Responsible Conduct of Research Manual

Office of Human Research Protection Program (OHRPP)

Foreword

For the vast majority of those engaged in the research enterprise, upholding the professionalism and integrity of research is the operative principle. Scientists want to conduct carefully designed experiments, taking into consideration the ethics of human and animal subject protection, recording of proper data and reporting results in the literature and at conferences as accurately as possible in order to advance knowledge responsibly.

With the rising demand for more responsible conduct of research in Singapore, this manual has put together best practices from around the world and hopefully will be a useful guide and resource for researchers in NHG Health and our partner institutions. We hope this manual would enlighten our researchers on what constitutes responsible research: for example, in cases of research misconduct, how to report it, how institutions can deal with it, and how research intensive organisations can institute practices that would reduce the risk of both unintentional and deliberate research misconduct.

As part of the OHRPP's effort to promote the Responsible Conduct of Research (RCR) awareness within our research community, we have put together this manual so that you will be better equipped with knowledge about RCR, and be better prepared to deal with any integrity dilemma that you will invariably encounter in your daily research activities and research career. This manual will provide you with insights to the outlines of the overall governance of research, provides procedural guidelines for meeting ethical requirements in research, and offer guidance on key ethical issues in your professional life.

** Disclaimer:

This RCR Manual should not be viewed as an official policy or statement. Any statement in this manual which is inconsistent with the local law, institutions' and regulatory authorities' policies or guidelines is thereby superseded. OHRPP always recommends researchers to ensure that they confer with their institution's policy and guidelines for any components in this manual that they are unsure of.

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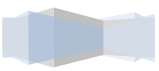

GENERAL PRINCIPLES OF RESPONSIBLE RESEARCH

1.1 INTRODUCTION

Institutions in which research takes place should strongly encourage a research culture that demonstrates:

- Integrity and honesty;
- Respect for human subject participants, animals and the environment;
- Good stewardship of grant or public resources used to conduct research,
- Appropriate acknowledgement of the role of the study team and others in research.
- Responsible dissemination and communication of research results or data.

The respective roles and responsibilities of institutions and researchers in maintaining an environment which champions responsible conduct of research will be discussed here.

1.2 INSTITUTIONS' RESPONSIBILITIES

Establishing responsible conduct of research

Institutions should promote the responsible conduct of research by:

- Advocating awareness of ALL guidelines, policies and legislation related to the responsible conduct of research,
- Earnestly encouraging mutual cooperation with open exchange of ideas between researchers, peers and respect freedom of expression and inquiry,
- Maintaining an environment in which responsible conduct of research and ethical behavior in research is expected.

Establishing good management practices & guidance

In order to encourage and support responsible conduct of research with researchers, good institutional management practices and guidance should be put in place and be readily available. This will promote the quality of research, apart from enhancing the institutions' reputation and that of its researchers, thereby minimizing the risk of harm for all involved.

Guide on good management practices and guidance:-

- Individual institutions should provide researchers an appropriate research governance framework in which quality, safety, privacy, risk management, financial management and ethical acceptability are assessed. The roles, responsibilities and accountabilities of individuals involved in the research should be precisely spelt out in the framework.
- While contractual arrangements may impose obligations, obligations from the local law may also arise from relationships between institutions, researchers and

participants. Therefore, the research governance framework should stipulate the compliance with ethics boards, institutional and regulatory authorities (if applicable) regulations, guides and policies governing the conduct of research within the institutions.

- Respective institutions should have readily available documents that help guide conduct, management and good research governance.
- Institutions should have a clear guide or policy on collaborative research projects with other organizations, with agreements to be contracted before a project commences.
- It is imperative for respective institutions to have a well-defined process for receiving and managing allegations of research misconduct.
- There must be a process for regular monitoring of the institutions' performance with regard to these guidelines.

Training of Staff

It is imperative that induction, formal training and continuing education for all research staff, including research trainees, are provided. Training should encompass ethics, research methodologies, confidentiality, data storage and retention of records, as well as regulation and governance. Institutions' policies and guidelines relating to the responsible conduct of research and other sources of guidance should be covered in the training too. Joint induction and trainings with other institutions/ organizations may be deemed necessary or suitable as well.

Advocate mentoring

Effective mentoring and supervision of researchers and research trainees should be advocated within the institutions. This includes advising on research ethics, research designs and methods, and the responsible conduct of research.

Establish a safe research environment

Respective institutions must ensure the establishment of a safe working environment for conducting research. For example, researchers who have on-going research should be granted "protected" time to carry out their research.

1.3 RESEACHERS' RESPONSIBILITIES

Maintaining high standards of responsible conduct of research

Maintaining an environment whereby intellectual honesty and integrity, scholarly and scientific rigor are valued and upheld, should be the researcher's highest responsibility. Researchers should:

- Respect the truth and the rights of those affected by their research,

- Manage conflicts of interests so that ethical and scholarly considerations are not compromised due to ambition and personal advantage,

- Adopt methods appropriate for achieving the aims of each research proposal,

- Comply with proper safety and security practices,

- Reference awards, degrees conferred and research publications accurately, including the status of any publications, such as whether it is under review or in the press,

- Foster adoption of responsible conduct of research practices and discourage deviations among colleagues

- Adhere to the policies and procedures stipulated by ethical boards, institutional, funding agencies and regulatory authorities.

Report research responsibly

Researchers should ensure that research data, findings and results are disseminated responsibly. For example, researchers should ensure that all reasonable steps are taken to ensure their findings are accurate and properly reported so that they can rectify any misleading or inaccurate statements about their work when they become aware of it.

Respect research participants

Ethical principles of integrity, respect for persons, justice and beneficence ought to be complied with. Researchers must obtain approval from appropriate ethics boards, regulatory agencies (if applicable) and relevant governing agencies prior to commencement of the research.

Reporting of Research Misconduct

A researcher should ensure that his or her allegations are made in good faith, and are reported in a timely manner and according to the institution's policies and guidelines.

1.4 REFERENCES & ACKNOWLEDGEMENT: GENERAL PRINCIPLES OF RESPONSIBLE RESEARCH

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RESEARCH MISCONDUCT

2.1 RESEARCH MISCONDUCT

Background

Any compromise of the ethical standards required for conducting research should not be tolerated. Even though breaches in such standards are rare, they must be dealt with promptly and fairly by all relevant parties in order to preserve the integrity of the research community. In order to preserve the integrity of the overall process of assessing potential misconduct, the process involves multiple steps. The process begins with an allegation, which shall first be assessed to determine whether it meets the criteria for research misconduct. If those criteria are met, there shall then be an inquiry into the allegation to determine whether there are enough facts to warrant an investigation. If an investigation is warranted, a formal examination and evaluation of all relevant facts shall determine if the allegation of misconduct is valid. If the allegation is valid, the process shall be concluded with an adjudication procedure.

Definition of Research Misconduct

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct, however, does not include honest error or differences of opinion.

Components of Research Misconduct:

- **Fabrication** refers to the deliberate making up of data or results and recording or reporting them.

- **Falsification** refers to the manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

- **Plagiarism** refers to the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

In cases of allegations involving individuals whose activities are submitted to or supported by a national agency, the definition and procedures for research misconduct specified in the agency's regulations will apply.

Confidentiality

Personnel involved in the inquiry and investigation shall strive to maintain confidentiality of information to the extent consistent with a fair and thorough process and as allowed by their institutional ethics board and regulatory authorities.

It is recommended that all researchers confer with their institutions' guidelines or policies pertaining to the reporting of research misconduct.

2.2 HOW COMMON IS RESEARCH MISCONDUCT?

Is this a real problem?

While the vast majority of researchers here conduct their research by adhering to high ethical standards and requirements of the NHG Health Domain Specific Review Boards (DSRB) and their institution's and regulatory authorities' policies and guidelines, occasional lapses in integrity still happen.

Recently, a researcher blew the whistle on a local cancer scientist contesting his result on a particular cancer gene. When this research misconduct was brought to light, the institution of the accused carried out a thorough investigation. It was conducted by an experienced and respectable professor and conducted in accordance to the institution's code of conduct, with opinions from expert international scientists while examining data and conducting interviews with the accused.

After the investigation, it was then reported that the findings were inconclusive of research misconduct.

Any allegation of research misconduct for a researcher can be most detrimental. Therefore, the onus is on the researcher to be knowledgeable and mindful of what constitutes to research misconduct.

Did you know?

In the United States, it is often asked whether these high-profile research misconduct cases are anomalies or representative of a real problem. It is difficult to assess whether misconduct cases have increased over the past 50 years, for example, because data on misconduct were not collected until the 1990s. The rate of overall research misconduct in the US has been estimated to be one case per 100,000 researchers in a population of about two million active investigators. The Associate Inspector General for Scientific Integrity, and others writing in the Fall/Winter 2002 Journal of Public Inquiry, reported that between 1990 and 2002, the Office of Inspector General (OIG) at the National Science Foundation (NSF) investigated 800 allegations of misconduct in 600 cases.

The investigations revealed that 60 of those cases, or 10 percent, were misconduct. Penalties levied ranged from debarment to reprimand, with some recovery of funds.

2.3 GUIDELINES FOR THOSE WHO REPORT MISCONDUCT

Protection for whistle-blowers

For their own protection, individuals who report allegations of misconduct will need to adhere to their institution's policies and or guidelines for whistle-blowing. This provides for remedies if it can be shown that a whistle-blower suffered discrimination in retaliation for the allegation brought under the legislation.

Procedures for allegation

How should a whistle-blower proceed with an allegation?

Here are some general guidelines for individuals who report allegations of misconduct:

- *Documentation:* When making an allegation of misconduct, clear documentation of who did what, and when they did it, will provide the best chance for a fair and timely resolution of the allegation.

- *Rules and procedures:* It is recommended that institutions handle misconduct according to their own internal policies and guidelines. As soon as an individual is involved in an allegation, the accused should review institutional procedures on the issue. A whistle-blower needs to know who should be apprised of the allegation, what constitutes evidence for or against an allegation, how the evidence should be obtained, who will review the allegation, what the whistle-blower's role will be, and how much time the process is expected to take.

- *Perspective:* Individuals with little experience in research should seek guidance before making allegations of misconduct. What might appear to be a serious action could be a misunderstanding. It might be appropriate to talk to peers, senior researchers in a team, Head of Department, or the individual in question.

- *Dispute resolution:* Some allegations of research misconduct might be resolved through other means, such as conflict resolution. This involves dealing with a problem as soon as possible; striving for an agreement rather than disagreement; emphasizing the problem, not the people involved; and using a third party, such as head of department, to clarify issues if necessary.

- *Motivation of a whistle-blower:* Whistleblowers should be aware that they may suffer retribution for their actions and that institutions are responsible for a misconduct inquiry and investigation. Institutions also should distinguish between facts and speculation and avoid speculating at the motives of others. Whistle-blowers should ask questions rather than draw conclusions.

Did you know?

In the US, an ombudsman is usually a government official or an individual who investigates and attempts to resolve complaints and problems against other officials or government agencies or between employees and employers or between students and a university.

2.4 THE INQUIRY, INVESTIGATION AND ADJUDICATION PROCESS

Responsibilities lie not only with local research funding agencies

Local research funding agencies commonly rely on *host institutions to bear primary responsibility for the prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of the alleged research misconduct which have occurred in their own institution. They rely on the host institution to make the initial response to allegations of misconduct. Research funding agencies also generally refer to the host institutions any allegations of misconduct made to them. Occasionally, agencies will perform their own inquiries or investigations regarding allegations.

Under certain circumstances, agencies may undertake investigations or act quickly to protect the public interest, such as when public health and safety are at stake.

* Host institution here refers to the institution or administering organization named in the grant letter of award as being responsible for the commitment and management of the research and the supervision of the grant funding.

Definition

- **Inquiry** refers to the assessment of whether the allegation has substance and whether an investigation is warranted.

- **Investigation** refers to the formal development of the factual record and the examination of the record leading to dismissal of a case or to a recommendation for a finding of research misconduct or to other remedies.

- **Adjudication** refers to the, recommendations which are reviewed and corrective actions, such as sanctions, are determined.

In order for an action to be termed misconduct, the action must have been committed intentionally or knowingly or in reckless disregard of known practices. The allegation must be proved by a preponderance of the evidence, which means determining whether the claim or fact is more probably true rather than apocryphal. The standards of "clear and convincing evidence" and "beyond a reasonable doubt" require a much higher burden of proof, derived from a thorough investigation.

2.5 THE REQUIREMENTS FOR REPORT TO OFFICE OF HUMAN RESEARCH PROTECTION PROGRAMME (OHRPP)

How do I go about reporting suspected research misconduct?

Research/ Host Institution is the first contact point

Research/ Host institutions are required to notify the appropriate local research funding agency and the OHRPP if the inquiry into an allegation of misconduct involving publicly funded research leads to sufficient evidence to proceed to an investigation.

When an investigation is complete, the research/ host institution is required to forward a copy of the evidence, the investigative report, recommendations made to the institutional official, and the subject's written response to the recommendations. Institutions must also inform the funding agency and the OHRPP about the decision of the institutional official and if any corrective actions have been or are being taken.

During an inquiry or investigation, if there is any immediate risk to public health or safety, the research activities should be suspended. If there may be violations of criminal or civil law, or if allegations are made public prematurely, the institution must notify the OHRPP & the relevant governmental and/or regulatory authorities immediately.

2.6 SANCTIONS

Sanctions

Sanctions against those found guilty of research misconduct can include:

- Taking appropriate steps to correct the research record
- Issuing letters of reprimand
- Imposition of certification requirements to ensure compliance with the terms of a grant.
- Suspension or termination of a grant; and/or personal suspension or debarment. Institutions are required by the regulations to impose sanctions on those found guilty of research misconduct. This guide does not proscribe specific sanctions.

If there is involvement of violations

Agencies also may issue additional sanctions beyond those of the institution. If criminal or civil fraud violations have occurred, the agency will refer the findings to the appropriate governmental authority for their necessary review and action.

Annex A

Whistle-Blowing Reporting Guide

1. According to Host Institution's policies and or guidelines for whistle-blowers:-

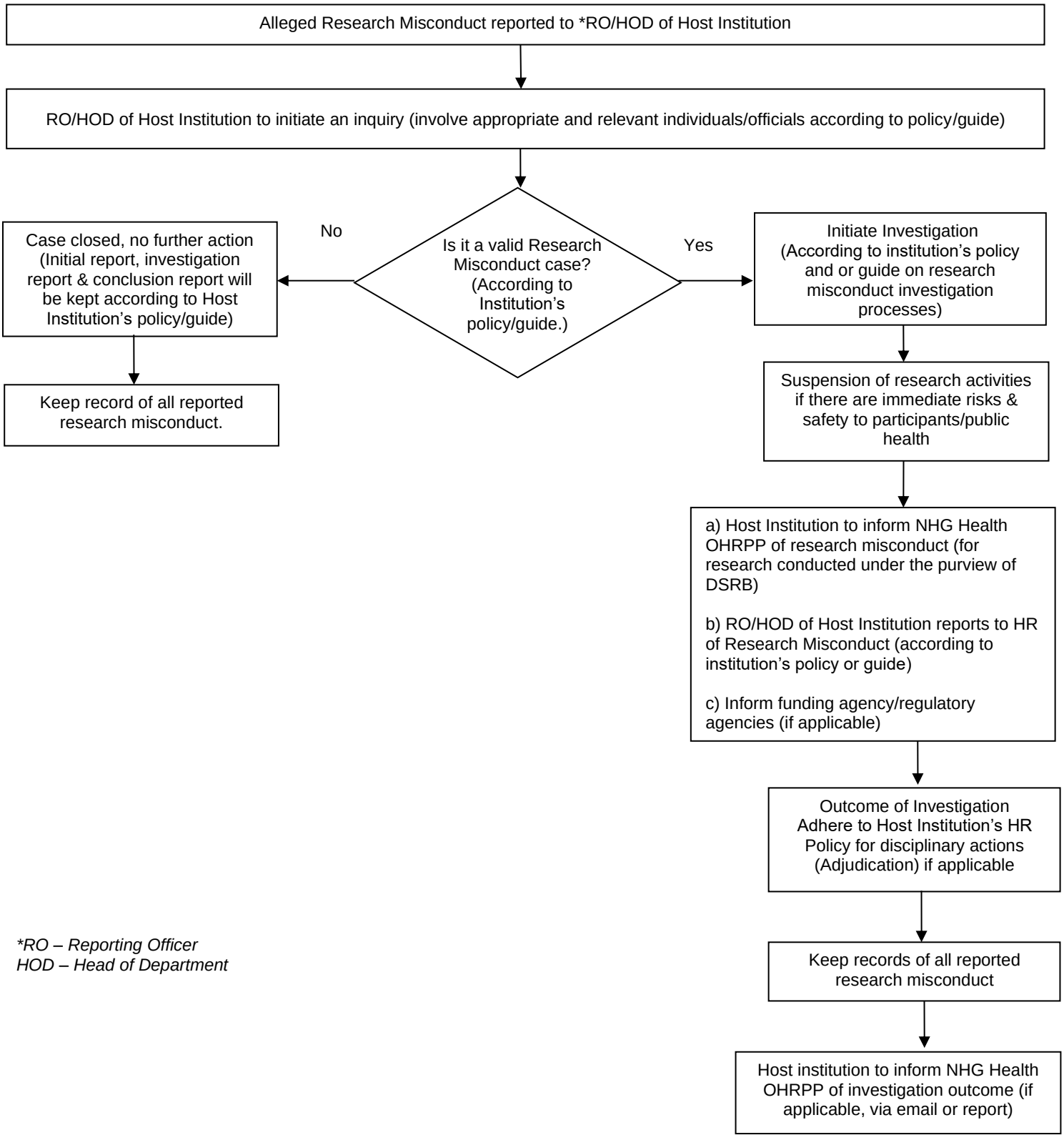
    a. The whistle-blower is encouraged to provide their identity as this may provide for remedies if it can be shown that a whistle-blower suffered discrimination due to retaliation for the allegation brought under the legislation.
    b. The identities of whistle-blowers must be kept confidential so as to protect them from against any retaliatory acts from others.

2. The Reporting Officer(RO)/Head of Department(HOD) of Host Institution and or Institutional Office who receives the allegation from the whistle-blower should take down the following information from the whistle-blower:

    a. Name
    b. Designation, Institution/Organization & Department (if applicable)
    c. Contact details (Telephone/Hand phone number, email address)
    d. Details of the alleged research misconduct
    e. Time and date of the report of the alleged research misconduct
    f. Evidence of the research misconduct
    g. Other information or details which would assist in the investigation

** This Reporting Guide for Whistle-Blowers serves as a guide and should not be viewed as an official policy or statement. OHRPP recommends researchers to ensure that they confer with their institution's policy and guidelines for any components of research misconduct reporting that they are unsure of.*

Annex B Research Misconduct Reporting Flowchart Guide



**RO – Reporting Officer*
HOD – Head of Department

An allegation of research misconduct is reported to the individual's Reporting Officer (RO)/ Head of Department (HOD) of Host Institution.

1. RO/HOD in consultation with appropriate and relevant individuals of Host Institution, determines validity of research misconduct allegations.

2. If the allegation does not contain sufficient specific information and does not fit the criteria of research misconduct, the RO/HOD in consultation with appropriate and relevant individuals of Host Institution then determines that the allegation is invalid and close the case, while maintain all documentations according to Host Institution's Internal Processes/ Standard Operation Procedures (SOP) to manage Research Misconduct.

3. If the allegation contains sufficient specific information and fits the criteria of research misconduct, the RO/HOD in consultation with appropriate and relevant individuals of Host Institution then determines that the allegation is valid, according to Host Institution's Internal Processes/SOP to manage Research Misconduct.

4. The Host Institution should then notify the alleged, NHG Health OHRPP, Institution's HR, the appropriate funding agency (if applicable), regulatory authorities (if applicable)in writing and initiate an inquiry to determine if the allegation warrants further investigation according to institution's policy and or guide. An investigation is warranted if:-

    a. There is a reasonable basis for determining that the allegation involves grant funding research, fits the criteria and definition of research misconduct; and

    b. Preliminary information and fact gathered from the inquiry by the RO/HOD, indicates that the allegation may be substantial.

5. Investigation process on research misconduct according to Host Institution's policies and or guidelines:

    a. The inquiry should be completed within the stipulated number of days, unless due to unforeseeable circumstances, an extension period may be warranted. The Host Institution should prepare a written report and provide the alleged the opportunity to review and comment on the inquiry report. The Host Institution should notify the alleged whether the inquiry found that an investigation is warranted and may also notify the complainant who made the allegation.

    b. The investigation should commence within the stipulated number of days after determining that an investigation is warranted and the alleged should be notified. The Host Institution should take necessary actions to ensure the procurement and custody of all the research related records, materials and

c. evidence required to conduct the investigation. Whenever additional and pertinent items become known or relevant to the investigation, the alleged should be notified. The investigation should be completed within the stipulated numbers of days.

d. The Host Institution should give the alleged a draft copy of the investigation report with a copy of the evidence (with supervised access) on which the report is based. The alleged response to the draft report should be submitted within the stipulated number of days. The Host Institution may also provide a copy of the draft report to the complainant.

e. Based on the outcome of the investigation, recommendations (which are reviewed) and corrective actions, such as sanction are required to be determined by the Host Institution. The Host Institution should adhere to their HR policies and or guides for disciplinary actions (Adjudication).

6. If at investigation, immediate risk to public health and or safety is apparent; all research activities must be suspended until further notice.

7. The RO/HOD of Host Institution should report the research misconduct to their HR or according to the institution's HR policy and or guide. If required, the Chairman of Medical Board (CME) or Chief Executive Officer (CEO) of the Host Institution may be involved.

8. If the outcome of the investigation warrants disciplinary actions; Host Institution should adhere to their HR policies and or guides for disciplinary inquiry for offences.

9. The Host Institution should inform OHRPP of the outcome of the research misconduct either via email or a formal letter, for valid misconduct cases.

10. If a valid research misconduct is determined, the Host Institution should inform the funding agency. A copy of the evidence, the investigative report, recommendations made by the institutional official, the subject's written response to the recommendations and if any corrective action have been or being taken should also be provided, if required by the funding agency.

* *This Research Misconduct Reporting Framework serves as a guide and should not be viewed as an official policy or statement. OHRPP recommends researchers to ensure that they confer with their institution's policy and guidelines for any components of research misconduct reporting that they are unsure of.*

2.9 References & Acknowledgment: Research Misconduct Framework Reporting Guide

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PROTECTION OF HUMAN SUBJECTS

3.1 PROTECTION OF HUMAN SUBJECTS

Background

The protection of human research subjects require that the evaluation of research applications that involve human subjects, take into consideration the risk to subjects, the adequacy of protections against risk, potential benefits of the research to subjects and others, and the importance of the knowledge to be gained. NHG Health DSRB policies and guidelines specify that reviewers should take into account, in determining overall impact that the project in the application could have on the research field involved the adequacy of the proposed protection for humans. Therefore, reviewers should evaluate the proposed plans to protect human subjects from research risks, as appropriate for the research proposed, as one of the review criteria that factor into the evaluation of scientific and technical merit. In addition to NHG Health DSRB, institutional and regulatory authorities regulations on the protection of human research subjects, there are policies set in place that require Clinical Trial applications to include a data and safety monitoring plan and for Phase III clinical trials to also have in place a data and safety monitoring board to monitor complex or potentially risky studies.

Did you know?

For Principal Investigator (PI) -initiated trials, data and safety monitoring should be performed by the PI and his/her team of Co-Investigators.

Definition of Research and Human subjects

Research is defined generally as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." It includes activities which meet this definition, whether or not conducted under a program considered "research" for other purposes. If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research. A human subject refers to a living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, or
- Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

3.2 ETHICAL PRINCIPLES GUIDING HUMAN SUBJECT RESEARCH

Ethical Principles Guiding Human Subjects Research

Documents such as the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report articulate fundamental ethical principles that represent the framework for the conduct of human subjects research. Researchers should be familiar with the three foundation principles of the Belmont Report: respect for persons, beneficence, and justice. Closely related to these principles is the concept of informed consent, which is crucial to conducting human subjects research responsibly.

Respect for Persons

Respect for persons refers (in part) to the ethical obligation to uphold autonomy, that is, the right of competent individuals to make decisions about their own lives. According to the Belmont Report, "To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others." Respecting autonomy requires, for example, that a researcher honor the decision of a potential subject who refuses to participate in a research protocol. OHRPP provides guidance for researchers if they are seeking to enroll subjects with diminished autonomy, such as children.

Beneficence

Beneficence obligates researchers to protect and uphold the well- being of others. According to the Belmont Report, beneficence requires one to "do no harm" and "maximize possible benefits and minimize possible harms" Beneficence further means that researchers are responsible for weighing the risks of a protocol against its potential benefits. Researchers must design protocols that expose subjects to the least risk possible. Being beneficent may, for example, require that a researcher cease work with a specific subject or halt an entire protocol if a subject has been harmed.

Justice

Justice calls for benefits and burdens to be distributed fairly. Justice might require researchers to develop a strategy for ensuring that subjects, or perhaps the population from which research subjects were drawn, receive a fair share of the benefits stemming from the research. According to the Belmont Report, "An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly." For example, because it is easy to recruit a particular subset of the population for a protocol, excluding other potential groups cannot be justified. All researchers have an obligation to treat human subjects in a respectful and honest manner, which includes obtaining proper consent from potential subjects before a protocol starts.

Informed Consent Process

Conducting research on human subjects in a responsible manner usually requires that informed consent, or what is often referred to as valid consent, has been obtained from potential subjects. Three fundamental components of informed consent are:

- Subjects must be adequately informed about the research protocol in which they are being asked to enroll, including being notified about the potential benefits and risks that may be associated with participation.

- The decision of each subject to enroll must be voluntary. In other words, the subject should not be unduly influenced or coerced into making a decision about participation. Undue influence or coercion includes, but is not limited to; offering potential subjects an exorbitant amount of money for enrolling It also would include pressuring a vulnerable person such as a prisoner to enroll by offering a reduced prison sentence in exchange for participation in the research protocol.

- A subject must be competent to voice a decision about participation. The subject must be capable of understanding the information presented about the research and of appreciating the consequences of enrolling or of declining to enroll. However, in certain circumstances a non-competent individual, such as a child could participate if that child's parent or legally authorized representative approves of their participation.

The Consent Form

Obtaining consent usually occurs through a process whereby potential subjects are asked to review and sign a consent form before being enrolled in to the research. The OHRPP which oversees DSRB sets out the following considerations that must at least be included in the informed-consent document:

A statement that the study involves research, an explanation of the purpose/s of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

- A description of any reasonably foreseeable risks or discomforts.
- A description of any benefits to the subjects or to others that may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained and that notes the possibility that the regulatory authorities, IRB, and sponsor's monitors may inspect the records.
- Should the research involves more than minimal risk, an explanation of any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject, and whom to contact in the event of complaints about research.
- A statement that participation is voluntary, that refusal to participate and withdraw from the research will not involve penalty or loss of benefits to which the subject is otherwise entitled.

A subject's consent is not valid if, for example, the researcher fails to describe adequately the risks associated with participation or if a consent form is overly technical and confusing. Because subjects in research may be vulnerable to harm, it is of the utmost importance that researchers explain the research clearly and thoroughly before the consent form is signed. This might include, but is not limited to, describing the research and answering questions in the participant's native language. Researchers also must ensure that consent forms are written at a reading level appropriate for potential subjects.

It can be difficult to determine whether the activity constitutes research on human subjects, and if so, whether a formal process for obtaining consent is necessary. In general, if the research involves human participants and can pose some non-trivial risk, it is highly likely that consent is required. It is critically important that researchers consult with the *DSRB to determine if and how guidelines for human subjects research, including those pertaining to informed consent, apply to their work. Merely complying with the law does not necessarily satisfy all of a researcher's professional obligations

when conducting research with human beings. However, researchers must fulfill obligations beyond those defined by laws or codes of ethics. They must always be mindful that their foremost responsibility is to the volunteering participants when conducting research on human subjects. The failure of researchers to protect their subjects not only risks harm to individuals and expense to them and to society, but also erodes profoundly the public's trust in research communities.

* The NHG Health Domain Specific Review Board (DSRB) is an independent committee responsible for ensuring that the research proposal protects the well-being, safety and rights of the research subjects. Research from other officials of institutions conducted under the oversight of NHG Health DSRB, may not override the decision of DSRB.

Do you know?

US FDA-regulated investigational new drug (IND) research activities cannot apply for waiver of informed consent and Exempt Review.

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CONFLICTS OF INTEREST & COMMITMENT

4.1 CONFLICTS OF INTEREST & COMMITMENT

Background

We often find ourselves in situations where two or more competing interests create the perception - or the reality - of an increased risk of bias or poor judgment. Such challenging situations come up regularly in both our personal and professional lives. Collectively, we refer to these as conflicts of interest. Such conflicts are not inherently bad. Instead, they should be expected. It is how they are handled that can lead to improper, inappropriate, or bad outcomes.

Scientists have professional, fiduciary, and ethical interests in the responsible conduct of research, but these interests may be compromised by personal interest. A common worry is that financial interest in the outcomes of research can result in unethical behavior or even criminal misconduct. However, it is also plausible that interests other than financial interests could compromise the responsible conduct of research. Examples of non-financial interests that might conflict with the integrity of science include career advancement, publishable results, service to patients or students, fame, power, or family and friendships. Another potential conflict can come in the form of conscience. An individual might suffer a conflict of interest if the mission or expectation of, for example, the institution is not compatible with his or her personal values.

4.2 CONFLICTS OF INTEREST AT THE INDIVIDUAL LEVEL

Bias in Judgment

Objectivity is the sine qua non of scientific discovery. But bias in judgment is virtually impossible to eliminate. There are often subtle and not so subtle, pressures that can influence how we perceive and how we act. All research professionals understand the pressures to publish, to get funding, appointments, promotions, and to earn respect from peers. Many strive for the ultimate validation and highest order of recognition - the Nobel Prize. In an effort to succeed, there are myriad areas where bias can influence judgment and diminish objectivity. A desire to validate a “pet theory”, overconfidence about a particular concept, over reliance on a belief held by a special group, ruling out data that don't support a hypothesis, and internal or external pressures to get a specific result are all influences that may lead to distortions in objectivity. Any of these biases or pressures may lead to what sociologists call selective in attendance. Your mind-set may cause you to overlook important data or to misperceive critical observations. Bias can be too subtle to recognize and too difficult to control. It can creep into how research questions are selected and framed, the choice of research design, the selection of research participants, and how the data are collected, analyzed, interpreted, and ultimately published. Whether you describe the glass as half empty or half full is influenced by what you want your results to look like. Bias can even influence the sharing of the results of the study.

Academic Conflicts of Interest or Intellectual Bias

"Academic scientists have special responsibilities to disseminate knowledge, to maintain academic standards, to critique the current state of knowledge, to synthesize existing knowledge, and to apply knowledge to solve basic and applied problems."

The peer-review system is the benchmark of the scientific process. An academic conflict of interest could occur if an individual interferes with the peer-review process for some type of intangible personal gain. For example, bias can cause a reviewer to respond positively to a manuscript because it presents results favoring a method or production in which the reviewer has a personal interest or a reviewer may act to delay the publication of a competitor's manuscript in order to strengthen his or her own chances for publication or funding. There are studies which mentioned that publication practices of researchers which found that researchers reported delaying of publication of results for their own advantage. In addition, negative results are less likely to be published but that even positive findings are withheld if this is perceived as advantageous for the authors. In one study, 20% of researchers reported delaying publication of results for their own advantage. These are intangible interests, and they are indigenous to every researcher. Indeed, the drive for recognition can be overwhelming, particularly when a future position or livelihood depends on these public achievements. These are the sources of "intellectual bias" that have long been recognized by the research community but that must also be recognized and addressed by the individual researcher.

Other Types of Conflicts of Interest

In addition to academic conflicts of interest, there are other intangible conflicts that can compromise objectivity. For example, conflicts of commitment, which may also be called conflicts of effort or conflicts of obligation, occur when the extent of time spent on a secondary activity competes with the time expected to be spent on teaching, research, or service by the primary employer. Most institutions and or universities have policies allowing 20% of a faculty member's effort, or one day a week, for outside activity. (Do confer with your institution’s policies and guidelines.)

A conflict of conscience occurs when personal beliefs influence objectivity in research. For example, a scientist may have a particular view on abortion that influences his or her view of the scientific merit of a study that uses human embryonic stem cells.

Clinical Research

Clinical researchers subscribe to three basic elements: scientific integrity, patient safety, and investigator objectivity. Yet these researchers are likely to experience conflicts of interest by virtue of their altruistic dedication to the pursuit of knowledge while striving to maintain the welfare of the human volunteers participating in their investigations. Bias and decreased objectivity are of particular concern in the clinical-research setting, where the rewards and risks are both potentially great. Here, bias in judgment might creep in not only to influence the questions pursued and the choice of research design but also affect the selection and retention of research participants, the reporting and attribution of adverse events, and the collection, statistical analysis, interpretation, and reporting of the data It is in the clinical setting that bias and loss of objectivity not only could it damage the entire research enterprise, which we know reduces the public's trust in research, but could also, more grievously, lead to injury and harm to study participants.

In assessing conflicts of interest, we need to consider the likelihood of bias as well as the consequences of the conflict of interest, because at times the consequences can be lethal.

Safeguards

Fortunately, there are safeguards that can be put into place to help reduce bias and improve objectivity. Conscientious application of the scientific method is one such safeguard. However, the investigator should declare to DSRB if conflicts of interests arise during the conduct of the study.

Financial conflicts of interest

Financial conflicts of interest are considered tangible conflicts, because they can be seen and measured. While they appear easier to deal with than intangible conflicts of interest, they may not be. Financial arrangements with sponsors are affecting many areas of scientific life. A growing literature is documenting, with disturbing accounts, how the new entrepreneurial environment is altering the publication practices and prescribing patterns of investigators and clinicians. Intangible conflicts of interest, as previously described are problematic, but they are widely recognized and shared. What has captured the attention of governments, the scientific community, and the public are those conflicts caused by money and financial relationships, the tangible conflicts of interest. Many fear that the cost of these relationships could be the integrity of science itself.

4.3 HOW TO PREVENT CONFLICTS OF INTEREST & COMMITMENT

Introduction

When there is a divergence between an individual's interests and their professional responsibilities such that an independent observer might reasonably conclude that the professional actions of that individual are unduly influenced by their own actions, is known as a conflict of interest.

In the research arena, conflict of interest is common and it is important that they are disclosed and properly dealt with. Conflict of interest has a high potential in compromising judgments and decisions that should be made with impartiality. Such a compromise could undermine the community's trust in research.

Financial conflict of interest are always on the public's mind, however, other conflicts of interest may also occur in research, which may include personal, professional and institutional advantages. It is also a serious matter and raises concerns about the integrity of the individuals and or the management practices of the institution should a perception that a conflict of interest exists.

There should be a readily available comprehensive policy in place within research community and institutions, looking at actual and potential conflicts of interest.

A. Responsibilities of Institutions

Maintain a policy

All institutions should have a policy for the management of conflict of interest. There should be a range of responses, depending on the nature of the conflict, to prevent researchers from influencing decisions unfairly and avoid unwarranted perception that a deaf ear has been turned unto a conflict of interest.

Institutions and organizations should ensure that the policies or guidelines on advising the management of conflicts of interest are made available. In addition to the individual's institution policies and guidelines, the following guides should be observed:

- The institution should ensure that the policy is clearly written and readily available to all.

- Encourage a full disclosure by those involved of the circumstances giving rise to concerns about each conflict of interest. A small group in confidence should be provided for people who are unwilling to disclose publicly. In situations where those involved are unwilling and unable to make any disclosure at all, they should withdraw from process that could be influenced by conflicts.

- When a circumstance constitute a conflict of interest, or may lead people to perceive a conflict of interest, the individual must not take part in decision making processes. The most satisfactory approach is for a complete withdrawal (e.g. leaving the room while the outcome of a review is being deliberated).
- Records must be kept of how each conflict is managed, even if confidential information is removed. The possibility of conflict of interest is acknowledged in each case along with a summary of how it was managed, is important.
- The policy should encompass the full range of possible conflict of interest, and the policy must be reviewed regularly to enable amendment informed by experience and legislative and regulatory developments.

B. Responsibilities of Researchers

Disclose conflict of interest

Researchers may have frequent conflict of interest that cannot be avoided. In research, decision making processes often require expert advice, and the community of experts in a field can be so minute that all the experts are linked with the matter under decision. An individual researcher should therefore preempt the conflict from time to time, and be alert and ready to acknowledge the conflict and make the disclosures appropriately.

Researchers' should deploy the following approach to manage conflict of interest:

- Read and understand the institution's policy on conflict of interest.

- Maintain records of activities that may potentially lead to conflicts, examples (but not limited to) board of directors, membership of committees, selection committees and financial delegation of in receipt of stocks or shares or cash from external parties to support research activities.

- When an individual is invited into a committee or equivalent, review current activities for actual or apparent conflicts and bring possible conflicts of interest to the attention of those running the process.

- Individuals must disclose any actual, apparent or perceived conflict of interests.

Do you know?

In the US, federal regulations defer, in part, to institutional definitions of conflicts of interest. Not surprisingly, institutional standards vary greatly. Regarding stock ownership, many use the federally defined threshold of $10,000 or 5% of total shares as a definition of significant financial interest that must be declared. However, some institutions have been somewhat stricter. For example, Harvard scientists are prohibited from working for a company in which they have more than $20,000 in stock.

Professional societies and journals are another important source for guidance on the management of conflicts of interest. These are quite variable in their scope and rarely enforced, but two examples are noteworthy. The first is a policy statement from the American Society of Gene Therapy (ASGT). In a statement adopted in April of 2000, the ASGT concluded that 'investigators and team members directly responsible for patient selection, the informed consent process and/or clinical management in a trial must not have equity, stock options, or comparable arrangements in companies supporting the trial.'

The second example is the stated requirements for publication in the New England Journal of Medicine. As early as 1984, the journal requested that 'all authors disclose to [the Editor] any associations they had with businesses that could be affected by their work – including direct employment and consultancy, stock ownership, and patent-licensing arrangements. These guidelines and regulations represent recognition by regulatory and scientific communities that the integrity of science is placed at risk by the presence of unmanaged or substantial conflicts of interest.

Professional Societies and Associations

Clinical researchers must be able to design and conduct their studies in an unbiased and objective manner that is free from conflicts caused by significant financial involvement with the commercial sponsors of the research. In this case, the only sure safeguard is for the investigator to have absolutely no financial relationship with entities that support his or her research. This approach has often been referred to as "zero tolerance."

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DATA MANAGEMENT PRACTICE

5.1 DATA MANAGEMENT PRACTICE

Background

Conducting research responsibly is more than avoiding intentional fabrication or falsification of data. This is because data provide the factual basis for scientific work and the value of research depends directly on integrity in the collection, use, and sharing of data.

Policies or guidelines which address the ownership of research materials and data, their storage, their retention beyond the cessation of the project and appropriate access to them by the research community is required. It is important to retain the research data because it may be all that remains of the research work at the end of the project. While it may not be practical to keep all the primary source of materials (e.g. biological materials, test results, questionnaires or recordings), durable records derived from them (e.g. assays, test results, laboratory and field notes and transcripts) must be retained and remain accessible. The researcher must then decide which data and materials should be retained. However, the retaining of such materials could be determined by institution's policies and guidelines, law and or funding agencies. (Do confer with your institution's guidelines and or policies.)

The main aim of retaining sufficient research data and materials is to justify the research outcomes and to defend them if they are challenged. Therefore, the potential value of the data and materials for future research should also be considered, especially where the research would be difficult or impossible to repeat.

What is research data?

Data is defined as a collection of facts, measurements, or observations used to make inferences about the world we live in. However, data in research can range from material created in a wet laboratory, such as an electrophoresis gel or a DNA sequence, to that obtained in social-science research, such as a completed questionnaire, videotapes, and photographs. Research data can include microscope slides, cell lines, climate patterns, soil samples, astronomical measurements, and spectrographic analyses. In addition, custom software or hardware and specialized methods can be considered as data too.

Who owns the research data?

Identifying ownership of research data and primary materials

Although graduate students, postdoctoral fellows, or even some faculty in academia performing research may believe that they own the data collected, they are wrong. Research institutions should have policies or guidelines on the ownership of the research data and materials acquired by staff during research. The ownership may be influenced by the possible funding arrangements for the project. However, as a general rule of thumb, all materials and data retained at the end of a project are the property of the institution that hosted the project. That would be the most satisfactory arrangement.

For example, if the host institution is Institution ABC, than all materials and data retained at the end of the project is the property of Institution ABC.

The PI takes responsibility for the collection, recording, storage, retention, and disposal of data. When data is published, the copyright is retained by the PI, who then assigns it to the publisher of the journal. Data and data books collected by undergraduates, graduates, and postdoctoral fellows on a research project belong to the host institution, and students should not take their data when they leave without making appropriate arrangements. Retaining copies of data is allowed with permission, and although this is not always done, it is certainly good practice.

When study team members leave an institution, they have to negotiate with the institution to keep their grants and data. With industry funded or privately funded research, data can belong to the sponsor, although the right to publish the data may or may not be extended to the investigator.

Do you know?

The Bayh-Dole Act
The Bayh–Dole Act or Patent and Trademark Law Amendments Act is a United States legislation dealing with intellectual property arising from federal government-funded research.

The Bayh-Dole Act of 1980 allowed universities to have control of the intellectual property, such as patents, generated from federally funded research. With a patent in hand, universities could exclusively license the patent to businesses. For the past 25 years or so, many universities, including Columbia University, have benefited from the licensing revenue. Recent inventions, in the form of new drugs and computer technologies, have also helped the public. The law has encouraged new relationships between academic researchers and companies, but critics such as Derek Bok (2003) have charged that Bayh-Dole promotes universities' selling out their interests to industry rather than relying on raising money from tuition and other sources.

5.2 BEST WAYS TO COLLECT DATA

Most institutions may not be equipped with the manpower or necessary skills to provide education and training resources needed to formally instruct trainees and junior

researchers in good data-management practices. Therefore, for the scientific enterprise to be productive in the long run there should be positive and comprehensive mentoring of students in data management.

In essence, there is no one way to keep data, but data should explain why research was done, how it was done, where primary data are kept, what happened and didn't happen, an interpretation of the data, and what's next. Data should allow another researcher the ability to repeat the experiment. The data also should be kept in a way that is easy to understand. Legally, federal sponsors of research have the right to audit data and examine records that are relevant to a grant. Data can also be important commercially, in new drug applications to the FDA and for patents on new technologies.

The practice of keeping research notebooks, paper vs. electronic

While many experts recommend collecting data in bound and paper-based notebooks with numbered pages on which the date and time of research can be clearly enumerated, many researchers employ a mixture of electronic and paper based approaches.

While both types of data can be manipulated by someone deciding to engage in misconduct, checks and balances in both can make it harder to do so. The British Medical Research Council advice on good record-keeping states that data should be stored in such a way that it permits a complete retrospective audit, and that it is monitored regularly to ensure completeness and accuracy. The following is a best-practice summary for good record-keeping:

- Raw data should be recorded and retained either in indexed laboratory notebooks with permanent binding and numbered pages or in a dedicated electronic notebook.

- Recording should be done as soon as possible after data are collected and specific note should be made as to whether it represents the date of the recording or the date of collection, if the two are not the same. Modifications should be clearly identified and dated.

- For paper records, a few pages should be kept at the front of a bound book for tables of contents.

- Writing should be done in permanent ink and legibly.

- Copies of original notebooks should be kept elsewhere for safekeeping.

- A second loose-leaf notebook should be kept for data, such as photographs, machine printouts, questionnaires, chart recordings, and autoradiograms that cannot fit into the primary record book.

- Supervisors should review and sign off on notebooks to signify their completeness and accuracy. Queries should be addressed as soon as possible and changes signed by both. Some data may need to be witnessed by a colleague. (Witnessing of data is especially important in commercial research laboratories.)

- Methodology used in an experiment should be written down or a reference to how an experiment deviated from a standard laboratory technique should be explained.

- Lot numbers should be recorded and special attention should be given to the hazardous-substance use.

- Equipment calibrations need to be recorded.

- Data should be noted directly into notebooks without putting it on scraps of paper or relying on memory beforehand.

- All raw data should be included. Be honest.

- Errors should be identified by crossing out the mistakes without obscuring the initial data.

- Material should be logged chronologically.

- Data interpretation should be carefully written.

- Areas in a notebook left blank intentionally should be indicated.

- Correspondence and note conversations related to experiments should be kept.

- Consent forms should be kept with raw data.

- Electronic records need to be carefully monitored.

- Electronic data should be backed up on a disk with a hard copy; relevant software must be retained to ensure future access, should security of data be an issue.

Authorizations to collect data

Institutional Review Boards and human-subject research

If in doubt, researchers should contact NHG Health DSRB or their institutional ethics review board on how to go about data collection in their research. The NHG Health DSRB, like IRBs elsewhere, is instituted to ensure the protection of the rights and welfare of human

subjects participating in research at Institutions as well as all institutions under the oversight of NHG Health DSRB. The boards have the power to approve, disapprove, or modify research protocols involving human subjects. The DSRB operates under the following guidelines and applicable regulations:

- US Department of Health and Human Services (DHHS).
- Regulations 45 CFR 46 – when the research is funded by US Federal Funds e.g. funded by NIH, NCI etc.
- US Food and Drug Administration (FDA) Regulations 21 CFR 56, 21 CFR 50 – when research is being conducted under Investigational New Drug (IND) Application or Investigational Device Exemptions (IDE) or when the results of research are intended to be submitted to FDA.
- International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice E6 (R1), Current Step 4 version dated 10 June 1996 – All clinical trials involving medicinal products is subject to ICH GCP.
- Medicines Act and Medicines (Clinical Trials) Regulations 2000 – All clinical trials involving medicinal products are subject to the Medicines Act and Medicines (Clinical Trial) Regulations 2000.

The NHG Health DSRB monitors studies and may suspend or terminate them if there is a danger to subjects or if a researcher is not complying with appropriate guidelines. The NHG Health DSRB is responsible for determining whether the benefit of the research is sufficient to counterbalance any risks associated with the project. They monitor the nature of the informed consent given to the research subjects as well as the issue of whether confidentiality is maintained during the study and afterwards. NHG Health DSRB also ensures that special protection is afforded to vulnerable groups, such as children, pregnant women, fetuses and neonates, the cognitively impaired, and prisoners. They also ensure that selection of subjects is equitable and that participation in a research project is voluntary.

Did you know?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted by the United States Congress and signed by President Bill Clinton in 1996.

The HIPPA expanded the confidentiality requirements set forth under 45 CFR 46 with respect to patient medical records and information. Researchers looking at clinical data need to know whether they are doing investigations that they can certify will not result in the disclosure of information about a patient; and whether they can obtain a waiver of authorization from a Privacy Board (a committee that looks at HIPAA issues at a university

and other institutions that don't use the IRB for privacy issues) or need authorization from a patient.

5.3 HOW LONG SHOULD RESEARCH DATA AND MATERIALS BE KEPT?

Institutions should provide facilities for the safe and secure storage of research data and for maintaining records of where research data are stored.

According to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice E6 (R1), (ICH GCP), it is recommended that essential documents (e.g. Ethics approval letter) should be retained until at least 2 years after the last approval of a marketing application and until there are no pending or contemplated marketing applications, or at least 2 years have lapsed since the formal discontinuation of clinical development of the investigational product, or 6 years after the completion of the clinical trial. These data should be retained for a longer period of time if required by the applicable regulatory requirements and or by an agreement with a sponsor. It is the sponsor's responsibility to inform the investigator/ institution when these documents no longer need to be retained. The documents may be archived by electronic means, microfilm or other suitable archiving technology. It is recommended that the researcher comply with his/her institution's policies or guidelines on how long research data should be stored and store it accordingly.

Did you know?

Legally, data need to be retained for patent protection and in case there is any misconduct allegations pending based on the data. Beyond the professional and legal obligations, researchers in practice will store data as long as they feel it is necessary. But confidential data has to be stored in such a way that access cannot be available. Audits may be necessary to determine whether data have been stored properly. Some investigators store electronic data with archival resources. Minimum storage period is 3 years for all research, and 6 years for clinical trials.

What are the obligations to share data?

There should be a policy on research data ownership and storage. This policy should:-

- Cover all situations possibly anticipated and potentially arising in research, including situations when researchers move to another or between institutions or when data are held outside the institution. Agreements covering ownership and research data storage should be reviewed whenever there is movement or departure of a research staff.

- Whenever appropriate and possible, research data should be held in that researcher's department or other appropriate institutional repository (NHG Health DSRB Database), although researchers should be permitted to hold copies of the

research data for their own use. Agreements for material held in other locations should be documented.

- In projects that involve multiple institutions, an agreement should be developed at the beginning of the research to cover the storage of research data and materials within each institution and these research data and materials must be stored in a safe and secure storage.

Do you know?

In 2003, the National Institutes of Health (NIH) Data Sharing Policy instituted a new policy on data sharing. The new policy applies to investigator-initiated one-year grants and may have an impact on smaller grants too. The goal of the policy is to expedite the timely release and sharing of final data to enhance the research enterprise. Release of data can be complex. Intellectual property considerations, nongovernmental sponsorship issues, and human-subject confidentiality protection must be considered before data are released. The NIH requires that investigators asking for funding include with their grant applications information about how they plan to share the data generated from their research. If a grant is awarded, the data-sharing plan must be enacted.

5.4 REFERENCES & ACKNOWLEDGMENT: DATA MANAGEMENT PRACTICE

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3) Harvard University Research Integrity Office of the Vice Provost for Research Webpage (https://vpr.harvard.edu/)
4) Harvard Office of Technology Development – Guidelines, Policies and Forms (http://otd.harvard.edu/resources/agreements/materialtransfer/#why)
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19) The European Code of Conduct for Research Integrity – March 2011 (https://allea.org/code-of-conduct/)
20) The University of Kentucky Office of Research Integrity - Data Retention & Ownership Policy (https://www.research.uky.edu/research-misconduct/data-retention-and-ownership-policy)
21) The University of Oxford, University of Administration and Services (UAS), Research Data Management (http://www.admin.ox.ac.uk/researchsupport/integrity/misconduct/)

MENTORSHIP AND TRAINEE RESPONSIBILITIES

6.1 MENTORSHIP

Background

Mentoring the next generation of scientists is a shared responsibility of all current scientists. A mentor should have a willingness to share his experiences with trainees and assists the trainee in understanding and adhering to the standards of conduct within their profession. In this way, senior investigators pass on the informal and possibly unwritten standards from one generation of scientists to the next. Within a small research group, this mentoring may readily occur. However, many current research groups are too large or competitive and regardless of whether or not this has changed the extent to which new scientists become aware of prevailing standards of conduct, it appears that issues of responsible conduct are not discussed frequently.

Significance of the Mentor-Trainee Relationship

Some commentators on this subject emphasize the personal nature of the mentor trainee relationship. Others caution that boundaries are important. In either case, no two mentors will behave in exactly the same way – each brings to the task his own strengths and preferences. However, every good mentor will act from a sense of responsibility and a commitment to the future of the trainee.

6.2 ROLES

Role of Institutions

Institutions must ensure that each research trainee, whether part of the institution or from overseas or elsewhere, has an appropriately qualified and trained supervisor by setting standards for supervision and mentorship. For effective intellectual interaction, the ratio of research trainees to supervisors must be appropriately low.

Induction for trainees

To ensure that research trainees understand the importance of responsible research conduct, the institution should:

- Provide induction and training for all research trainees. Technical matters appropriate to the discipline, research ethics, occupational health and safety and environmental protection should be covered in the training.

- Maintaining key documents on the responsible conduct of research, institutional guidelines and policies on the conduct of research, NHG Health DSRB requirements for research involving humans, privacy and confidentiality and

institution's guideline or policies for dispute resolution should be made readily available.

Researchers and Mentors

- Ensure training – Researchers and Mentors should ensure that training commence as soon as possible for a trainee. Training should encompass discipline-based research methods and other relevant skills, including the ability to interact with the industry and work with diverse communities and disciplines.

- Provide support – The mentor should guide the professional development of a trainee and provide guidance in all matters relating to research conduct and oversee all stages of the research process. This includes identifying the research objectives, obtaining NHG Health DSRB and HSA, approvals, if applicable, obtaining grant approvals and fundings, conducting the research, and reporting the research outcomes in the annual report forms as required by NHG Health DSRB, HSA or other relevant funding bodies, where applicable.

- Ensuring the validity and accuracy of research – Supervision of trainees includes having an oversight of their research outcomes. The researchers or mentor must be satisfied that the research methods and outcomes by the trainees are appropriate and valid.

- Ensure appropriate attribution – Supervisors or mentors should ensure that appropriate credit is given to trainees for their work and or contribution.

Trainees

- Seek guidance – A trainee must demonstrate a professional attitude towards the research. Frequent open communication with the mentor or supervisor is pertinent. This will require the cooperation of both parties. The trainee should not wait until approached by the mentor or supervisor or a problem arises, but should be engaged actively in maintaining an appropriate schedule of meetings.

- Undertake induction program and training – A trainee should complete all induction and relevant training courses as soon as possible after commencing in an institution.

The Role of the Mentor

Although the role of the research advisor or supervisor can lead to mentoring opportunities, the mentor's role is different from that of a supervisor or adviser. The essence of mentoring has been described as being an adviser, teacher, role model, and friend. In many cases, the mentor is ideally an advocate for trainees. The role of the mentor is often complex and takes on many forms. A true mentor is typically someone who possesses:

- Experience with the research and challenges that trainees face.
- The ability and willingness to communicate that experience.
- Special interests in helping another person develop into a successful professional.

A mentor might be a departmental adviser or another colleague, a project leader, a fellow student, a wise friend, or simply another person with experience. A trainee or protégé in the research setting could be anyone in a junior or apprentice position, such as an undergraduate or graduate student, a postdoctoral fellow, or a junior research staff member. To appreciate potential contributions of mentors it is helpful to consider the wide range of needs to be met:

- Mentors in the sciences should help trainees develop as capable researchers. A mentor can contribute to the trainee's technical development in many dimensions of research, including methods, directions, creative thinking, completing academic or professional requirements, and communication skills.

- Trainees also need support for career development and preparation for the job market. Mentors can help by providing suggestions on the current job market, create opportunities to make contacts with leaders in the trainee's field of research, facilitate introductions to people working in his or her discipline, or networking," and making aware of the range of career options. A mentor also can help a new scientist win grants by providing guidance on the grants to apply for and tips on writing a strong proposal.

- Another focus of mentoring is the socialization of trainees. Such socialization should include guiding ethical development, fostering an understanding of the political, economic, and social elements of interacting within the academic community, and instilling a sense of collegiality. This approach to mentoring includes promotion of skills for teaching, communication, working in teams, and leadership. It also encompasses management of people, interacting with others, listening, expressing ideas, administration and planning, and budget management.

- A particularly important mentoring role is that of an advocate. There are times when the mentor has to step forward and defend or advocate for the trainee where it is appropriate.

6.3 RESPONSIBILITIES

Responsibilities of Mentors

Scientists have a complementary responsibility to be mentors just as trainees in science have a responsibility to seek mentors. Taking an active role in helping to train the next

generation should be part of the definition of a scientist. For this reason, the enterprise of science depends on effective communication not only with regard to scientific concepts and principles, but also about the practice of science, standards of conduct, and ethical and social responsibility. This obligation extends to all members of the community, not just senior researchers. For example, a newly arrived undergraduate student will benefit from the mentoring of a graduate student, technician, or a more senior undergraduate.

a) Be Available

At the core of mentoring responsibilities is the simple admonition of availing oneself. However, some researchers make the mistake of thinking that mentoring will somehow take over their professional lives and leave no time for their research responsibilities. It doesn't have to be this way, nor should it. In the span of a few minutes, a mentor can effectively assist her trainees by being attentive to a few key elements, through careful listening and keeping in touch.

b) Listen Carefully

Listen carefully, focus away from the nuances of word emphasis and body language. Through careful response and a few well-placed questions, clear communication can proceed and support and encouragement provided for trainees.

c) Keep in Touch

Communicating regularly with trainees is essential. The mentor should try to give at least a few minutes to trainees every other day or so. These short exchanges could help the mentor stay aware of what is going on and anticipate problems.

d) Allow for Differences

Successful mentoring, as with any close personal relationship, depends on the personalities of the parties involved. Some trainees learn readily with a minimum of nurturing or guidance, or at least believe that they require a minimum of help. In such cases, frequent and probing discussion initiated by a mentor may be perceived as invasive and micro managerial. Other trainees may require the reassurance of being closely monitored with frequent feedback – both positive and negative. Some mentors are uncomfortable with offering advice or initiating discussions unless first asked, whilst others will readily volunteer information and advice.

e) Let Trainees Make Decisions

The role of the mentor is to provide advice, help, and encouragement. However, the trainee should not be bound to follow suggestions made by the mentor. Ultimately, the trainee must act responsibly in the context of his or her own values, goals, and experience

f) Teach by Words and Example

If a mentor argues for rigorous authorship criteria, but fails to follow his or her own advice, the trainee may have the perception that the mentor is an unreliable source of information and that the standards of conduct in research are poorly defined. It is critically important that mentors explain their actions clearly, because the rationale for even the most exemplary behavior may be esoteric to the uninformed observer, especially for those of different cultural backgrounds.

g) Keep Learning about Effective Mentoring

Responsible mentors should strive to continue learning about effective mentoring, through experience and through the available resources on mentoring. It is also suggested that a discussion about and comparison of mentoring techniques be added to faculty meeting agendas or other faculty events, such as retreats.

Responsibilities of Trainees

Most young or aspiring scientists have at least a modest idea of their ultimate career goals and may have internalized the usual worries that accompany those dreams. The obvious solution is to seek out more senior scientists, and sometimes peers; who have the experience that is lacking. Finding someone who will be an effective mentor should primarily be the responsibility of the trainee.

a) Identify Career Plans

In seeking a mentor; the first step for a trainee is to identify their particular needs. Trainees should assess their skills, talents, and interests, and seek advice from someone who is knowledgeable about suitable career options. Someone who can help with this initial look at career plans may be, or may become, a mentor, but this is not essential. An Individual Development or Career Plan could help in this regard.

b) Locate Prospective Mentors

A trainee should seek prospective mentors; individuals who have succeeded in their own careers on a path the trainee aspire to follow. For example, for some women it would be invaluable to seek the help of women scientists who have met the challenges that they, as trainees, are likely to face. For other women, as well as men, the topical or research experience of a mentor may be more critical.

Qualities to look for in potential mentors include:

- Experience in areas relevant to the trainee's personal and career development,
- An interest in the trainee and his or her career,
- A willingness to make time to meet with the trainee, and
- An ability to provide the trainee with useful advice.

An ideal mentoring relationship depends to a great degree on personal compatibility. Assessing the interpersonal skills of the prospective mentor is much more difficult than gauging his or her success as a researcher. However, because research is defined by

personal as well as professional relationships, personal qualities are as important as any other criteria in identifying a supervisor, thesis adviser, or mentor.

Here are some practical suggestions that new graduate students may consider as they begin a career in research:

- Talk to as many Principal Investigators (PIs) or lab heads as possible.

- Obtain information on the lab from other students in the department. Find yourself a mentor whom you respect and trust. This doesn't have to be set up formally; it should simply be someone you can talk to. It can be a PI, post-doctorate graduate, or a senior graduate student.

- Talk to as many lab members as possible to get information about a lab. Contact previous grad students. Ask candid questions such as:

  “What is the PI's mentoring style? Hands on or hands off? High pressure or laid back? What is the male-female ratio in the lab, and, if the ratio is skewed, is there a significant reason for it?

c) Distinguish between Supervisors and Mentors

Not everyone has the qualities of a good mentor. While the terms "mentor," "thesis adviser," and "research supervisor" frequently are used interchangeably, thesis advisers and research supervisors are not necessarily mentors. Thesis advisers are responsible for ensuring that students fulfill departmental and institutional requirements for the graduate degree and for giving advice about research directions, methods, and publication. Mentors provide information that is essential for professional success, such as how to obtain funding, manage a research lab or group, use time effectively, and understand departmental politics and institutional committees.

d) Be Clear about Needs and Expectations

A mentoring relationship should not be a passive one. The trainee must take an active role in identifying and communicating his or her needs and expectations as a professional-in-training. Although a mentor can provide a unique and invaluable perspective, the mentor's advice should not be accepted without reflection. The trainee must evaluate the mentor's advice in light of his or her own values, goals, and experience.

e) Keep Learning about Effective Mentoring

Trainees should seek to continue learning about the mentoring process to optimize their own experience and to prepare to be effective mentors themselves. Furthermore, faculty and graduate students might encourage one's program or department head to add mentoring as a topic for seminars or colloquia.

Dealing with Problems in the Mentor-Trainee Relationship

The best approach to addressing problems between mentors and trainees is based on an understanding of existing procedures and guidelines in advance of encountering problems. When graduate students and postdoctoral fellows are asked what would improve their dilemma, many request written guidelines. They want to know what to expect and how to deal with problems. Many academic institutions, graduate schools, and individual departments have developed written strategies for dealing with problems, concerns, and conflicts. These might range from "Speak first to your immediate supervisor or the faculty member involved" to "The department graduate adviser is the person with whom you should consult."

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COLLABORATIVE RESEARCH

7.1 COLLABORATIVE RESEARCH

Background

For many reasons, Science is increasingly dependent on collaborations. Firstly, no single person has the skills, knowledge, and resources to address all research problems; a judicious choice of collaborators can save considerable time and money. Secondly, the funding and structure of science tend to favor programs in which recognized authorities are involved from each key area. Thirdly, breakthroughs are often more likely to come from collaborations across disciplines than by adherence to tried and true methods. Fourthly, collaboration within the private sector is highly prized. Institutions and academia are being encouraged by their own institutions' legislation, industry (which recognizes the benefits of the expertise and reputation of academics), and academia itself (which can benefit from immediate and long-term sources of private funding). Finally, collaborations are easier now than before. With obvious improvements in communication (telephone, facsimile, e-mail), shipping (one-day delivery), and travel (to national and international conferences), potential collaborators are more likely to find each other and are more able to maintain their collaboration.

Whatever the reason, collaborations are increasingly beneficial and possible. Nevertheless, problems could also arise from collaborations because it can take such different forms. It certainly implies two or more people joined together for a common purpose, but this might involve almost any arrangement, from shared time, work, resources, unique materials, data, ideas, to money. Once the work is completed, credit and responsibility might then be shared in a number of ways. Collaborations may not even begin because of reluctance to share or work together, and if started, collaborations can be marred by misunderstandings of what is to be provided by each of the participants. This may include unhappiness with a slow collaborator, disagreement about what and when to publish, or conflicts regarding authorship and credit. Although there is no panacea for such problems, it is evident that any solution needs to begin with improved communication.

What is collaborative research?

Research can involve a vast scope of collaborations within departments of institutions, between institutions and internationally. Collaborative research has increased significantly recently and has raised specific issues, such as managing research findings, managing conflicts of interests, sharing intellectual property and commercializing research outcomes. Though research practices differ between institutions, researchers should make every effort to adhere and comply with all relevant policies and guidelines when conducting their research.

Collaboration has been intrinsic to the research process for the past 50 years, but collaboration per se usually refers to researchers who work within the same discipline,

either within an institution or in different institutions. Multidisciplinary research is a form of collaborative research that involves researchers working across disciplines, either within an institution or in different institutions. A physician working with an engineer to manufacture a new imaging device, or an epidemiologist working with a political scientist on a tobacco-control initiative, is an example of a cross-disciplinary research project. When the pharmaceutical industry works with a medical center to perform a clinical trial of a new drug, it is a form of collaboration across industry and academia. Each of these interactions creates different expectations and requires a variety of modes of communication to ensure that the collaboration is successful.

7.2 FACTORS THAT CONTRIBUTE TO COLLABORATIVE RESEARCH

Funding sources

The National Medical Research Council's (NMRC) has started to focus on strengthening the capabilities and capacity for local Translational and Clinical Research (TCR). With the funding support from the National Research Foundation (NRF) and guided by the Biomedical Science Executive Committee (BMS Exco), NMRC has overhauled its grant framework for the purpose of turning Singapore into a buzzing center for TCR.
NMRC has developed a comprehensive and transparent set of grant schemes to grow and support the research environment in Singapore with the revamped grant framework; so as to engage all levels of expertise of clinical investigators and researchers by ensuring adequate opportunities for research support and career development. With this process, NMRC hopes to establish research programs which will be oriented around strategic disease areas with the purpose of integrating, to establish research programs, coordinating and leveraging the full chain of research capabilities in Singapore from basic science to clinical research. Lastly, institutions have also set up funding streams to support innovative approaches within their institutions.

Ease with new telecommunications technologies

E-mail and Web-based technologies have changed the way many people in research-oriented countries interact, and scientists are among the beneficiaries of the new communications technology. While the wider use of fax machines, in the 1980s, allowed documents and data to be sent across phone lines, shared computerized databases at that time were more difficult to manage. Today, Web-based technologies allow researchers to input and manipulate data in shared databases with ease. Web-based telecommunications systems also allow people from across the world to communicate by simulating face- to-face meetings.

7.3 POTENTIAL PROBLEMS OF COLLABORATIVE RESEARCH

Difference in styles of investigators

As in any relationship, people have different styles of relating. Some people are more formal, while others are more laid-back and relaxed. Likewise, in science some researchers have collaborations in which they develop a project over a beer and a handshake at a conference and the tenure of the tie remains informal throughout. Others require more documentation and rigorous enumerations of responsibilities. However, even if a researcher works easily with another researcher, shared grants, data, and materials require more formal written agreements involving grants-and-contracts offices at their respective universities.

Difference in styles of research across and within disciplines

One collaborator believes that peer-reviewed papers should be short and should use a limited amount of data. Another collaborator believes that more data should be collected and the "story" of the research should be developed before anything gets published. This kind of disagreement can occur with collaborators in the same field or in different fields. Disciplines also suggest, in different ways, who should be an author on a paper. In certain fields, people who have not contributed substantially to the intellectual process of the research are not included, while, in other fields, people get authorship if they participated in doing the research at any level. Different research disciplines also have varied approaches in work habits. Biomedical laboratories, for example can operate for 24 hours a day because of the nature of performing experiments, but other disciplines may have more routine, 8- to 10-hour days.
Furthermore, different types of work may follow different timetables. Statisticians working on analyzing data may move faster than the social-science researchers surveying hundreds of people in a population for data. Researchers collaborating internationally may also speak different languages. In addition, technical jargon exists within subspecialties within a discipline and across various disciplines. It can be challenging for researchers to create a language understood by all across all disciplines. The crucial point is, to presume nothing and to place everything on the table for discussion as early in the relationship as possible.

Differences between academic and industrial research with respect to sharing of data and results

The free exchange of information at scientific meetings and in publications is the ethic and lifeblood of academia However, in commercial enterprises research data could have financial repercussions, so data is carefully vetted before it is published, if it is ever published. When academics and business researchers work together on projects, each party has to come to an agreement about how data and materials will be shared. Institutions do not allow hindrance of publication in research collaborations with industry. Other universities are willing to forego the freedom in exchange for funding, access to industrial ideas, and opportunities to train students in commercial types of research endeavors.

Do you know?

In the US, the issue of industry sponsoring drug trials at academic research centers and not allowing the recipients to publish papers on the results of the trials has become front-page news. The New York Times reported in late 2004 that medical-school researchers funded by the pharmaceutical industry had sought access to unpublished data in an antidepressant trial to determine whether the drugs increased the risk of suicidal behavior in children. Drug companies denied the researchers access to the data and would not allow them to communicate with other researchers who had participated in the same study at another institution. Drug companies performed the clinical trials at multiple locations and kept the data centralized, with each institution not blinded from the results from elsewhere. An editorial in the Times commented that it may now be time for all institutions to negotiate contracts with drug companies that would "ensure researchers' access to data and prompt publication of results.

Ethical considerations may affect research across institutions and nations

Institutions everywhere may have different standards for the nature of disclosure of potential financial conflicts of interest. While one institution/academic medical center would not allow a researcher who developed a drug to be involved in the clinical trials of that drug, another might permit it as long as safeguards were in place that would prevent the researcher from knowing the progress of ongoing trials.

7.4 HOW TO ENHANCE COLLABORATION

Responsibilities of Institutions

a) Establish agreements for each collaboration

- An agreement should be reached with the partners on the management of the research in a joint research project of organizations involved. The agreement should adhere and follow the general principles of the RCR manual, including integrity, honesty and a commitment to excellence.

- The agreement should be in writing and it must cover intellectual property, confidentiality and copyright issues; sharing commercial returns (if applicable); responsibility for ethics and regulatory authorities (if applicable) submissions and approvals, and the reporting to appropriate funding agencies. The protocols to be adhered to by the study team when disseminating the research outcomes and the management of primary research materials and research data should be addressed.

- The agreement may take various forms, including a legal contract signed by the Chief Executive Office of the institution, or a research management plan read and

- signed by all study team members or appropriate representatives from the study team.

- Each organization / institution must ensure that its researchers are made aware of, and fathom, the policies and agreements governing the joint research collaborations.

b) Management of conflicts of interest

A policy for managing conflicts of interest that may potentially arise in collaborative research must be readily available in the institutions (see section 3).

c) Management of access to research materials

i) Communication first second and throughout.

No one in collaboration should assume anything. Establishing, maintaining, and even continuing communication is important for the project to continue. If two researchers exchange data, personnel, or materials without a formal collaboration in place, perhaps they need to address whether one should be established. Once collaboration is formally created then discussion about data, ideas, and personnel issues should occur. Researchers need to communicate effectively, whether the other person is across the hall or on the other side of the globe.

Communication is particularly important in collaborations between academia and industry. Special requirements may be imposed on the publication of material or on the invention and patents. Whether a graduate student participates in such an academic-industrial project must be resolved early on if the research may not be published in a timely fashion. Also, patent lawyers, technology-transfer administrators, and marketing personnel from industry need to establish a common ground for communication.

ii) Discussing in advance who will do what in a project while understanding that the research may evolve

Parties in collaboration should define goals in such a way that they could not have been established without the collaboration. Setting goals leads to expectations and outcomes. Who will take charge of the collaboration also needs to be defined. As multiple laboratories or groups of researchers may be involved, coordinating the effort among the participants requires management (and communication). When a research project changes direction, how that will impact participants needs to be addressed as well. Authors may be added or removed. Finally, it is pertinent for researchers to determine when a collaboration is over.

d) Discussing authorship in advance

Different disciplines have varying standards for determining authorship. The criteria for authorship among collaborators have to be established beforehand so everyone involved will know what to expect. But with authorship comes responsibility, so collaborators need to determine how they will deal with the differing expertise levels of each author, who will actually write the manuscript and be responsible for the input from collaborators. If the research changes direction, someone expecting authorship might be disappointed, so the evolution of a project has to be considered and made known. Finally, the list of collaborators to be acknowledged should be addressed.

e) Discussing data and material management in advance

This is an example of what can happen among researchers who share resources and data. Laboratory A, for example, has purified a protein and prepared antibodies to the protein. Laboratory B will screen an expression library to find the clone. Laboratory B will get the monoclonal antibody and the clone will be shared. But will Laboratory B also get the cell line that makes the monoclonal antibody? How such a question is resolved affects the ability of the laboratories to replicate work and to perform independent work at the end of a collaboration. The issue of who owns data is governed by the type and source of funds used to support research. Investigators and institutions also have rules for the custody and retention of data, to which all parties must adhere.

Also, the transfer of materials among collaborators is subject to so-called "material transfer agreements," or MTAs, developed by administration offices. They include:

- Limits on the use of the material, usually for non-commercial research purposes
- Prohibitions on the redistribution of the material
- Conditions of use, including prohibitions of use in animals or humans
- A hold-harmless cause, meaning that the donor has no liability resulting from the use of the material
- The issue of the return of unused material

f) Discussing intellectual property issues in advance

All investigators want to be able to protect results that might have potential commercial application. Disclosing results early could prevent collaborators from being able to obtain patent protection. All parties should know of institutional and granting-agency policy regarding intellectual property and patent procedures.

g) Managing accountability

Each institution has to abide by certain regulations, policies, and laws. Researchers working with animals, humans, or hazardous substances have to conform to the appropriate regulations, policies, and laws. Basic research scientists might have access to patient data from the clinical arm of a study and must be aware that they need to maintain the confidentiality of patients. Also, clinicians should inform bench researchers of the potential hazards of certain human tissues. Researchers also need to inform one another of any potential conflict of interest that they might have in the project.

Responsibilities of Researchers

a) Comply with multi-institutional agreements

Researchers involved in a joint research endeavor must be aware of, and adhere and comply with all policies and written agreements affecting the project, particularly to those relating to the dissemination of research findings and the management of research data and primary materials.

b) Declaration of conflicts of interest

Researchers must disclose as soon as possible any actual, apparent or perceived conflict of interest to any aspect of the projects when establishing research collaboration.

Do you know?

A new protocol amendment is required to be submitted to NHG Health DSRB by the PI on behalf of a study team member if a new study team member who has conflict of interest is added to the team.

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Authorship and Publication

8.1 Authorship and Publication

Background

Authorship is the most visible form of academic recognition and credit. However, because credit for publication is also important in disputes and allegations of research misconduct, it is worth considering why authorship credit is more than a matter of personal gratification. Indeed, attribution of credit and responsibility is central to the structure of science. The framework of science depends in part on the ability of institutions, policy makers, and the public to identify who is responsible for the work and its interpretation. Funding agencies consider past success, as evidenced by authorship, in the allocation of research grants. Research institutions often use authorship as evidence of creative contributions that warrant promotion. Scientists themselves may use credit for past work as a mechanism to attract both new trainees and willing collaborators. Finally, in an era of increasing emphasis on commercialization, authorship and credit help to define intellectual property rights. These and other reasons explain scientists' desire for the credit of authorship, and also make clear why the assignment of authorship is central to the responsible conduct of research.

Publication

Publication of results is an integral and essential component of research. All researchers are encouraged to promote their work through publishing and other forms of dissemination. Publishing includes:

- Publishing in peer-reviewed journals and books
- Publishing in non-peer-reviewed journals
- Conference presentations (peer-reviewed and non-peer-reviewed) and/or published in proceedings
- Posters presented at conferences
- Reports commissioned by external organizations
- Promotional reports and materials on research
- Articles in the popular press and other media
- Publication in web-based journals and project web sites

As the aim of research (particularly publicly funded research) is to promote the advancement and dissemination of knowledge, publication and presentation of results to the specialist research and wider community is recognized as a fundamental part of the research process. As research is assessed by mechanisms such as the Research Excellence Framework, the impact of outputs and publication are of considerable importance. Researchers are encouraged to publish their work in peer-reviewed publications and media, including research journals. Researchers

should give priority to publishing in those publications which employ rigorous standards of peer review.
Researchers are also encouraged to follow best practice in publication as detailed in guidelines issued by, for example, the Singapore Medical Journal (SMJ) or the widely acceptable International Committee of Medical Journal Editors (ICMJE). Researchers can also receive guidance in press liaison from their institutions' guide or policy with respect to articles in the press, the broadcast media and other high profile reporting

Good conduct in publication practice

In publication and authorship, as in all other aspects of research, researchers are expected to follow the principles of good research conduct supported by the institutions they worked with. It is essential that the parties involved in research and publication discuss and agree on:

- Authorship
- Recognition of other contributions
- Acknowledgement of sponsors
- Declaration of any conflicts of interest

Authorship

Generally, an author is considered to be someone who has made substantive intellectual contributions to a published study. This includes anyone who:

- Made a significant contribution to the conception, design, execution or interpretation of the research study
- Drafted or substantively reviewed or revised the publication
- Approved the final version of the publication

There is great variation in practice among different disciplines and research fields. Thus there are no universal sets of standards for authorship which can easily be formulated. The widely accepted ICMJE guidelines set a high standard but there are different practices about who should be included as an author on a paper. This places most of the responsibility for decisions about authorship on the researchers who participated in the work reported in each publication. These decisions are best made early and at the start of each project to avoid misunderstanding and authorship dispute later on.

The SMJ also stipulates that all individuals designated as authors should qualify for authorship. However, each author should have sufficiently participated in the work material submitted to SMJ to justify the authorship according to the ICMJE guidelines on Uniform Requirements for Manuscripts Submitted to Biomedical Journals (see 8.2 for further information).

Authorship guidelines

Researchers should seek to publish their results in a manner which conforms with current best practice and in compliance with any relevant sponsors/ grant's terms and conditions. In doing so they should take steps to ensure that they:

- Use the most appropriate means to publish the results of their research;
- Publish their data in an appropriate form, typically as papers in refereed journals;
- Comply with the Institution policies and funder requirements in the dissemination of the results of research and, where appropriate, seek guidance and approval to report data to the media;
- Publish a coherent report of the work and not report the data more than once (unless in a secondary analysis) or sub-divide the data (unless this was a predefined approach), reproduce the data in total, or in part, in a number of reports (unless clearly referenced and justified);
- Report and discuss the findings of their research and include all data generated by the study;
- Analyze the data using appropriate methods of statistical analysis;
- Provide a summary of the work written in terms that will enable the layman to comprehend the work and to provide appropriate feedback to those who took part in the study, including any professional or lay groups that have contributed to, or took part in, the study;
- Acknowledge and cite the work of others where appropriate, fully and accurately attributing relevant sources;
- Take steps to ensure the accuracy of the data reported and act immediately to correct any genuine errors or misunderstanding that might subsequently be revealed in the data or its interpretation;
- Acknowledge the funding, support, sponsorship and other forms of input (including that of the Institution) to the work in an appropriate way;
- Give notice of intention to publish and seek approval, where appropriate, to publish, from all partner organizations;
- Openly declare all relevant interests, as required by the publisher and by the Institution's conflict of interest policy;
- Do not seek media exposure for research which has not been subject to peer review, unless sanctioned by the Institution and all other parties involved in the research;
- Handle the release of research data which might have high impact and/or which might have an impact in the commercial world (positive and negative) with appropriate care and sensitivity, consulting the Institution and other partners as appropriate;

Where the work has more than one author, the researchers should also:

- Agree on the contribution each will make to reporting the work and review this commitment regularly as the work progresses;

- Appoint a lead or executive author to lead for communication on the work;
- Report the work fairly according to the contribution each author has made to the work and neither omit nor underplay a contributor's input or overplay such input or add in someone who did not contribute to the work in a way that would justify their inclusion as an author or co-author
- Comply with the definition of author and co-author as defined by the journal in question or that of international organizations such as International Committee of Medical Journal Editors
- Provide a formal offer of authorship (which should be accepted or declined in writing) to those meeting the agreed definitions (see above)
- Maintain a file of all relevant signatures in case of disputes

Ranking of multiple authors

Well, how should the order of authors be determined? The ICMJE now says only that "The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed."

This provides precious little guidance, let alone advice for dispute resolution. An earlier version of the guidelines required the following process:

> Step 1. Conception of the work represented by the article, design of the work, analysis and interpretation of data or other evidence presented in the article, or all of these.
>
> Step 2. Drafting the article or revising it for critically important content.
>
> Step 3. Approving the final version of the article for publication.

The relative contributions of authors to the intellectually most critical aspects of the work should determine their sequence. Contributions in Step 1 should be given the greatest weight. The first author should have made major contributions in Steps 1 and 2; the following sequence of authors should represent progressively lesser contributions. But this process met with a number of objections and was omitted. Still, it gives a sense of the values that should be brought to bear in making these decisions. What emerges as the best strategy, in any case, is open and frank discussions about the publication plan, the authors to be named and their order should be held early in the life of a scientific project, and revised as necessary.

8.2 INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS

International Committee of Medical Journal Editors

Perhaps the best-known attempt in all the sciences to establish criteria for authorship is that of the International Committee of Medical Journal Editors (ICMJE). The group's periodically revised "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" provides a suite of standards for publication and authorship. Here, from the ICMJE Web site, are the criteria for authorship.

Authorship credit should be based on:

- Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
- Drafting the article or revising it critically for important intellectual content; and
- Final approval of the version to be published

Conditions to be met

When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgements. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript.

- Acquisition of funding, collection of data, or general supervision of the research group alone does not justify authorship of data;
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

These guidelines are imperfect and open to debate, but what emerges is crystal clear in terms of maintaining the credibility and utility of the biomedical corpus. Moreover, it is important to note that these guidelines have been developed and refined by journal editors themselves, often physicians and scientists with their own track records as authors. This means that the rules have not been imposed by outsiders or regulators or moralizers looking for trade, or to pass judgment. The guidelines should be seen as internal to the professions to which they apply. Of these requirements, one is particularly vexing to graduate students and certain others: "... collection of data ...alone, does not justify authorship." One might speculate that thousands of people have been made co-authors precisely and exclusively because they did no more than collect data. While data collection is an essential and non-trivial task, it is not a sufficient justification for credit as an author: The data collector has not

contributed intellectually to the project in a way comparable to the effort of those cited by the ICMJE. There is a happy solution to this: include graduate students in the intellectual life of the project so that they participate in design of the work, drafting of the article, and final approval of the manuscript. This approach would not only ensure that their authorship is deserved and bona fide, but that it also produces a more comprehensive education and training experience.

8.3 HOW SHOULD MULTIPLE AUTHORS BE RANKED?

Determining the One

There is some reason to believe that authorship (what is required to be listed as an author, as above) and the order of authors' names are the greatest sources of conflict among scientists. How should multiple authors be ranked? A number of social forces and customs are at work here, too.

Generally, the "first author" is and should be regarded as the most important one, that is, the one who made the most critical contribution. This practice, however, has been diluted. Now, senior scientists and mentors, hoping to advance their protégées' careers, have adopted what has been called an "after you, Alphonse" approach whereby the junior scholar is made the first author and the senior is demoted; in multi-authored papers, the senior might even become the last author listed. A number of codes for the "most important" author have also evolved. In papers with many authors listed alphabetically, the "first author" is the nth author, identified as the "corresponding author" or the one from whom to request reprints.

Ranking

The ICMJE now says only that "The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed." (See 8.2)

8.4 PROFILING

Redundant Publication and Self-plagiarism

There are additional ways to inflate one's CV besides "getting one's name on a paper" without doing any of the research. These include publishing the same paper more than once. According to the ICMJE, "Redundant (or duplicate) publication is publication of a paper that overlaps substantially with one already published in print or electronic media". Why is this wrong? The answer *should* be obvious by now. Redundant publication corrupts - and unnecessarily bloats – the scientific corpus by suggesting that a particular scholar is more prolific than he or she actually is, which is

deceptive. Any student or scholar hoping, for instance, to study or review the work of Professor So-and So, and who goes to any length to obtain copies of that work, will be frustrated, disappointed and perhaps angered to find that more than one article says the same thing. The feeling will be of frank betrayal when it is discovered that two or more articles are literally the same, word for word - except perhaps for the title. Such cases, in which one copies one's own work and then passes it off as novel, are sometimes called "self plagiarism". This is a particular problem for many students across the curriculum, as for instance when a term paper written for one course is resubmitted later for another. There are some justifications for what the ICMJE calls "secondary publication," but they all require some sort of disclosure in print, permission of both editors, etc. It should be uncontroversial to point out that not only must such redundancy be disclosed in print but also that it should also be disclosed or labeled in one's CV.

Fragmentation

Another way to inflate one’s CV is to divide the results so as to generate several articles, or even as many as possible. That is, one might want to analyze data in such a way as to justify their reporting in as many journals as possible. Such fragmentation has come to be called the search for the "least publishable unit" or LPU. While there is something droll about that term, its acronym and their use, the actions involved might constitute another corpus-bloating deception. The rationale for such fragmentation matters. If a scientist's intent is to generate as many articles as possible, the better to impress colleagues, get grants, or win promotion, and then we should regard this strategy as deceptive and therefore blameworthy. If, however, a compelling or even reasonably adequate scientific case can be made for subdividing the reports, then the strategy might be permissible. Suppose, for instance, that an experiment or research program credibly addresses different questions, and that these questions are of interest to different audiences. In such a case the multiple publications would be appropriate (though their relationship to each other should be disclosed in print). As with the order of authors' names, the question of what constitutes an appropriate publication strategy should be discussed and debated by the research team early in the research process.

Acknowledge other contributions fairly

Even the act of thanking someone can raise ethical issues. One of the most interesting deceptions is the acknowledgment of someone of status in hopes of enjoying a halo effect or benefiting from reflected glory. Therefore, researchers must ensure that all those who have contributed to the research, such as facilities and materials are properly acknowledged. This includes researcher assistants and technical support as well. Written consent must be obtained from individuals if they are to be named. It is not clear how great or what kind of contribution is adequate for an acknowledgment; this is a judgment call. But the demand for permission from the acknowledged is one way to try to reduce this kind of deception. One might surmise

that some of those who are asked for such permission will not feel collegial if they refuse, which makes their consent a kind of acquiescence to the deception. Moral courage is perhaps the only way out of such tight spots.

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PEER REVIEW

9.1 PEER REVIEW

Background

The term “peer review” is used here to describe the impartial and independent assessment of research by fellow colleagues or others working in the same or related field. Peer review has a number of important roles in research and research management. This includes the assessment of grant applications, the selection of materials for publications, the review of performance or researchers and teams, and the selection of staff.

Institutions should encourage participation of peer review process as it provides expert scrutiny of a project and help to maintain high standards and encourage accurate, thorough and credible research reporting.

Peer review on its own cannot ensure research integrity. However, peer review has been important in detecting fabrication and fraud in research.

Responsibilities of Institutions

Encourage participation in peer review

The importance of the peer review process, encouragement and support of researchers to participate should be recognized by the institution.

Responsibilities of peer reviews

It is important that reviewers/participants in peer review:

- Are unbiased and timely in their review
- Act in confidence and do not divulge the content or outcome of any process for which they are involved
- Declare all conflicts of interests. Do not permit personal prejudice to influence the peer review process, and do not introduce considerations that are irrelevant to the review criteria
- Do not take calculated or undue advantage of knowledge gained during the peer review process
- Ensure that the criteria to be applied to are informed and complied with
- Do not agree to engage in peer review outside their area of expertise
- Give proper consideration to research which challenges or changes accepted ways of thinking.

Responsibilities of Researchers

a) Do not interfere during the peer review process
Researchers whose work is undergoing peer review must not seek to influence the process or outcome.

b) Participate in peer review
Researchers whose research is being funded, have a responsibility to participate in peer review process.

c) Mentor trainees in peer review
Supervising researchers have a responsibility to guide trainee researchers to develop the necessary skills for peer review and understand their obligation to participate.

d) Declare conflicts of interest
Relevant conflicts of interest must be declared by peer reviewers.

Reviewing the work of others

Peer review is recognized to be central to the current mechanism of research assessment. Researchers should exercise judgment in taking part in peer review and should declare all relevant interests they have in the field as required. Those invited to review for the first time are advised to take any training that might be offered, follow the guidance provided by the organization making the request, acquaint themselves with good practice and consult/discuss with their mentor and/or colleague as appropriate. Where appropriate, reviewers should contribute comments that will be attributed. Those taking part in peer review should:

- Apply rigorous objectivity in all assessments;
- Review in accordance with the guidance provided for the process, complete the review as specified and on time;
- Respect the confidentiality of any information sent for review and not disclose any information provided, any opinions given, or the details of the invitation to review;
- Report any conflicting interests as required by the requesting organization and Institution's policy;
- Do not allow vested interests or personal bias to influence their impartial assessment of work to be reviewed in either a positive or negative way;
- Only accept assignments for which they have the expertise, returning any which are outside their expert knowledge;
- Do not take advantage of any new data or privileged information they have had access to during the review process either in the capture of ideas to further their own research and/or activities;
- Conduct a fair assessment of the work and not deliberately disadvantage a competitor in the field;

- Review objectively work that challenges accepted views, crosses traditional boundaries and/or is wholly innovative;
- Be aware that the review may identify practice which falls below good conduct (which might be a genuine error or malpractice) and which should be reported as concerns.

Submitting work for review

Researchers should not take actions, directly or indirectly, to influence the review of their own work or that of others, positively or negatively. Where work is reviewed the authors usually respond to reviewer comments. Authors should accept comments and respond to the factual points made. Where an author suspects an infringement of the principles outlined above this should be reported to the appropriate authority (e.g. journal editor, grant manager). Where an author considers there might be reasonable grounds for appeal he or she should first discuss the details with colleagues within the Institution.

9.2 POTENTIAL PROBLEMS IN THE PEER REVIEW SYSTEM

Peer Reviewer Issues

Although peer review has been an accepted practice for more than 200 years, it has also been the subject of criticism. For example:

- Reviewers may have biases which they do not recognize or fail to consider and disclose when they review a grant application or paper. Such biases can include:
  - Dislike for an author's or applicant's institution;
  - Personal likes or dislikes of the author or applicant;
  - Competition with the author or grant applicant.
- Peer review might restrict controversial or innovative research from being considered for publication or being used as the basis for a grant application.
- Peer reviewers may fail to disclose financial or other conflicts of interest that might affect the objectivity of their review.
- Persons asked to act as reviewers may not admit their lack of expertise in the research area addressed in the paper or grant application.
- The peer-review process is not sufficiently reliable in detecting errors.
- Peer review does not prevent poor quality papers from getting published. For example, a manuscript might be rejected by one journal, but a persistent author might get it published in another.

Peer Review Benefits Outweigh the Costs

Scholars acknowledge problems with the peer review system, but generally believe that the merits outweigh the drawbacks. Peer review often improves the quality of the research presented in a manuscript or grant application. It is not always clear, however, whether the editors, reviewers, or authors are primarily responsible for the improvement. Two alternatives to peer review are first, leaving publication decisions to editors; or second, allowing government grant-awarding agencies to determine who is awarded grants without separate independent review. A third option, of course, is allowing publication of almost anything without distinguishing between quality and nonsense. Surely none of these alternatives would be an improvement.

The key to improving peer review is an awareness of the problems inherent in the process, such as the potential for bias or the misappropriation of information. Such an understanding of possible abuses can help researchers avoid falling victim to ethical lapses by reviewers. Until another method is developed, peer review remains the best way for experts to assess the quality of research being considered for funding or publication.
Those who perform reviews with competence and integrity are fulfilling their obligations to the scholarly community. Honest, capable reviewers uphold accepted standards when they reject work and improve the field by offering constructive criticism. If an author believes that a manuscript has been rejected unfairly, he or she can express those concerns to the editor.

The reviewer does not necessarily have the final say. Appeals are built into the grant-application process. For example, an author or grant applicant (or anyone else with knowledge of the review process) may believe that a reviewer has misappropriated or otherwise improperly used the author's or applicant work. The injured party can seek legal representation and petition the reviewer's institution to initiate an investigation of plagiarism. Advising the granting agency or the journal might also be appropriate. Although it is ethical for a reviewer to use confidential information to modify the direction of the reviewer's own research, if the new information clearly shows that the reviewer's research is headed in the wrong direction, the reviewer must do so with care and integrity. The appropriate approach would be to explain the situation to the author applicant, and attempt to establish collaboration.

Up the Process of Peer Review

Instead of the traditional peer review system, modifications which have been introduced are:

a) Blinded Review

Some suggest a need to "blind" reviewers to the identities of both the author of a manuscript being reviewed and the author's institution. Blinded peer review can remove bias which might result from a reviewer's knowing whose work he is

reviewing and the author's institution. In principle, blinded reviews might be of higher quality, because it allows reviewers to focus on the substance of the research question and conduct rigorous and impartial critique of the work.

b) Open Review

It has been observed that accountability would be enhanced if authors and reviewers know each other's identities, because reviewers would be less inclined to seek unjustified arguments or to misappropriate data- as they are under the guise of anonymity. Some argue that open reviews, in which the author knows the reviewer and the reviewer knows the author, would improve the peer-review process.

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THE ETHICAL USE OF LABORATORY ANIMALS FOR MEDICAL RESEARCH

10.1 REGULATIONS & RESPONSIBILITIES

Background

Animal research needs to be carefully regulated just like human research. Animals may benefit from the information gained through animal experiments and some research involving animals is conducted specifically for the purpose of improving animal health (e.g. veterinary medicine and animal husbandry research). But most animal research is conducted primarily for the benefit of humans, not animals. Moreover, unlike humans, animals cannot consent to participate in experiments or comment on their treatment, creating special needs that should be taken into consideration in their care and use.

Regulatory, Institutional and Voluntary (Local and/or Overseas) Oversight

Where animal research is involved, research institutions would be required to adhere to the local regulatory and/ or voluntary oversight.

- Animal & veterinary Service, Animal & Birds (Care and Use of Animals for Scientific Purposes) Rules (https://www.nparks.gov.sg/avs/resources/legislation)
- National Advisory Committee for Laboratory Animal Research, Guideline on the Care and Use of Animals for Scientific Purposes (2004) (Animal & Veterinary Service (a cluster of National Parks)
- Institutional guideline(s)

Responsibilities of Institutions

Institutions should assure that researchers adhere to the regulations and guidelines for the responsible care and use of animals. There may be an Institutional Officer, who in turn appoints a mandated Institutional Animal Care and Use Committee (IACUC), and administers institutional matters relating to the care and use of animals at the institutions.

The IACUC would oversee and evaluate all aspects of the institution's animal programme, procedures and facilities. Its members may include veterinarians, scientists, non-scientists and members who are not affiliated with the institution. Many IACUCs also have a researcher who does not use animals or a member who has expertise in ethics.

IACUC members are appointed by their institution and their responsibilities include:

- Reviewing and approval of all research protocols using animals
- Reviewing the institution's animal care programme
- Inspecting the institution's animal facilities (at least twice a year)
- Receiving and reviewing concerns raised about the care and use of animals

- Submitting reports to the Institutional Official

IACUCs, like that of the Institutional Review board; also have independent authority to suspend research projects if they determine that they are not being conducted in accordance with applicable requirements and/or regulations.

Research institutions with large animal research programmes generally have centralized animal care and use units that provide veterinary support, training in procedures and advice on analgesics, anesthesia, euthanasia and occupational health and safety. The staff employed in these units cannot approve research protocols nor make decisions specifically assigned to the institutions' IACUCs. However, they as animal professionals are an excellent source of information about the responsible care and use of animals in research.

Responsibilities of Researchers

Researchers intending to use animals in their research should:

- Know what activities are subject to regulation(s)
- Understand and follow the rules for research approval
- Obtain appropriate training
- Accept continuing responsibility for compliance through all stages of the research

In addition, regardless of the level of invasiveness on the use or study of living animals in a research, researchers should familiarize themselves with their responsibilities and check with someone in a position of authority before making any plans or undertaking any work.

Responsibilities of a research facility

Under the Animal & Birds (Care and Use of Animals for Scientific Purposes) Rules (Animals and Birds Act, Chapter 7, Section 80, 2007 Edition), any research facility that uses animals for scientific purposes must obtain a licence from the Animal & Veterinary Service (a cluster of National Parks). For Application Procedure & Conditions of Licensing, please click here.

As part of the licensing requirements, a research facility must comply with the Guidelines set forth by NACLAR for the proper care and use of animals for scientific purposes and allow the Animal & Veterinary Service to carry out inspections of its facilities.

10.2 PRINCIPLES FOR THE RESPONSIBLE USE OF ANIMALS IN RESEARCH

Before deciding whether to conduct an experiment on animals, researchers must decide whether it is ethically acceptable to use the animal in the experiment, given the purpose of the study, the experimental design, the methods used and the species of the animal. If it is decided that the animal has some moral value and that the experiment would harm the animal in some way (e.g. by causing pain, suffering, disability or death), then the experiment must be ethically justified given the expected benefits.

Researchers can conduct experiments on animals provided that sufficient moral justifications for the experiments are provided. Because many different animal species may have some degree of moral value, the moral burden of proof rest with researchers who intend to conduct experiments on animals; researchers do not have a moral free ticket regarding animal experimentation. Moreover, because animal species may differ with respect to their moral worth, an experiment can be morally acceptable in one species but not in a different species. For example, it may be morally acceptable to create a transgenic mouse that is prone to various forms of cancer instead of a chimpanzee or monkey as they have a greater moral value than mice by virtue of their higher degree of similarity to human beings.

Many animal welfare organisations find that some scientifically necessary experiments is acceptable, however, it should be kept to a minimum and conducted on animals low on the phylogenetic scale in ways that minimize pain and suffering. Should extensive animal experimentations be necessary and moral, sound scientific practices utilizing quality animal care, along with minimization of pain and distress should be justified. The Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research and Training is a guiding principle for researchers and IACUCs to make decisions about the responsible and appropriate use of animals in research. These principles specify the requirements for planning and conducting research and are useful for investigators and IACUCs. Apart from these principles, local regulations, and institutional guidelines provide further criteria for researchers and IACUCs to consider in assessing protocols.

Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research and Training:

- Follow the rules and regulations for the transportation, care and use of animals;
- Design and perform research with consideration of relevance to human or animal health, the advancement of knowledge or the good of society;
- Use appropriate species, quality and the minimum number of animals to obtain valid results, and consider non-animal models;
- Avoid or minimize pain, discomfort, and distress when consistent with sound scientific practices;
- Use appropriate sedation, analgesia or anesthesia;
- Painlessly kill animals that will suffer severe of chronic pain or distress that cannot be relieved;
- Feed and house animals appropriately and provide veterinary care as indicated;

- Assure that everyone who is responsible for the care and treatment of animals during the research is appropriately qualified and trained, and
- Defer any expectations to these principles to the appropriate IACUC.

The NACLAR Guidelines on the Care and Use of Animals for Scientific Purposes covers all aspects of the care and use of animals for scientific purposes including their use in teaching, field trials, environment studies, research diagnosis, product testing and the production of biological products. The NACLAR Guidelines aims to promote humane and responsible care and use of animals for scientific purposes. Further practical advice on ways to assure appropriate respect for animals are based on the principles of the 3Rs – Replacement, Reduction and Refinement.

- Replacement – When it is possible to answer a research question without using an animal, replace the animal with a methodology that does not use animals, such as cell studies or computer modeling. When it is possible to answer a scientific question using a morally "lower" species of animal, replace the "higher" species with a lower one.

- Reduction – When it is possible to answer a research question using a smaller number of animals, reduce the number of animals used.

- Refinement – Wherever possible, refine research methods, techniques, concepts and tolls to reduce the need for animals in research and to reduce harms to animals.

The 3Rs can be justified on the grounds that they minimize harm to animals and promote animal welfare within the context of animal experimentation. These 3Rs make sense only if one believes that the research protocols are likely to yield results with scientific, medical or social value. Thus, a fourth R should also apply to animal research:

- Relevance – Research protocols that use animals should address questions that have some scientific, medical or social relevance; all risks to animals need to be balanced against benefits to humans and animals.

According to Shamoo and Resnik (2009) a fifth R is also important (which plays a key role in the U.S. animal research regulations):

- Redundancy avoidance – Avoid redundancy in animal research whenever possible. Make sure a thorough literature search is carried out to ensure that the experiment has not already been done. If it has been done, provide good justification for repeating the work.

Avoiding redundancy is important to avoid using animals unnecessarily and wasting research resources.

Discussions about the responsible use of animals in research are not likely to dissipate in the near future. If animals are essential to the research and cannot be replaced; if researchers cannot reduce the experiment; and if researchers cannot further refine their methods to reduce pain and suffering, then presumably researchers have done all they can to meet their responsibility. However, do not forget that society does not have to permit the use of animals in research. It can seek to protect animals through complex and expensive regulations if it loses confidence in the research community's ability to regulate itself.

[The following chapter was adapted from the ORI Introduction to the Responsible Conduct of Research, U.S. Department of Health and Human Services (HHS), Steneck, N 2007.]

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