilizing agents must be appropriate to the species, and should at least parallel their use in current medical or veterinary practice. Where it is established that the purpose of the project precludes the use of anesthetic or analgesic agents to alleviate pain, the planned endpoint of the project must be as early as feasible to avoid or minimise pain or distress in the animals. Neuromuscular blocking agents must not be used without appropriate general anesthesia, except in animals where sensory awareness has been eliminated. If such agents are used, continuous or frequent monitoring of paralyzed animals is essential to ensure that the depth of anesthesia is adequate to prevent pain or distress. Death as an end point must be avoided wherever possible. Scientific and teaching activities involving the use of animals must be of minimum duration compatible with the objectives of the project.

ETHICAL ISSUES IN AGRICULTURAL RESEARCH

1. Sustainability: The ethical dilemmas arise when short term problems are preferred over long term ones. Institutional capacities to address long term problems require different kinds of reinforcement than otherwise. Ethical dilemma also arises when certain sectors, segments, social classes and seasons are preferred over others while choosing problems or locating them, solving them or diffusing the solutions obtained. Inter species and inter sectoral concerns also influence the sustainability of the outcomes. Not all local practices need to be sustained. Sustainability is as much about continuity as about discontinuity (that is innovations or fundamental change in values).

2. Eco system health: When scientists know about the concomitants of the eco system health and yet develop technologies which impair the health, they are not only making a trade off but also passing a value judgment. Transferring costs of near term trade offs over the longer term stakeholders may neither be ethical nor economically very judicious. Eco system health is also affected when long term consequences of certain chemical

inputs are known or anticipatable, and yet these are continued to be used. Judgments are involved when chemicals banned in western countries are allowed to be used in developing countries, when the precautionary principle is applied or not applied, and while technologies are transferred to countries which may or may not have capacity to assess the consequences.

3. Responsiveness: In any context, not everybody‟s problem is equally important. Michael Lipton once drew attention to the biases that existed in favour of interesting pests‟ vis-à-vis the relevant ones. When certain problems remain unsolved or unaddressed for centuries, surely it says something about the dominant ethics in the society which does not generate a dilemma or a discomfort despite sustained inertia and indifference. A good example is the cooking stove used by millions of women or carrying water pots on the head for long distance, transporting grass or twigs on head on the hill slopes by women or transplanting paddy by keeping feet under water and thus getting fungal infections, etc.

4. Accountability: Researchers seldom share their findings with the people from whom they collect the data. Not only that. They often do not even calibrate their criteria of relevant or not so relevant research by involving the users of research in calibration. Ethical dilemma also arise when a large multi national corporations inform the consumers of its chemical inputs about a desirable resource use practice in west but which they do not share in the developing countries. The community of corporations has to evolve its own code of conduct censoring such behaviour.

5. Capacity building: Any society which has to grapple with risk and uncertainty inherent in agricultural resource management has to learn to create capacity not only to anticipate but also address the future problems. The education and training of young minds thus becomes a very important determinant of the capacity to face emerging challenges in future. When the education system does or does not include content or pedagogical means which make a potential leader aware of the challenges, an ethical judgment has been made. When certain crops and/or other agricultural products are deliberately portrayed as inferior in the educational curriculum, on cultural grounds rather on nutritional or other scientific grounds, values have already been expressed. Lack of periodic review of the skills that are being developed to address such concerns about

externality, diversity, inter sectoral linkages, etc., invariably involve making trade offs about what should be told and what should young people learn on their own.

6. Location specificity: It is well known that agro ecological environment in rainfed regions is much more heterogeneous. Developing technologies which would diffuse only in a small region poses an institutional challenge apart from technological challenge. Organization incentives are often provided, commensurate with the diffusion or potential reach of a solution. If a technology is addressing problems of small community, it may not invoke a significant encouragement or incentive. Consequently, either such problems don‟t get addressed or the people who address such problems become marginalized. In either case ethical judgments have to be made by the decision makers. When research infrastructure, allocation of human resources and priority in research are biased in favour of better endowed regions and communities, the ethics of neglecting the bypassed communities and regions has to be made explicit. When hand tools receive less attention than energy intensive technologies, judgments have been made.

7. Asymmetry in rights of and responsibilities towards knowledge holders: No agricultural research council in developed or developing countries ever requires the asymmetry between rights and responsibilities towards the knowledge holders of informal sectors be deliberately overcome. The respondents in research with communities are not acknowledged, do not receive the findings of the research for which they provide data and do not receive any share in the benefits that are generated from the application or commercialization of the knowledge provided by the respondents/knowledge providers.

8. Empowerment of informal innovators and knowledge holders: It is obvious that creativity exists in formal as well as informal sectors. Just as the scientists can generate a creative and innovative solution to a problem, a farmer or an artisan can too1. The global bias against innovations in informal sector is very obvious. Inability of formal research system to listen to and learn from informal innovators not only deprives the organized sector of agricultural research and technology of the insights from the margin but also prevents it from being inspired by the values of many of the grassroots innovators. The ethical tradeoffs in such matters invariably affect the efficiency, equity, excellence and environmental consequences of resource and institutional management