Whistle blowing in Clinical Research: Some Perspectives from Good Clinical Practice and the Role of Research Ethics Committees.

Lorraine Africa

Student Number: 331999

In partial fulfilment of the degree of MSc Med (Bioethics & Health Law) Steve Biko Centre for Bioethics, Faculty of Health Sciences, University of the Witwatersrand

Supervisor: Prof Donna Knapp van Bogaert

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Declaration

I, Lorraine Africa, declare that this research report titled *Whistle blowing in Clinical Research: Some Perspectives from Good Clinical Practice and the Role of Research Ethics Committees* is submitted for assessment for the MSc Med (Bioethics & Health Law) course. It is my own unaided work except where I have explicitly indicated otherwise. I have followed the required conventions in referencing the thoughts and ideas of others. This research report has not been submitted before for any degree or examination at this or any other university.

Signature:

Date: 02 December 2011

Dedication

For my father, Rodger Africa (1933-2010)

Always remembered

Abstract

'Whistle blowing' means to blow a whistle calling attention to practices which an individual considers as immoral or illegal and harmful to the public. Some people think whistle blowing is a good or right act; others consider it wrong. There are numerous reports concerning blowing the whistle in scientific research. I place whistle blowing in the context of institutions, focusing on good clinical practice and Research Ethics Committees. Many research activities take place resulting in monetary and personal gain which may influence research conduct. I explore some issues in the development and organization of Research Ethics Committees, discuss the nature of whistle blowing and whistle blowers, and examine some whistle blowing incidents in scientific research. I conclude that although the function of Research Ethics Committees does not necessarily include mechanisms for whistle blowing, that this idea has merit and should be considered.

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Chapter 1Introduction to the Study

1.1 Introduction: Synopsis of the research report

The term ‘whistle blowing’, means to blow a whistle on actions that an individual believes to be illegal or immoral which will harm the public. There are numerous reports concerning blowing the whistle in medicine, scientific and clinical research. Globally, clinical research represents over a billion United States (US) dollar industry. In South Africa, as well as internationally, many research activities take place resulting in monetary as well as personal e.g. academic gain for clinical researchers. This research report investigates the nature of whistle blowing and whistle blowers through analysing some of the incidents of scientific and medical research misconduct. I point out both the positive and negative aspects of whistle blowing. Additionally, Good Clinical Practice (GCP) standards of research practice and the role of Research Ethics Committees are evaluated as well as some of the mechanisms in place which accommodate whistle blowing and the protection of the whistle blower.

In particular this research report looks at the role and functions of Research Ethics Committees (REC) and discusses the pros and

cons of their taking on the function of whistle blowing measures. Good clinical practice, the role of RECs and the topic of whistle blowing in medical, scientific and clinical research are irrevocably intertwined. This is because of the potential impact on human health should breaches in GCP occur, the fact that RECs serve as ethical gatekeepers and because often it is only through whistle blowing that scientific misconduct is brought to the attention of the public.

One of the consequences of going to the public with allegations of scientific misconduct is that the blame is often placed on the REC which authorized the research to commence in the first place. I explore some of the less-discussed areas concerning Research Ethics Committees such as tenure, and composition, identify some of the innovative tools used by some institutions to promote whistle blowing and note some of the South African legislation pertaining to protection of whistle blowers.

In my research report, I suggest that because of the voluntary nature of Research Ethics Committee members and the time involved in reviewing protocols that to add the function of oversight by way of a system to allow for the anonymous reporting of perceived scientific misconduct would be difficult. However, I conclude that because the major responsibility of Research Ethics Committees is to protect human participants in research that the idea of developing a mechanism for whistle blowing and the protection of whistle blowers

still falls under their ethical duties and that they should work with their institutions to provide such a service.

1.2 Problem statement

The problem is that scientific integrity and public protection are put in jeopardy because of scientific misconduct. This misconduct often reaches the media usually through a whistle blower and results in concerns about the safety, reliability and integrity of clinical research. The aim of scientific research is to increase scientific knowledge. When misconduct takes place in research, the very nature of scientific inquiry is damaged. In clinical research, scientific knowledge aims to benefit humanity. To this end, codes and guidelines of GCP are used to promote ethical and moral standards in clinical research. In addition, the approval of all research protocols, i.e., medical and non-medical must be approved by a Research Ethics Committee. Despite such safeguards, there are still reported cases of scientific misconduct or non-compliance with the ethical codes of conduct in the practice of research.

1. 3 Objectives

1.3.1 Overall Objective

The overall objective of this research report is to explore the nature of whistle blowing in medicine and clinical research specifically as it concerns good clinical practice and the role of Research Ethics Committees.

1.3.2 Specific Objectives

- To describe key issues in the development, roles and functions of Research Ethics Committees in relation to whistle blowing.
- To analyze Good Clinical Practice codes and guidelines to ascertain if they include considerations of whistle blowing and whistle blower protection in the reporting ethical malpractice in clinical research.
- To suggest that the inclusion of whistle blowing guidelines be developed for Research Ethics Committees for the purpose of identification and prevention of scientific misconduct.

1.4 Methods & study design

The method used in this research report is an analysis and ethical reflection of literature concerning whistle blowing, Research Ethics Committees, good clinical practice and organizational ethics.
Through critically analyzing relevant literature I will clarify the terms, consider alternative views, and obtain as many facts as possible concerning cases of whistle blowing in medical and clinical research settings. In the context of whistle blowing, I will examine case studies, GCP codes and guidelines and consider the roles RECs play in ensuring the ethical practice of research. I will follow a standard form of ethical evaluation: studying and reflecting on right and wrong actions.

In my study design I will obtain literature from search engines such as Google Scholar and the numerous academic search engines available through the University of the Witwatersrand library. I will use keywords such as ‘whistle blowing’, ‘whistle blowers’, ‘Research Ethics Committees’, ‘research misconduct’, ‘responsible conduct in research’, and ‘good clinical practice’ in my Boolean searches. I will then analyze and ethically reflect on the literature in terms of the practicality of adaptation of whistle blowing mechanisms for Research Ethics Committees.

1.5 Organization of research report

Following this Introductory Chapter, I will comprehensively look at the development, roles and functions of Research Ethics Committees. This will provide the reader with an understanding of some barriers Research Ethics Committees face when considering putting in place mechanisms for potential or actual whistle blowers. In Chapter 2, I will discuss the institutionalisation of Research Ethics Committees identifying some of their advantages and disadvantages. In Chapter 3, I will identify ways in which the nature of scientific misconduct has changed over time. I will reflect on two particularly important areas which are relevant to scientific misconduct in academic institutions: the push to publish and the importance of research replication. In Chapter 4, considering organizational ethics, I will reflect on scientific misconduct as an individual or collective responsibility. Chapter 5 presents a particular example of scientific misconduct in research

and carries on with a discussion of the idea of individual responsibility introduced in the previous chapter. In this chapter, I ask if whistle blowing might have made a difference to its outcome. Having given the reader a comprehensive background and introduced the idea of whistle blowing, in Chapter 6 I continue to describe and discuss the idea of whistle blowing generally and as part of institutional structures. I also identify some of the measures that are suggested for protection of whistle blowers as well as the debate concerning the character of whistle blowers. Chapter 7 consists of my concluding remarks. In this chapter I suggest that while understanding the limitations of Research Ethics Committees, it is from them that discussion and consideration should be given towards developing mechanisms to allow for whistle blowing and protection of whistle blowers.

Chapter 2 Institutional Review Boards, Institutional Ethics Committees and Research Ethics Committees

2.1 Introduction

The idea that there is something uniquely moral in a doctor-patient has been foundational in the practice of medicine. This thought, although appearing later in history, also extended to the researcher-participant (or 'subject') relationship.[1]

The institutionalization of the moral approach to a researcher-participant relationship began after World War II. This followed from the findings of horrific human experimentation programmes conducted on prisoners by Nazi scientists and doctors. The fact that doctors and scientists, perhaps the most globally socially esteemed categories of professions, were engaged in these experiments shocked the public. Following the 1946 Nuremberg trials, where twenty-three Nazi doctors, scientists and administrators were found guilty of crimes against humanity, the Nuremberg Code was formulated (Annas 1998:130-133). The Nuremberg Code was published in 1948, and institutionalized the idea that there is a moral approach to scientific research. It was the first international document to mandate research participant (or subject) 'consent'. The Nuremberg Code expressed the idea that the benefits of research

[1] (Note) Doctors, in their commitment to their patients and scientists, working for the good of society were perceived by society to act beyond the common level of morality - and of course, many of them did so.

should outweigh its burdens. Perhaps, most importantly, it communicated to the world that the advances of scientific research should not be prioritised over that of a single human life (Rothman 1998: 55; Annas 1998).

In tandem with the advent and growth of mass media technology there grew a greater global focus on scientific or clinical research. In 1964 the World Medical Association (WMA) promulgated a set of ethical guidelines, formulated in part from the Nuremberg Code. The intent of the declaration, known as the Helsinki Declaration (1964), was to provide more practical guidance to the research community. It was considered the world's most influential institutionalized research ethics guideline of its time (Human and Fluss 2001). Since its first appearance it has undergone changes reflecting the various currents and interests of changing societies (Schüklenk and Ashcroft 2000: 159-172).

The Declaration of Helsinki gave great importance to GCP measures in its focus on ethical practices. However, researchers and scientists appeared not to have given credence to the ethics of research. They were shamed in the public's perception as the facts unravelled about the knowingly, planned and systematically continued abuse of humans in research: *The Tuskegee Syphilis Study.*

Six hundred African-American men, mainly share-croppers, had been used in a 40-year study (begun in 1932) concerning the natural

progression of syphilis. The progression of syphilis was known to be halted by penicillin (marketed in the 1950's) and a recognized cure, but it was denied to the participants. Moreover, documentation shows that when participants were diagnosed as having syphilis by other physicians, researchers intervened to prevent their treatment (Jones 1993).

Public response to the 'Tuskegee Trials' resulted in the United States of America's (USA) creation of their the National Research Act of 1974 which lead to the development of a special commission, the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. This Commission was tasked with the development of ethical guidelines designed to protect research participants and resulted in the Belmont Report (1979).The Belmont Report outlines the basic ethical principles and guidelines that should assist in resolving ethical problems surrounding the conduct of research using human participants.[2] To fortify against further moral digressions in research, the USA government, in 1981,

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[2](Note) The Belmont Report's ethical principles and their corresponding applications include: 1.*Respect for persons* .Individuals should be treated as autonomous agents; Persons with diminished autonomy are entitled to protection; Informed consent: Participants, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them; The consent process must include three elements: information, comprehension, and voluntariness. 2. *Beneficence*. Human participants should not be harmed; Research should maximise possible benefits and minimize possible harms; Assessment of risks and benefits: The nature and scope of risks and benefits must be assessed in a systematic manner. 3. *Justice.* The benefits and risks of research must be distributed fairly; there must be fair procedures and outcomes in the selection of research participants (Belmont Report 1979).

mandated that all national research protocols involving human subjects must be reviewed and approved by an Institutional Review Board (IRB) before an intended research could commence. They extended this to all research funded in whole or in part by the USA federal government. This, in short, heralded the national and international formalisation and institutionalization of Research Ethics Committees[3] and the ethical guidelines setting out the moral basis of good clinical practice in research.

2.2 Institutionalization of Research Ethics Committees

When an institution accepts the responsibility of forming an Institutional Review Board (IRB), an Institutional Ethics Committee (IEC), or a Research Ethics Committee (REC), it commits itself to follow institution-based, national, and /or international research ethics standards of GCP. Based on these practices, the REC ultimately can either accept or reject scientific / clinical research protocols.[4]

Research Ethics Committees are organised structures which are formal, codified, and designed to address the possible harms and benefits to human participants involved in any proposed research (Bozeman and Hirsch 2005: 271). Moreover, they should include

[3](Note) An Institutional Review Board (IRB), an Institutional Ethics Committee (IEC) and a Research Ethics Committee (REC) are the three most common terms used to define a group of persons who have the formal function of reviewing, approving or disapproving and monitoring scientific research protocols which involve humans. Although IRBs and IECs, as indicated by their name part of institutions, many institutions which have RECs do not use the term. In this research report, I will use the term 'REC' as synonymous with IRB and IEC.

[4]In this research report I will use 'clinical' research and 'scientific' research synonymously

some methods to ensure compliance or enforcement of the scientific and ethical premises which guide GCP in research (GCP 2006).[5]

As a form of institutionalized ethics, RECs have many advantages but as many are currently construed, there are also disadvantages.

2.3 Advantages and disadvantages of institutionalized Research Ethics Committees

A major advantage of an institutionalized REC is that there is some public assurance that research conducted with human participants under the auspice of any given institution will result in an overall good (Meslin 1990; Snyderman and Holmes 2000).

This good, according to Snyderman and Holmes (ibid) may be viewed from different perspectives.

1) A *societal good* in that the research results lead to greater scientific knowledge or to benefit society. Simultaneously, public knowledge that participants in the research are protected leads to the public trusting research conducted at the institution.

2) A *personal good* for the Principal Investigator (PI) / Researcher in that his or her research holds the potential for personal gain. This

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[5](Note) Concerning REC's in South Africa, The National Health Act No. 61 of 2003 (South Africa)outlines their functions: 1) Reviewing of research proposal and protocols to ensure that research will be conducted to promote health and to prevent or cure disability and disease; 2) Ensuring that humans involved in research are treated with dignity and that their well- being is not compromised; 3) Ensuring that informed consent is obtained in the case of human participants; and 4) Granting approval in instances where research proposals and protocol meet ethical standards.

may be realised for example, by way of personal pride, public acclamation, job advancement, and the potential for further research funding.

3) An *institutional good* in that an institution producing quality scientific research has the potential to draw more academic researchers to its institution, increase its research budgets through funding and 'make a name' for the institution.

Some disadvantages of institutionalized REC's are that although all RECs should share common aims (e.g. protection of vulnerable populations, provisions concerning confidentiality, proper risk-benefit ratios, valid informed consent procedures) the achievement of these aims is dependent on their individual organizational structure as well as their regarded (or not) position within an institution.

For example, if a REC is unable to act independently from government or other influence, it cannot meet the aims of GCP in scientific research; if REC members are unskilled in research ethics decision-making, flawed judgments may occur; and if a REC does not include processes regarding committee membership tenure, control may be limited to only a single group (Lemmons and Freeman 2000: 548-550). So while the ethical aims remain consistent, world-wide there is a great variety in organizational structure and composition of institutionalized RECs as well as the place and value they hold within institutions.

Decisions concerning what are considered appropriately and properly designed research protocols, the canons of ethics and rules developed, any legal considerations consistent with the RECs locale, the institution's own research agenda, the appointment-base of REC committee members (e.g. voluntary, elected or appointed, particular interests, ethics knowledge, duration of tenure) are some of considerations that play a part in the organizational structure of institutionalized RECs.[6]

Apart from the ethical rules, regulations and guidelines governing RECs, much emphasis in the organization of REC's is placed on the composition of REC members. The ideal is to ensure that committee members are drawn from a variety of persons interested in and knowledgeable concerning scientific research and research ethics processes. Thus the usual composition of institutionalized REC's are academics, clinical, scientific and social science researchers, ethicists, (more recently) a legal representative, a member who is not attached to the same institution, and a 'community' or 'participant' representative.

While the knowledge-based composition of committee membership is a very important consideration, the organizational rules governing the committee are also vitally important to consider as they have direct relevance to the protection of research participants. They do so

[6](Note)The same considerations could apply to non-institutionalized RECs as well.

because as Goldman and Katz (1982) identify, RECs are organizations or ‘structures’, as Gabriel and Schwartz (1999: 177) put it, which are grounded on both the ethical ideals of GCP and rules which define the roles and responsibilities of individual REC members.

It is natural to see that the rules governing the REC *per se,* e.g. its terms of reference, formulation, tenure, membership, payment, continuing education, and budgets are important as they have the potential to influence REC decision-making. Another factor to be considered is that such rules will necessarily vary from one institution to another.

As pointed out by the European Medicines Agency (2006) the legal status, composition, operations and functions of REC’s may differ from country to country. What must remain a constant in all institutionalized REC’s are the rules, regulations and ethical guidelines specific to GCP. Concerning the latter, there is reported inconsistency in the implementation of them (ibid: 179-180) as well as what Barber, *et al.* (1973) describe as a “propensity for subversion [of the rules]”. If this is the case, then it does merit some concern.

2.4 Research Ethics Committees, rules, regulations, and good clinical practice guidelines

To remedy inconsistency or subversion of GCP guidelines[7] that govern scientific research, as well as the specific functioning of the REC and its individual members, Shaul (2002: 121-122) suggests both be tightened. He (ibid: 121) writes,

> *Vague notions of accountability, although well-meaning and sentimental, offer little guidance to those they are intended to direct and little comfort to those they are supposed to protect.*

On the other hand, as Bozeman and Hirsch (2005: 280) point out,

> *... in most instances of organizational failure, and especially when there is a perceived need for greater accountability, the first response is to develop more rules, more precise rules, more standard rules, rules with greater reach, and more training in the rules. Often this does more harm than good, undermining existing rules, setting up conflicts among rules and making rule implementation more and more complex.*

The increasing complexity of rules on both the micro and macro levels for REC members is a growing concern. For institutionalized REC members, their position as mostly voluntary, apart from their other duties makes free time (viz. to become *au faire* with new rules) difficult. Researchers as well, may find new regulations difficult to

[7] (Note) Henceforth in this section, while admitting the differences between them, I will refer to "rules, regulations, and guidelines" interchangeably.

incorporate in their proposals as well. This is particularly the case when they are involved in multinational research. Often the regulations from one country require an extensive amount of detail and there are potential problems of the way in which these are interpreted.

As pointed out by Bozeman and DeHart-Davis (1999: 149-153) regulations include inherent subjectivity in their interpretation, particularly the ones that deal with ethical ideals. The subjectivity of the interpretation of regulations is a topic also raised by Schüklenk and Ashford (2000: 160) as well as Snyderman and Holmes (2000: 595) who write:

> *… well-meaning individuals and institutions may interpret regulations differently...*

Concerning interpretation, Resnik (1998: 300) states that ethical standards as articulated in the rules, guidelines and regulations which frame GCP are universal just as are the general GCP principles of research involving human subjects. However he suggests that they are not *absolute* because their interpretation relies on social, economic, and cultural factors which exist in the REC's and researcher's environment as well as in how each individual REC member interprets them (ibid: 301-302).

The major aim of all RECs is the protection of human participants in research. This is accomplished through expert review of research

protocols. So just how rules are subjectively interpreted by REC committee members is an important consideration when research protocols are reviewed.

In cases where the research protocol is ‘black or white’, interpretation of GCP regulations is not a problem. For example, if a researcher neglects to provide an account of his or her process involved in the obtaining of informed consent as well as failing to include the necessary form in his or her protocol, then there is little need for a discussion; the participants are not protected therefore, the research protocol is rejected. Likewise, if a research protocol is judged to be scientifically unsound, the protocol is rejected.

In areas which are not so clear, such as when decisions are made concerning risk-benefit ratios, the judgment may be more complex. This is because REC members may fail to remember that such decisions are always probabilistic, and often decisions are made without the input of persons who will actually bear the consequences of the REC’s decision. This returns us to the importance of a ‘community member’ on the REC who is actually *au faire* with the implications of a particular type of research on its participants.

This is a particularly difficult area to tackle in the confines of REC structures. The first reason why it is difficult is that RECs must be limited in size and secondly, its members must necessarily share a sufficient common ground of ethical, technical, and scientific

expertise (Ross 2002: 56-57). To have an actual participant-representative from each and every type of scientific research protocol under review is most likely logistically impossible. This is principally so because if one considers the probable cost, knowledge of the 'language' of scientific research as well as having an understanding of ethical considerations, the task of finding a participant who meets these needs may prove difficult.

At the same time, much can be said about the ideal of participation in scientific research from the perspective of a participant (Schensul 2002; Chopyak and Llevesque 2001). Without an actual research participant representing each research proposal, REC members should keep in mind their duty to be ever-cautious and empathetic, viewing the research from the perspective of the participant, particularly when making risk-benefit judgments (Meslin 1990: 11).

Other problems with interpretation of rules are extensively highlighted from the perspective of decisions made by RECs in developing countries in relation to international research ethics rules. These concern e.g. the feasibility (or not) of the demand for 'best proven diagnostic and therapeutic methods of treatment for all research subjects' and whether it should be upheld, as well as questions surrounding 'who owns international research ethics rules, guidelines, and regulations' (Schüklenk and Ashcroft 2000: 159-172; Hellman and Hellman 1991: 1589-1592).

2.5 Good clinical practice and the institutionalization of Research Ethics Committees

Globally, good clinical research practice (GCP) guidelines aim at ensuring that clinical research is conducted according to ethical and moral principles which ensure that the wellbeing of clinical research participants. The role of RECs is to ensure that research conducted on human participants does not violate the rights and welfare of the participants. Given this statement, it remains the task of Research Ethics Committees to approve proposed clinical research protocols on human participants based on qualifying safety parameters. There however exists a shortcoming on the part of RECs in that they cannot be aware of improper conduct on the part of researchers unless such acts are brought to their attention.

To understand the context in which research protocol evaluation takes place, it may be helpful to look back at how and why REC's became institutionalized. As shown earlier in the aftermath of the Tuskegee Syphilis Study. Bozeman and Hirsch (2005: 272) note, "It is a history characterised by disaster response".

There are always three steps involved in this disaster. They include: 1) 'the researcher, who by way of a defective moral character, greed, arrogance or ignorance is involved in research misconduct, 2) the public exposure of his or her unethical research practices and usually, 3) the development of controls such as rules, policies,

guidelines, declarations, and training programmes geared to reduce the likelihood of unethical practices reoccurring' (ibid: 264)

As mentioned previously, the duty of an REC is to protect the rights and welfare of participants of research. This is accomplished through reviewing research protocols, particularly noting the informed consent document and the ensuring of an acceptable level of risk. The idea that REC's should monitor as well as the level and extent of monitoring research is a source of much debate as will be further discussed later. This is an important issue as it is directly linked to whistle blowing.

Despite the good intentions of the institutional review process, some have claimed that the activity is "… a charade … to mask the ugly ethical fact that subjects enter research without fully understanding what they are doing" (Robertson: 1982: 1) and,

> *… [IRBs spend] too much time to the production of paper promises and almost no time to the enforcement, investigation, or general assurance that promises will be kept* (Caplan 1982:8).

If such claims are true, then we need to know the extent of the problem so we can judge the rightness or wrongness of them. This is the topic of the following chapter.

CHAPTER 3 Changing Conceptions of the Scientific Misconduct Problem

3.1 Introduction

Twenty or thirty years ago scientific fraud and misconduct[8] did not receive great media attention. Medicine and science were still regarded as 'special' professions which did not involve themselves in unsavoury activities. The changes which occurred were most likely due to a combination of factors such as advances in media communication, leaps in science, medicine and technology, the vast array of different research activities due to the rise of new and emerging diseases, divergent international collaborative research activities and the growth of pharmaceutical industries. Fuchs and Westervelt (1996) write,

> *The public impression of scientific deviance is based on a few individual cases, dramatized by the media with generous doses of human tragedy and failure*.

From,for example, Tuskegee, Willowbrook, radiation experiments, and grave errors in gene-therapy clinical trials, there is a sizable

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[8](Note) Research misconduct is defined by the National Institute of Health (USA) (NIH) "… as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results … Fabrication is making up data or results and recording or reporting them. Falsification is manipulating 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 is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit."

list of publically recognized scientific misconduct (Snyderman and Holmes 2000: 595). So we can say that focus on the 'misconduct problem' has been accompanied by major shifts in the public's perceptions concerning scientific research in general.

It was once believed that scientific misconduct was extremely rare. This idea is firstly attributed to the social status that clinical researchers hold in society. The second reason why scientific misconduct was thought to be rare is the folk-belief that scientific research is always objective, value-free.[9] When accepted by the public as true, then scientific research would need no outside interference or regulation. The idea that the 'institutional norms of science' serve as an internal mechanism to self-regulate scientists and researchers has a long history.

Self-regulation based upon the institutional norms of science means that autonomy is given to the scientists and researchers by the public to keep its own trust. This means in practice e.g. that scientists publish their findings, provide full documentation of their work so that their research findings can be independently verified, and for scientists to answer honestly any criticisms and questions concerning their work by their peers openly and publicly (Teich and Frankel 2002; Feynman 1985:344). Thus, it would appear that detection of scientific misconduct is likely, and possibly sorted-out by the

[9] While science *per se* is considered value-free, scientists and researchers as individuals are subject to all human frailties.

scientifically community, particularly if the research results are important to the scientific research agenda.

Before the ± 1970, the number of cases of scientific misconduct which reached the public's domain was small. This was particularly so when compared to other areas of public interest, such as celebrity lives, crimes, wars, and the economy. During the 1980's the traditional view came under attack (Woolf 1981: 147; Koshland 1987: 235-141). Many science-observers lost confidence in the claim that scientific misconduct is extremely rare. They questioned the effectiveness of detection by way of the institutional norms of science. Moreover, as Broad and Wade (1982) suggest, many instances of research misconduct went undetected.

The reasons they (ibid) offer for this is because there are steps leading to public exposé of research misconduct arising out of institutions. These stages are that 1) the research in question was actually done, 2) whatever discrepancies present in the research or researcher were noticed, 3) they were reported to someone or structure within the institution, 4) the research was investigated e.g. by credible persons in the institution, 5) research misconduct was confirmed, and finally, 6) research misconduct was disclosed to the media. At any stage before public disclosure, although with increasingly difficulty keeping with the step progression, it is possible to stop the process. It would be to the overall benefit of an institution

to internalise such an investigation to avoid adverse publicity, so it is conceivable that such actions have been taken.

The control methods used by the scientific community for self-regulation following research publication (such as peer-review and replication of findings), should remain strong enough to detect any wrong-doing. And one could assume this to be true. However, one hurdle to overcome is the appreciation of the ever-increasing complexity of scientific research. I will now turn to two major problems faced by researchers.

3.2 'Publish or Perish'

In science and technology there is an intense struggle for scarce research resources. Research scientists and their institutions "invest substantial resources … and incur substantial opportunity costs" towards their research goals (Martinson, et al 2006). The single best way to become known is through publication of one's research findings in a subject-specific internationally recognized peer-reviewed journal.

Under the umbrella of publication there are a variety of unethical practices. These may range from problems with the policies of the journal, the publisher or editor, the researcher author(s), the language of publication, or the manuscript reviewers.

Some of these unethical practices include 'honorary authorships' (or inclusion of those who contributed nothing substantive to the

publications that bear their names) (McCook 2006:26-34; Fuchs and Westervelt 1996; Goodstein 2002), neglecting to divulge that the research results were based on historical controls (De Vries, et al. 2006:44), failure of peer-reviewers to declare conflict of interest when reviewing manuscripts (McCook 2006 :26-34); the repeated publishing of the same data (Kreutzberg 2004: 330-332; Fuchs and Westervelt 1996) and misrepresenting statistical data (Sox and Rennie 2006: 609–613; Goodstein 2002).

Patsopoulos, Ioannidis, and Analatos (2006:1061-1064) also point out that there is an increase in article citations based on particular types of research funding. One might also consider that a political bias also exists, similar to Schüklenk and Ashford's (2000) arguments concerning international research ethics guidelines.

Generally, it is recognized that the mentality of 'publish or perish' exists in all academia. The more a researcher publishes in an 'important' journal, the better his or her chances become for career development. Often this push-to-publish results in a scientist taking the results of one research project and splitting the findings into categories which can potentially be submitted to many different journals to produce more publications (Lawrence 2003:259). As Lawrence (ibid) notes, there is also pressure placed on institutional

scientists to not only publish, but to publish in “top-tier” journals such as *Science*[10]and *Nature*.Lawrence (2003: 261) writes:

> *Although there are good reasons for publishing papers where they are more likely to be read, when we give the journal priority over the science we turn ourselves into philistines in our own world*.

3.3 Scientific articles and peer-review

Linked to publication pressures is the idea of scientific peer-review. Peer-review, in the sense of the moral ideal of sharing scientific findings for the betterment of society, has historically been a mechanism in which the institutional norms of science controlled scientific misconduct. This is because researchers and scientists must rely on the integrity and honesty of their colleagues to further the aims of scientific research (Schensul 2002:199-202). While the members of the scientific community may argue against a particular research finding and question e.g. its methodology or statistical analysis, this is considered part of the way in which, at least ideally, and the scientific research community controls itself (Fuchs and Westervelt 1996).

Scientific findings are judged on their scientific and moral merit.It is mainly through publishing that this is accomplished.Like REC’s which

[10](Note) According to McCook (2006) *Science* receives 12,000 submissions per year. Of this number, less than eight per cent are accepted for publication.

make a judgment concerning acceptance of rejection of a research protocol, persons who serve as scientific research article peer-reviewers carry a great responsibility.

With the global increase of submission of research articles for publication, the push to conduct research, political pressure, and the increasing complexity of scientific research it is a challenge for editors to 'recruit and retain', if you will, persons who are able to meet such needs (McCook 2006: 26–34). While it may be easy to place blame on editors or peer-reviewers when scientific misconduct is alleged (or proven) in a previously published article, if the institutional norms of science are to be regarded, then the following point as reported by Lawrence (2003: 259-261) has merit:

> *… After all, if researchers and editors cannot safely assume, even as a starting point, that scientific results are essentially true as reported, then the advancement of science is in serious trouble*.

Nath, Marcus and Druss (2006: 152-154) reported that in 395 retracted publications in international biomedical journals from 1982 to 2002 the majority were withdrawn by publishers due to experimental errors as opposed to scientific misconduct.[11] However, a worrisome note is raised by Sox and Rennie (2006: 611)

[11](Note) Of the articles, 61.8% were withdrawn due to unintentional errors; 27.1% were retracted due to scientific misconduct (Nath ,Marcus and Druss 2006).

considering the possibility that journals might fail to retract articles they know to be fraudulent. In another study concerning plagiarism, Giles (2005: 258-259) showed an empirical variance from 0.02 per cent to ± 25 per cent of plagiarism of all articles. However, his results should be considered hypothetical because the number of unreported cases is unknown.

3.4 Research result replication

Another way the institutional norms of science purport to internally control scientific misconduct is through research replication. At one time it might have been possible to replicate a scientist's research, or parts of it, thus supporting his or her hypothesis. Now, although admittedly it can still be accomplished, the great advances in science and biotechnology as well as Intellectual Property (IP) rights in the form of patents and the high cost of replication have put barriers in place concerning attaining this ideal. For example, the types of materials used in some research such as specific cell lines, and the exact equipment used by the original researcher may simply not, for a variety of reasons, be obtainable.

It has been questioned whether the idea of exact reproducibility is even expected anymore (Goodstein 2002). In addition, institutionalized academic researchers must field pressures for dynamic results, publications, and funding. Combined, the effect may lead to what Lawrence (2003: 259-261) refers to as an

> *… antiscientific culture in which pushiness and political skills are rewarded too much, and imaginative approaches, high-quality results and logical argument, too little*.

If reproducibility no longer becomes a goal, or is impeded as a goal, then there is an opening for scientific misconduct (Broad and Wade 1982).

A Norwegian survey in 1999 showed that of 274 medical scientists, twenty-two per cent knew about serious cases of scientific misconduct, three per cent were aware of false data and nine per cent admitted that they had contributed on one or more occasion in misconduct (Nylenna, et al 1999: 57). Researchers Martinson, *et al*. (2005: 737–738) surveyed over 3,200 early and mid-career NIH-funded scientists concerning scientific misconduct. One third of the respondents admitted one or more transgressions which included 'lack of critical reflection concerning their findings' and "changing the design, methodology or results of a study in response to pressure from a funding source" (ibid: 737). The position the author's (ibid) take is,

> *… Historically, professionals and the public have focused on headline-grabbing cases of scientific misconduct, but we believe that researchers can no longer afford to ignore a wider range of questionable behaviour that threatens the integrity of science.*

The traditionally conceived 'institutional norms of science', such as peer review and scientific replication, as we have seen, still exist as internal mechanisms of self-regulation for scientists and researchers. They have, and are, undergoing change. This is primarily due to the fast growth of scientific technology and development and pressures placed upon scientists to both produce and publish well.

Clinical researchers also face the dilemma of recognising the boundaries between research funding from the private and from the public sectors. This often-vague boundary may present moral problems as scientific results are increasingly in many ways bound to the interests of financial shareholders. Concerning research misconduct, industry has funded many of its most notorious cases. Patsopoulos, Ioannisis and Analatos (2006: 1061-1064) write,

> *… Clinical research is dictated by the need to promote products of industry. In this sense, academics might have indeed lost control of the clinical research agenda*.

Many scientists and researchers argue against this, claiming that research misconduct is not wide-spread, it is just the case of a 'few rotten apples that rolled into the public domain' (Broad and Wade 1982) or the occasion of a 'black sheep' (Check and Cyranoski 2005). A discussion concerning this follows in the next chapter.

CHAPTER 4 Scientific Misconduct in Research: Some Considerations

4.1 Introduction

Notions of who or what is responsible for the problem of scientific misconduct has grown broader during the last few decades. In the context of scientific misconduct, the reasons for it may be viewed in different ways. Moral responsibility on the part of individuals and institutions of course is the major issue. But to narrow the focus, looking at the ways in which causal, and political responsibility feed into the whole may serve to explain the complexity of ascription of blame.

4.2 Individual and collective responsibility

Moral responsibility raises issues about 'the right': What is the right thing to do? What are our duties? What principles shall we follow? (Beauchamp and Childress 1994; Beauchamp and Walters 1994). Viewed narrowly in research misconduct, at least following the institutional norms of science's traditional view, it would hold that scientific misconduct is due to a flaw in a particular scientist's moral character; a deviant from the norm. This is the simplest view and, of course, does occur. Yet, it fails to take into consideration the idea that institutions also have a moral responsibility to ensure that the principles of GCP are followed.

When causal responsibility is considered then there is an attempt made to decipher the aetiology of the problem; it is concerned with the features of the ways in which scientific research is organized. As we have noted, there are pressures placed on individuals to publish, scarcity of resources (including funding), deficiencies in the scientific peer-review system, inadequate procedures for record-keeping and the diffusion of responsibility for jointly authored publications may all be considered to fall under reasons why, or contributing factors to research misconduct.

This does not mean that the individual or primary person is dissolved of his or her moral responsibility; it only serves to provide understanding into ways in which the institution may contribute to an individual's steps into misconduct. Institutional mechanisms, such as communication amongst scientists, and some degree of common knowledge concerning what is being researched by whom and where are a part in institutional oversight. While still focusing on the deviant character of an individual, the moral responsibility for research misconduct is increasingly viewed as being shared with various others.[12]

Political responsibility concerns the overall organizational structure in which scientific misconduct took place. It looks at those in a position

[12](Note) For example, co-authors of articles who fail to check carefully the data, peer-reviewers of articles who only give a cursory look, research department heads who are not aware of research taking place in their laboratories.

of responsibility to ‘do something’ about the problem. Often in the case of research misconduct, the first group to investigate (or blame) is the REC. The political structure of the institution in terms of its ‘research agenda’ and commitment to researchers and scientists would be included under the idea of political responsibility.

4.3 Curbing and understanding the problem of scientific misconduct

Major scientific organizations, books, journal articles, and research ethics guidelines discuss scientific misconduct (NIH a, b & c; Safecall; Benham 2007: 156; Hilgartner 1990: 1-5). Various methods to both curb and understand the problem are often the topic at conferences and meetings. Their ideas may be summarised into four overlapping considerations:

1) Tightening institutional oversight and monitoring. The first one looks at increasing institutional oversight and monitoring processes by increasing the focus on research results, data management, and laboratory practice. This idea views the problem of scientific misconduct as not only on the individual, but institutional level. So institutional policies concerning e.g. the recording and retention of data, research audits (in the forms of verifiability and reproducibility) are recommended.

2) Scientific research support. Considering one of the problems to be a lack of professional standards and education in the profession of a scientific researcher, this approach looks at ways in which

researchers can be re-professionalised or their professionalism greater-supported. In this position, there would be emphasis placed on the importance of the work of scientific research as well as requirements for all research scientists to be educated in the ethics of research equal to that of research methodology. In addition, this view supports more intense interaction between senior scientists and students and emphasising GCP.

3) Structural changes in academic research award system. This standpoint looks at the academic reward system. Causally, since the great emphasis on appointments, promotions and grants as rewards for research are linked to scientific misconduct, it has been suggested that changing the system regarding same should be considered. In this way, incentives for people to cut corners in their research activities for academic rewards could be reduced.

4) Anonymous disclosure of actual of perceived research misconduct. The last idea focuses on detection and deterrence of research misconduct. To this end, it requires an efficient and fair examination of allegations.

There has been a great amount of controversy concerning these ideas. If put into place, some of them might change the ways in which research is conducted. The proponents of change make the point that they are necessary to maintain public trust (Jonas 1984; Meslin 1990; Lurie and Wolf 1990). Others say that such ideas will

diminish the independence and creativity of the scientific community by adding to the already-burdensome bureaucratic processes involved in research. A final worry is that increased regulation of scientific research will facilitate those with political agendas to control research.

Points such as these are taken seriously. However, the moral imperative to protect the participants in scientific research when taken as a mandate, has in spite of researcher objection, been acted upon in various ways by different institutions

As we have seen, at least traditionally it was assumed that serious misconduct in research such as faking results and data only involved a deviant individual (Luria 1975:18). Viewed in this way, the attention was placed on a single individual's psychopathology. For example, from the purported scientific findings of Korea's Hwang to revelations of his scientific misconduct, followed by his fall, were highly publicised (Check and Cyranoski 2005: 1056–1057). The results demonstrated to the public how scientific institutions manage a single rogue researcher.

The problem was, as Hilgartner (1990: 3) explaining the traditional position states, "… the moral failure of an individual." When viewed in this way, the institution, the institution's REC, and other scientists or persons who might have been directly or indirectly involved in the misconduct are not the major focus of attention. The institution, it's

REC and (one might consider at least in some way involved) others are sufficiently, for public concern, vindicated.

4.4 A case of scientific misconduct

During the year of 1999, the head of Clinical Oncology and Haematology at the University of the Witwatersrand, Professor Werner Bezwoda, delivered a paper on his clinical research findings to both the American Society of Clinical Oncology (ASCO) and later in the same year at the European Cancer Conference (Schneider and Schüdlenk 2003).

His previously published research results in the *Journal of Clinical Oncology* (Bezwoda, *et al.* 1995: 2483-2489) caused excitement in the oncology community. His paper was titled, "Randomised Controlled Trial of High Dose Chemotherapy (HDC) for High Risk Surgically Treated Primary Breast Cancer." Other scientists had researched this area but found no results indicating a significant benefit in using high-dose chemotherapy for that particular group of patients (Schneider and Schüdlenk 2003). However, the reputation of the researcher and his institution were such that the research community gave credence to his 'randomised clinical trial'.[13]

[13] (Note) Researchers who are unable to replicate another's work usually consider in some way that they have made a mistake. Making and recognizing honest errors is a part of everyday scientific work.

Following his dual presentations, the ASCO sent a delegation to South Africa with the purpose of developing a large study with their European counterparts. This was in an attempt to duplicate Bezwoda's results (Sprague Jones 2000). After the ASCO representatives found Bezwoda able to produce the clinical files of only about one third of the supposed number of participants and none from the control group, the delegation became disturbed (ibid).

They then contacted the Chair of the University's REC with their concerns. The REC's Chair, along with high-ranking university officials immediately began an investigation. Soon it was discovered that Bezwoda never conducted a randomised controlled trial. Rather, he performed a retrospective review of patient files which he manipulated to represent a randomised controlled trial (Weiss,*et al*. 2000).

Further investigated, his breaches of GCP included: 'by-passing the institutional REC, forging documents attesting both research and investigational drug-use approval by the 'Pharmacy and Therapeutics Committee' of the Johannesburg Hospital, failing to record any patient's informed consent, using potentially falsified or fabricated data, misrepresenting the race of his research participants and lying about treatments that were used' (Sprague Jones 2000: 36).

At a formal disciplinary hearing, Bezwoda admitted his guilt. The University of the Witwatersrand found him "guilty of bringing the University into disrepute, contravening the rules and regulations of

the University and he was summarily dismissed from the University's staff" (Cleaton-Jones 2000: 1011-1012).

4.5 Reflection on individual culpability

With the attention placed on a single individual, the traditional idea of a single morally deficient character is fortified. In spite of the evidence that absolved the University, its REC and others (who one might conceive had some knowledge of duplicity) scientific research as a whole was tarnished. From the publication of his articles to delivering presentations at international conferences, the consequences of Bezwoda's actions were wide. The chemotherapy regimen he purported to have successfully developed was extremely expensive and debilitating to patients (Weiss, Gill and Hudis 2001: 2776-2778). Yet, for those patients at high-risk of dying from breast cancer, as well as their clinicians, it created hope for a 'cure' (Sprague Jones 2000: 59). Thus, if Bezwoda had not been unmasked, many women would have suffered unnecessarily. Moreover, the time and resources other researchers might have put into replication would have been in vain (ibid).

Another repercussion of Bezwoda's actions was that all of his prior work became cast in doubt. In addition, as in many research publishing endeavours, there are often multiple authors. A scientific publication with multiple authors often serves to dilute the personal acceptance of scientific integrity. In the case of Bezwoda, the

reputations of his co-authors and co-researchers became tainted but beyond embarrassment, they faced no major consequences (Weiss, Gill and Hudis 2001: 2771-2779).

Let us make an assumption that someone did know or have a suspicion that Bezwoda was falsifying data. We can make that assumption because there are many actors, from secretaries to laboratory staff to other scientists, to persons in finance or formal research departments, as well as his co-authors who could conceivably have known something about his "research." Yet, as the final verdict stood, blame was placed on a single individual who shamed himself, his institution, and his profession. Now, we will ask, is it that simple?

Imagine that one of these persons had approached a highly respected scientist within the university with her concerns. What advice might be given?

A clinical research scientist, John Edsall (quoted in Lang 1993: 43) commenting on a research misconduct case said,

> *… If a young scientist believes that he or she has witnessed a case of fraud, and comes to me about reporting it to authorities, I would have to warn him or her emphatically about the dangers of doing so. If the potential whistle-blower decided nevertheless to proceed**, I would admire and greatly respect the person and the***

decision, but I would have severe anxiety about the future of that individual, as the system operates today. (My emphasis added)

In the previous chapters I have purposely focused on roles, functions and duties of Research Ethics Committees in an institutional context. As I have pointed out, such committees are all guided by good clinical practice in research. Despite the emphasis on ethics and moral responsibility, it appears to be a reality that those who feel they have a moral duty to expose unethical behaviour in scientific research are somehow defeated by the very institutions or individuals with which or with whom they are associated.

Chapter 5 Whistle Blowing

5.1 Introduction

Having provided an inclusive overview of the major factors contributing to research misconduct, in this chapter I will centre on the issue of whistle blowing generally and then turn to examples in clinical medicine and scientific research.

Miceli,*et al.* (2008: 5) define whistle blowing as the

> *… disclosure by organizational members, former and current of illegal, immoral or illegitimate practices under the control of their employees, to persons or organizations that may be able to effect action.*

They (ibid: 6) further explain that whistle blowers often disclose organizational practices and omissions that are considered as ethical breaches of public trust. Hersh (2002: 243) adds to the definition by writing that whistle blowing includes the deliberate disclosure of ":…dangerous. discriminatory actions".

Richard De George (1993: 516) argues that whistle blowing is a term used in wide range of activities including disclosures of improper conduct of fellow employees or superiors to executives in a firm. Additionally, De George (ibid: 517-518) differentiates between types of whistle blowing. He explains that "internal whistle blowing" is the disclosure of misconduct reported to someone within the

organization. Should an employee not get any satisfaction reporting internally, they may be forced or feel compelled to report the problem to someone externally. Only then, he contends, can it be called “whistle blowing.”

Combining these ideas, generally we can say that that whistle blowing involves deliberate disclosure to the public of non-trivial information which is believed to the immoral, illegal, or dangerous or to otherwise involve wrongdoing, generally by current or present organizational members (Miceli et al. 2008; Hersh 2002; De George 1993).

5.2 Use of the term

While some debate exists to when the term was first used, it became popular in the media as a case involving engineering and business ethics: The infamous event of a Ford Motor Company engineer ‘blowing the whistle’ on the company-known yet ignored defaults of one of their vehicles, the Ford “Pinto” represents the classic whistle blowing event that gained international media attention (Velasquez 1998; White 1993). Another claim made as to the term’s first usage is found in the case of Mr. Otto Otopeka who, in 1963 was involved in giving classified security risk documents to the chief council of Internal Security in the USA (Vinten 1994: 3-20).

The pictorial image of “blowing the whistle” as I personally recall is thought to come from the official who referees a soccer game, who

blows a whistle to stop an action; that the image is derived from a cartoon where the main character (a “bulbous-cheeked English Bobby”) wheezes away on his whistle while the innocent maiden cries “stop thief”.

Although the meaning of the term as associated with sports and cartoons is clearly recognized, ‘whistle blowing’ was used quite seriously in the USA during the 1960’s to differentiate between groups of dissenters or “inside informers” from government moles who gave evidence e.g. against the Mafia, those who “named names for the FBI”, or to those who were involved in major business fraud.

According to Jonson (2003:4), the term was further legitimized at a conference organized by Ralph Nader in 1971 and used specifically to refer to insiders who publically expose scandals within their organization. Overall as Johson (2003) says, the term is used to describe a dissent in a bureaucracy, particularly involving issues of public health and safety, fraud and abuse of office.

5.3 ‘Whistle blowers’: Individuals of high character

While it is admitted that ‘whistle blowing’ captures certain images, a whistle blower may be defined from person to person somewhat differently (Near and Miceli 1986 De George 1993; Judd, 1999). Many views exist concerning the type of person who whistle-blows and the circumstances of disclosure. According to Miceli and Near (1985) whistleblowers often have multiple motivations that may not

be easily identified but they may influence the manner in which the whistle blowing process plays itself out. However, this theory cannot be tested unless various cases of whistle blowing accounts with varied motives are considered (Sprague 1993; Near, et al. 1993; Near and Miceli 1986; Miceli and Near 1985).

Ethically, De George (1993: 518-519) argues that people in organizations (e.g. commerce, business, academia) "have a moral obligation to prevent others from doing serious harm if by doing so there is little cost to themselves." He goes on to say that the obligation an employee has to protect others from harm is complicated. What follows is an example from the Boisjoly case (Boisjoly, et al 1989).

Following USA investigation into the space shuttle Challenger's explosion, it was identified that one of the NASA engineers, Boisjoly, had reported to his superiors a grave concern about the temperature range for the rocket's boosters. His concerns were over-ridden. Boisjoly though, from the time of his first complaint, kept a record of the occasions when he further raised his concerns as well as the negative responses he received. During the investigations into the space shuttle's crash these revelations came to light. He suffered greatly in his professional career with NASA and was ostracised by his colleagues.[14]He lost his promotion and was regarded as a traitor

[14](Note) Hunt (1995 155: 156) classifies employee/ employer reactions to a whistle blower from minor to aggressive: 1) *Hot Air:* this occurs when the recipients of the

to the industry (Boisjoly, et al. 1989). In 1986, Boisjoly was asked if, in light of the consequences he experienced, he would do it again, he responded:

> *… My answer is always an immediate "yes". I couldn't live with any self-respect if I tailored my actions based upon the personal consequences* (ibid).

Boisjoly's response is fairly representative of ethical whistle-blowers. The difference is that he did not, at least according to De George's view, actually 'whistle blow' as he stayed within the establishment and his concerns were only made public during the inquiry. Nonetheless, the response from his employer and some colleagues describes the ways in which whistle blowers are treated (Dozier and Miceli 1985).

To be a 'classical' whistle blower requires the moral choice of an individual, one who acts on the highest or 'post-conventional level of

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complaints share concerns about the complaints but this amounts to nothing. Much is said but nothing is done and if any action is taken it is on the basis that the complaint is trivial. 2) *Send to Coventry*This isexplained as a change in the mood by the recipients of the complaints , this is when the complainant is viewed in a more serious light and starts feeling the brunt of being the one to raise concerns within the organization. The complainant is either ignored or avoided or left out of decisions.*Close Ranks:* This occurs when the complainant feels alienated in the company as he or she is labelled as a trouble maker for having complained about a wrong doing. According Hunt, (ibid) this signifies the stage, in which colleagues hold different views on the complainant because of the complaint laid. *Stonewall:* The barriers are closed; the complainant is no longer a member of the 'team'; he / she is an outcast.

morality' (Kohlberg 1971). From whistle blowing in e.g. the advertising industry, medical industry, plutonium industry, and in research (Snyder and Loring 2006; Rivilin 2004; Lynn 1998: 21; O'Hara 1998: 64-69); this type of individual whistle blower feels obligated to take a stand against certain organizational practices he or she believes to be immoral and threaten the public good (James1995: 409; Glazer and Glazer 1989). Graham (1993: 683) writes,

> *…among the research findings that may surprise many readers if that whistle-blowers are typically above-average performers who are highly committed to the organization, not disgruntled employees out for revenge.*

Whistle blowers are characterised as principled individuals who have strong levels of moral convictions, universal standards of justice, self-efficient, and high levels of internal control. They are often satisfied with their jobs, but not their pay, when compared to other members of the organization (Zhang et al. 2009; Miceli and Near 1992). In addition, researchers have found that whistle blowers have a distinct approach to moral values which allow them to act against institutional and organizational situational pressures (Bagozzi 1999; Jos, et al. 1989: 559; Brabeck 1984). If this is the case, then why do whistle blowers have such a bad name?

5.4 Whistle blowers: "Traitors"'

A prevailing view particularly amongst management and business executives is that a whistle-blower is a traitor to his or her organization (De George 1986: 225). Whistle-blowers spread disloyalty and disunity amongst organizations (Dworkin and Baucus 1998). They are trouble-makers and because of this, institutions are forced to anticipate disloyalty and require e.g. employees to sign confidentiality agreements ensuring that the business of their business remains secret (Lubalin and Matheson 1999). In this view, anyone who blows the whistle is guilty of dissent, breach of loyalty and false accusation (Bok 2000: 71). Thus, from a strategic management perspective, the implementations of more rules to protect the institution or organization at any cost are necessary.

Certainly, whistle blowing as a tactic used by anyone who feels they have been victimised by their employer is possible (De George 1986: 228). It could also represent a cover-up by an employee for their own incompetence. Whistle blowing on the part of an employee has also has been considered to be based upon some personal grudge or a vendetta held against the organization (Judd 1999: 80). There are instances where employees have unjustifiably blown the whistle and caused damage to a company, organization, or institution (Lubalin and Matheson 1999).

However, in cases of whistle blowing, a focus should also be placed on organizational or institutional practices and procedures as the whistle blower and the *circumstances* under which he or she blows the whistle cannot be separated Martinson, et al. 2006; Needleman 1994; Wigodsky 1984).

5.5Whistle blowing: The role of institutions

A whistle blower, says De George (1986:418), is a "person who raises concerns about wrongdoings occurring in an organization or body of people." Often the concerns are described as violations of ethics and the law or issues raised in the public interest which may include fraud, health or safety violations and corruption(Jonson: 2003). Such concerns may be raised internally or to an external organization such as regulators or law enforcement agencies, the media or concerned advocacy groups (De George as quoted in White1993: 516-517).

The general consensus concerning whistle blowing is that the issue brought to attention must be a serious one (De George 1993, 1986; Miceli and Near 1985 and 1992). This would exclude petty differences of opinions between management and employee(s), or employee between employee. Secondly, the whistle blower is obliged to follow organizational rules, that is, to follow the channels of

communication in reporting his or her concern within the organization or institution. De George (I986: 231) writes,

> *Once an employee identifies a serious threat to the user of the product or to the general public, he or she should report it to his or her immediate supervisor and make his or her moral concern known. Unless he or she does so, the act of whistle blowing is not clearly justifiable.*

In practice, although dependent on extenuating circumstances, this is the usual manner in which one should proceed. Because the issue is viewed by the possible whistle blower as serious, urgent, and lacking of workable alternatives to its resolution, management should to respond positively to the issue raised (ibid: 232-233). Moreover, because the act is ethical, viz. the person raising the issue will not benefit, their motive is good, the organization will benefit if it takes the problem seriously. But this good outcome relies on the organization or institution's policies, procedures, and management personnel.

Because of this, there may be circumstances which hinder the potential whistle blower from being able to follow all the channels of communication. James (1995: 413-414) notes that if there is a great urgency, it may not be possible to follow the channels, as the problem itself may be due to a supervisor or someone else higher in the organization. For such reasons, there may be delays or failures to act. Moreover, the first response of an institution to the report of

problems is frequently retaliatory (Graham 1984; Near and Miceli 1986: 137-145). Concerns such as these raise questions concerning the structure and values of the institution or organization itself.

It may be said that some organizations and institutions by the nature of their responses to employees concerns are responsible for creating a whistle blower. Often employees get into trouble by merely raising their concerns (Near and Miceli 1986: 143). The act of raising an issue can render the employee an outsider:

> *To be a whistle blower is to step outside the group's chain of being, to join not just another religion, but another world. Sometimes this world is called the society of margins, but to the whistle blower this feels like outer space* (Alford 2001).

The whistle blower is often isolated and vulnerable and often stands alone. Also, while there are many who do not support the whistle blower, through fear of retribution, there are those who provide evidence against the whistle blower, usually for personal gain (Rivlin 2004:140).

In practice, this aspect of whistle blowing control is defined by the retaliation received by an employee for having simply spoken out (as opposed acting out of ethical concern) about something or someone in the organization. The retaliatory response may be equated to a case in which colleague A reports colleague's B 's wrong doing to his

superior and colleague B becomes aware of it and retaliates against colleague A. This is not termed ‘whistle blowing’. Yet, interestingly, the term is often used when an employee makes any type of allegation against a superior or superiors in a company. In such cases, as Alford (2001) says, ‘organizational power takes the lead in relation to employee concerns’. Organization power may be exerted on an employee who has spoken out against his or her superior and is punished. This is often used as a way in which institutions and organizations may enforce via example, group control (Greenberger, Miceli and Cohen 1987: 529; Jensen 1987).

Heacock and McGee (1987) explain that whistle blowing is more likely to occur to occur in organizations that have complex technological tasks and that have new scientific technological tasks and developments. The authors (ibid) add that established organizations by merely taking on new responsibilities may prompt whistle blowing. This is because institutions and organizations that previously held on to rigid practices (e.g. the boss’s motives are never to be questioned) may have to conform to the new complexities of a changing organizational environment. For example, ‘open door’ policies that encourage internal transparency have the potential to turn into employee traps if the abuse is planned by those in charge (Bok 1981).

As Jubb (1998:8) explains, “whistle blowing is a deliberate non-obligatory act of disclosure, which gets into public record and is

made by a person who has or had privileged access to data or information of an organization, about non-trivial illegality or other privileged wrongdoing whether actual, suspected or anticipated *which implicates and is under the control of that organization* (italics added).

Summarising a review by Hersh (2002: 247-248) it is noted that large companies and unionised companies perceive higher levels of external disclosure, and that companies with enforced mechanisms of disclosure (e.g. confidentiality clauses) have higher rates of internal and external disclosure. Organizations that have policies that listen to employees seemed more aware of the importance of this facet of management structure. Indirect and complex lines of communication and authority, discouragement of thought and technical and other dissent, lack of knowledge of communication channels, complicated hierarchies and a management that is not respected all are institutional factors that researchers contend encourage whistle blowing (ibid).

5.5 Whistle blowing in medicine and scientific research

One might suppose that traditional measures such as peer review and an increased emphasis on mentoring of junior scientists should be sufficient to decrease research misconduct. However, in most cases of scientific misconduct, the evidence of wrongdoing would not come to light without reports made by whistle-blowers. Considering

the risks to whistle-blowers, it seems likely that a substantial amount of research misconduct is never reported.

For example, in 1992, the Research Triangle Institute (RTI), a part of the USA Department of Health's Office of Research Integrity identified that sixty-nine per cent of whistle-blowers reporting alleged scientific misconduct had experienced negative responses: Nineteen per cent were fired from their jobs or their appointments were not renewed. Twenty eight per cent were not given salary increases, promotion or tenure. Of particular interest in this study was that senior administrators, laboratory chiefs and department heads all suffered retaliation.

The personal, including financial, costs and damages to whistle-blowers can be severe (Barnes 2006; Devine 1998; Lubalin *et al.* 1995Barnett, 1992) and there are few rewards other than the sense that one has done what is right (Lindblom 2007: 425-426). Teich and Frankel (2002: 21-23) stated that reporting misconduct contributes to science and should be viewed in this light as opposed to betrayal of a colleague. Deceptive research harms all scientists and researchers and has important societal repercussions (Check and Cyranoski 2005; Ernhart *et al.* 1993: 91; Miceli and Near 1992).

Particular to whistle blowing in science and research is that it is usually the reporting of a colleague's or other employee's misconduct as opposed to a particular management problem. Also, because of

the implications of scientific research, misconduct may result in a greater burden for society than that seen in other areas of misconduct (Chopyak and Levesque 2001).

In the case of Bedwoza for example, the level of suffering women would have unnecessarily undergone because of his false randomised clinical trials, or when clinical trials show a particular drug to be 'effective' based on fabricated data. Moreover, as mentioned in an earlier chapter, scientists are expected to regulate themselves and this is often dependent of various forms of reporting (such as publications and peer-review).Published reports of scientific misconduct, though tell a different story, namely that this system is not fool-proof (Wenger et al. 1999; Martin, Anderson and De Vries 2005; Shuman 1998; Vaughn 1989). Experiences of retaliation by colleagues and institutions follows the same practice in science research and medicine as it does in other fields. For example Hersh (2002: 257)identified that in one study of accused but *exonerated* scientists, nearly one-quarter were fired or did not have their contracts renewed, some were denied promotions or salary increases or lost research opportunities As Lubalin, et al (1999) point out, the mental health of such wrongly-accused persons suffers greatly.

5.6.1Whistle blowers and the pharmaceutical industry

Concerns about organizations such as the pharmaceutical industry withholding, manipulating or refusing to have their research results

published which disprove their hypothesis or any articles concerning it also reflects scientific misconduct. The following are two examples both of which involve a whistle blower and a pharmaceutical industry giant. The first example is relayed by Barnes (2006).

In the claim against the pharmaceutical company Pfizer, Dr. Peter Rost a then-employee was fired because he blew the whistle on what he termed, Pfizer's "illegal activities". Dr Rost, employed in an executive position at Pfizer, accused the company of defrauding the USA's Medicare Programme by promoting a drug called Genotropin® (a prescription growth hormone). According to the claims raised by Dr Rost, the drug Genotrophin® was also being promoted for its anti-aging effects in adults and for unapproved genetic disorders in children. The off-label marketing of this product resulted in an overall turnover market value of $50 million in illegal drug sales which were estimated at 25% of the total of all illegal drug sales (Barnes 2006).

According to USA law, it is a federal crime for any growth hormone to be promoted off-label. This is because there is potential abuse and harm associated with the use and marketing of growth hormones'. In this case, Dr Rost claimed that he had tried in vain to meet with his employers and that he was left with no alternative but to take matters in his own hands. He was fired from his position after he launched a False Claims civil case against Pfizer. They reacted by filing a motion to have Dr Rost's civil case dismissed stating that it was the Pfizer lawyers and not Dr Rost who should be acknowledged as the true

whistle blowers by informing the federal officials of Genotrophin® irregularities long before Dr. Rost had filed the law suit. Dr. Rost then laid an unfair dismissal case against Pfizer because he was fired only after he had raised concerns regarding the illegal activities in which Pfizer had been engaged.

Another case which received much attention was a lawsuit against the pharmaceutical company Novartis (Klesse 2000). This occurred when a senior employee complained to a senior official at Novartis that improper statistical data submitted to the USA Food and Drug Administration (FDA) and that the safe guarding of research participants had been compromised. It was claimed that the company had failed to carry out the research according to the protocol policies and procedures which had resulted in serious protocol violations regarding an oncology clinical trial concerning a drug called Tasigna®. Following this claim, the complainant, Mr Olangunju, was harassed, threatened and was terminated from his position at Novartis. Olangunju, who had been on the receiving end of retaliation by an organization, reportedly gave this advice to future whistle-blowers,

> *If you are young, think twice before doing this, you really shouldn't blow the whistle unless you are wealthy.*

He (ibid) advises that people wanting to blow the whistle should rather report the misconduct to the authorities and not to the company. This he states would have made his life much easier. He

had first complained to his superiors and had refused to be part of the improper conduct that the company was involved in. Olangunju still believes he acted in good faith and is quoted (ibid) as saying,

> *If I meet my maker tomorrow, at least I will have peace in my heart because I would have done the right thing*.

5.7 The seriousness of whistle blowing

From these examples we can ask some of the questions that separate a disgruntled employee from a whistle blower focusing on motive, and subject. *Motive:* Is the whistle blowing done out of a sense of justice and rightness e.g. to further the public good without personal benefit? Or can we discern a rather egoist motive, because of personal benefit, regardless of whether or not this furthers public good? *Subject*: Does the subject involve a minor infraction of ethics or the law? Is it of potentially or actually of major consequence to the good of society?

The means to which organizations and institutions will go to silence or retaliate against a whistle blower (Welcome 1993; Fox and Swazy 1992) the consequences faced by whistle blowers (Gunsalus 1998: 51-64) and their families[15] (Ernhart, Scarr and Geneson 1993:73-79) such as the end of careers[16] (Goodeham 2000; Teich and Frankel

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[15](Note) "One of Scarr's daughters was told by a professor that her mother was 'slime'"(Ernhart, Scarr and Geneson 1993:90).

[16](Note) According to Goodeham (2000), Margaret Haywood, a nurse, was struck off the British Nursing Registry for exposing poor standards of care at Brighton and Sussex Hospitals. He (ibid: 338) argues that health workers have a professional

2002) are indications that the act of whistle blowing is taken seriously - albeit often in most unethical ways - by businesses, institutions, organizations and their employees (Anand, Ashford and Joshi 2004; Miceli and Near 1992).

ethical duty to raise concerns in order to protect their patients and failure to protect patients from harm may be in breach of this duty. Another case, that of Dr Bolsin, known as the 'Bristol whistle blower', who raised concerns about unsafe children's heart surgery ended up in his dismissal, his career stalled and he now works "on the other side of the world"(ibid: 340).

CHAPTER 6 Organizational Structures and Whistle Blowing: Some Measures for Protection

6.1 Introduction

People generally have a moral obligation to prevent harm to others if this occurs with little cost to themselves however, this obligation decreases should the personal cost increase (De George 1993). Whistle blowers may be aware of what whistle blowing is as well as knowing the consequences. But these are probably not fully realised by them until they experience such situations. When whistle bowing is viewed as an act performed by a person whose beliefs transcends ordinary morality, then it may be suggested that the personal costs become secondary to the act itself.According to Kohlberg's (1971) theory of moral development, an individual who reaches this stage acts out of universal principles based upon the equality and worth of all living beings. Persons are never means to an end, but are ends in themselves, as in Kantian ethics. When this sense of 'rightness' is internalized, it means one must act for justice and the good because the good of others is of equal or more importance to one's own. There are very few people who reach this stage of moral development. In addition, it is now recognized that thestructures of organizations and institutions also play a major role in whistle blowing and whistle blowers. There are increasingly more measures put in place to afford them protection

6.2 Whistle blowing, whistle blowers and organizations

Campbell and Miller (2004: 212) tell us that modern organizations and institutions can be the locus of administrative evil and wrongdoing. On an internal or external level this wrong doing impacts both inside and outside an organization. Thus, they say that there is a turning point in employee response that accompanies the time when the organization, which is guilty of wrong doing, becomes publically exposed (ibid: 213).Often, when the discovery is first made, some employees in the organization admit they were aware of wrong doings or were aware that others had knowingly engaged in harmful practices (ibid 215-218).At this juncture, employees first tend to respond justifying the wrong-doing by saying e.g. that they thought what was going on was benign, or that the actions would benefit the organization. It is only after the full public disclosure of the organizational liability that employees may share a sense of guilt and shame which is attributed to being 'loyal' to one's company or institution (ibid).An institutional whistle blower who acts in the interest of the public often lands in a hopeless situation no matter how brave and courageous their actions are deemed to have been as they do not have the safeguard of a political office and are often naïve to the power of the institution which holds a large purse and thus greater power.

Concerning institutional response, Tronson (ibid) points out that the primary focus of an institution is to protect itself and that anyone who

poses a challenge to the institution will face some personal cost; this has been the historically the fate of a whistle blower. Thus, he asserts, if there was there was anything positive to be said about the role of the whistle blower it would be that they acted on their conscience irrespective of the personal cost experienced (Ibid). Alford (2001) agrees that a whistle blower is someone who acts in the name of public good. However, he argues that a whistle blower is defined more by the retaliation they receive and less by having spoken out. For example, one would rarely be dismissed for reporting bad behaviour of a subordinate, but, it is usually when a superior is implicated in wrong-doing that turns the person reporting the behaviour into a whistle blower. Thus, it is suggested that an organization creates or defines a whistle blower by its response.

6.3 Rationale for protecting whistle blowers

In an article in *Christian Today,* Tronson (2001) argues that institutional whistle-blowers act because their conscience dictates that it is the right thing to do and often they do so without any institutional protection. Camerer (2001), explains that protective legislation is important in that it may enable employees making a protected disclosure to be secure from the retaliation tactics which the employer might engage in such as demotion, dismissal, intimidation, suspension from work, being transferred against one's will or being subjected to disciplinary action. Without some form of

legislation employees are not protected against the retaliatory backlash of employers.[17]

Most laws and international treaties hold the view that people who report any wrong doing disclose on the basis of an honest belief on reasonable grounds. Others hold the view that whistle blowing laws will encourage provide a false sense of security to whistle blowers who disclose as they think that they will always be protected. Nonetheless, whistle blowing legislation is encouraged as a means of protecting the whistle blower and it also serves as an avenue for employees to report on matters that are of public concern (NIH a 2001; NIH b 2002; NIH c 2006). While the scope of protection is limited, other laws such e.g. anti-corruption laws, completion laws, employment laws, and freedom of information have increasingly included whistle blowing protection in their policies (ibid). Positive aspects of whistle blowing protection methods are two-fold 1) it empowers employees in reporting wrong doings by proving legal protection and 2) it also encourages organizations to adopt cultural practiced which are open and transparent.

Chene (2009) suggests that whistle blowing protection programmes should include the following five objectives, namely to:1) Support public interest disclosure by facilitating disclosure of wrong doing; 2)

[17](Note) Chene (2009) also makes this point noting that it is employees, rather than outsiders who mainly report issues of concern, such as misconduct or fraud within an institution or organization. At the same time, it is the employees who are often victimized by their employers for having exposed the wrong doings. The consequences of acting in good faith often results in considerable cost to their personal and professional lives.

Protect whistle blowers against potential retaliation; 3) Ensure that public interest disclosures are properly assessed investigated and acted upon; 4) Promote and protect a culture of transparency , integrity and openness and accountability; and 5) Prevent abuse and misuse for personal advantage and vendettas against the employer. Whistle blowing protection legislation has been adopted by many countries to promote public accountability and protect the whistle blower from retaliation by the employer.

6.4 Protective measures

In 1977, the USA's Government Accountability Project (GAP) was founded (GAP 2000). It is a whistle blower protection and advocacy organization located in Washington DC. This government accountability project serves as a nonpartisan public interest group. One of the functions fulfilled by GAP is to lead campaigns to enact whistle blower protection laws both on a domestic and international level. GAP aims at protecting whistle-blowers by promoting and advancing occupational free speech, and empowering citizens and activists (GAP 2000).

In many countries, whistle blowing is recognized as part of international law. The United Nations adopted *The Convention against Corruption* in 2003 which was signed by140 nations. Similarly, the Council of Europe ratified the *Civil Convection on Corruption* which provides to protect whistle blowers as part of their

overall anti-corruption strategies[18].The first international anti-corruption legal instrument was adopted by the Organization of America States (OAS) in 1996. Added to this is the mechanism for follow up on the Implementation of the Inter American Convection against Corruption (MESICIC), a body within the framework of the OAS which supports the member states.One of the aims of MESICIC is to facilitate the exchange of information, best practice experience and the harmonization of the legislation of the state parties regarding corruption and corruption reporting practices. MESICIC's mandate is to remain impartial and objective in its operations as it seeks to provide balance between confidentiality and transparency in its activities 19

Legislation in South Africa concerning the protection of whistle blowers came into effect in 2004 in the form of the *Protected Disclosure Act No. 2000 of 2004.* This Act makes provision for the disclosure of information by an employee, and provides protection for those employees who make the disclosure. This is in keeping with the democratic values of dignity, equality and freedom as provided

[18](Note) The Council of Europe Civil Law Convention on Corruption was adopted in Strasbourg on 4 November 1999. It is the first attempt to define common international rules in the field of civil law and corruption. In particular, it provides for compensation for damages as a result of acts of corruption.

[19](Note) The mechanism for follow-up on the Implementation of the Inter-American Convention against Corruption (MESICIC) is an inter-governmental body established within the framework of the OAS. It supports the states parties in the implementation of the provisions of the Convention through a process of reciprocal evaluation, based on conditions of equality among the states. In this mechanism, recommendations are formulated with respect to those areas in which there are legal gaps or in which further progress is necessary.

for in the South African Constitution.The law in South Africa makes provision for the protection of employees in ensuring that employees who a make public disclosure is not subjected to occupational detriment. The *Protected Disclosure Act No. 2000 of 2004*also ensures that

> *… any disclosure [s] made in good faith and which are substantially true and does not make disclosure for the purposes of financial gain is a protected disclosure if amongst others: in all circumstances it is reasonable to make the disclosure and given this the person making the disclosure also has reason to believe that he will be subjected to occupational detriment if disclosure is made to his or her employer or that the employee making the disclosure believes that evidence with regard to the disclosure may be concealed or destroyed if disclosure is made to the employer.*

Furthermore, the *Protected Disclosure Act No 2000 of 2004*also provides protection if employees have previously made such disclosure to their employers without reasonable change and if it is thought that the impropriety is likely to occur in future.

Currently South Africa has no legislation which specifically covers scientific research misconduct. This is not unreasonable in that compared to well-resourced countries, the level and extent of scientific research is not the same.

In the USA, there is legislation which specifically refers to scientific misconduct. It is part of their National Institute of Health and falls under the S*pecific Agency Intramural Research Integrity Official (*AIRIO).They state: “If individuals believe that they have evidence of or have observed research misconduct, they may share their concerns or seek advice from individuals they trust. National Institute of Health employees are required to report suspected or apparent misconduct in science to the AIRIO or Deputy Director for Intramural Research (DDIR).False allegations of misconduct may do irreversible damage to the reputation of an accused scientist even when he or she is later exonerated (NIHc 2006).

Therefore, an employee who intentionally makes a false misconduct allegation will be subject to disciplinary action. In order to bring a formal complaint, allegations of research misconduct must be made in writing and contain sufficient details to make clear the nature of the activity and a description of the facts, events and circumstances that led to the allegation. The signed allegation document is sent to the Agency Intramural Research Integrity Official (AIRIO). The AIRIO may consider and act upon any information that reasonably suggests the occurrence of research misconduct [20] and *the identity of the*

[20](Note) It goes on to further state (NIH c) : The AIRIO may decide: 1) the allegation warrants an Inquiry which will initiate the Inquiry phase of the process; 2) the allegation does not warrant an Inquiry, in which case the complainant will be notified in writing, the matter will be closed, and the records held for 5 years; or 3) the allegation describes events or conduct that may pose a threat to human or animal research subjects, a violation of safety regulations, financial irregularities, discrimination, sexual harassment or criminal activity, in which case the appropriate NIH official will be notified (NIH b).

complainant may remain confidential unless the allegations lead to an Inquiry." (my italics added).

It is in the final sentence of this quotation that a potential whistle blower may be caught in a dilemma – anonymity or not. On the one hand, if the research misconduct is believed to be real and of harm to the public good, then ethically it should be reported. On the other hand, the consequences of reporting, despite assurances, may exceed what is ethically required so the potential whistle blower is under no obligation to do so (De George 1993). Again, following Kohlberg's (1971) theory of moral development, a potential whistle blower may be compelled to act or not.

From the position of a person or organization charged with scientific misconduct, one could take the position that it is reasonable to know the identity one's accuser. On the other hand, if the report leads to an inquiry and a finding of research misconduct, then the safety of the public, it could be argued, should override the AIRIO's requirement that the identity of the whistle blower be known to the accused.

6.5 Protection of whistle blowers and strengthening of organizational ethics

In tandem with the need to protect whistle blowers is a need to strengthen institutional and organizational ethics. Rossouw (2002: 3-6) points out that ethics concerns itself with what is good or right in human interaction; ethical behaviour can be summarised as

behaviour that considers the good both in oneself and in others. So applied the concern of businesses should not be its economic activity but also its ethics - 'business ethics' (De George 1986 and 1993; White 1993).

In agreement, Alford (2001) argues that if it is in the nature of an organization or institution to avoid concern for public welfare then legislative protection of the whistle blower will not be enough. What is needed he argues is,

> *… a change in corporate governance leadership, and an organizational ethics which fosters an organizational and institutional culture that encourages a collective sharing of ideas and transparency* (ibid: 46).

If enacted, these measures will provide the ways in which organizations and institutions, including Research Ethics Committees, can approach the problem of research misconduct and promote the values of good clinical practice.

Whistle blowing, as identified in previous chapters, is a phenomenon that affects all types of businesses, organizations and institutions including scientific and clinical research. I have shown that scientific research was grounded as a moral enterprise and believe that is the way it should remain. For researchers and RECs, this is represented as Good Clinical Practice. Good clinical practice is articulated in research ethics declarations and guidelines which encompass the moral and ethical requirements of scientific research practice.

Despite some variations, there are internationally set standards concerning RECs which are common. Research Ethics Committees function as formal institutional (although there are independent RECs as well) bodies designed for the purpose of reviewing, accepting, or rejecting research protocols based on GCP.[21] In addition, RECs

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[21](Note) Along with national and international guidelines (e.g. the Helsinki Declaration and CIOMS) *The Guidance for Industry International Conference for Harmonization Guidelines* set the standards for clinical research practices and provides ethical and scientific standards for the designing, conduct and recording and reporting of clinical research. Compliance with the guidelines provides assurance that the safety and rights and wellbeing of clinical trial participants will be given prior consideration. This guidance was developed within the Expert Working Group (Efficacy) of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human use (ICH) and has been subject to consultation by regulatory parties in accordance with ICH Process. This document was endorsed by the ICH Steering Committee at Step 4 of the ICH process, April 1996. At the step 4 of the process, the final draft is recommended for the adoption to the regulatory bodies of the European Union, Japan and the United States. The European Medicines Agency describes good clinical Practice as a standard for the design, conduct, performance, monitoring, auditing, recording analyses and reporting of clinical research trials.

serve to ensure that researchers concerned with trials have the necessary knowledge, qualifications, and experience to conduct research responsibly. Both individuals within a particular institution as well as those from outside (such as international or multinational joint research) wishing to conduct clinical research must first seek protocol approval from a relevant REC. Research Ethics Committee members place particular emphasis on the nature of the research, its scientific relevance, the associated risks and benefits, the principles of respect for persons (for their autonomous choices), non-maleficence/ beneficence, and justice, as well as the regulations surrounding informed consent.[22]

The mandate of Research Ethics Committees includes the ideal of monitoring research. Routine follow-up or monitoring of approved research protocols is uncommon globally. This is problematic as the consequences of scientific research misconduct pose deep and far-reaching harm to the public good. Moreover, the institutional norms of science, once considered to be self-regulatory concerning scientific misconduct are increasingly under threat. This is due to the ethical (or not) structure of organizations as well as the complex situational pressures placed on researchers.

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[22] (Note) Regarding the terms of reference of RECs in South Africa, the RECs are obliged to inform its appointing authorities, namely the National Research Ethics Committee concerning all matters regarding research conducted on humans and animals.

Whistle blowers in the classic sense, as I have shown, are persons who are compelled to act up on their inner sense of right and universal justice. The term whistle blower has extended to those who are e.g. seriously concerned by a lack of ethical behaviour in research which they have observed; who know explicitly of research misconduct (or have good reason to suspect research misconduct) however, because of the repercussions concerning revealing misconduct, are afraid to report it.

As mentioned, some situational pressures which may lead to scientific misconduct are those rising in academia. Some examples of these are institutional pressures to produce 'cutting edge' results and to publish widely and impressively. In addition, changes in peer-review systems, the norms of science, and funding pressures (both actual funding and type of funder, particularly from the pharmaceutical industry) as well as individual scientist / researcher integrity[23] are factors which are shown to contribute to scientific misconduct.

When scientific misconduct comes to the attention of the media, usually by way of a whistle blower, it may be said to take on a life to its own. This is particularly true in medicine and science where the issue of trust is necessarily involved. The first place that comes

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[23] (Note) Fuchs and Westervelt (1996) state that society tends to abrogate fraud to individuals and in that way, defends institutional norms of science which would be demolished if distrust in medicine and science should become "global and pervasive".

under question is the institution's or organization's Research Ethics Committee.

A variety of workshops and conferences concerning whistle blowing in scientific research have taken place They mainly concern the following aspects of whistle blowing: 'the exploration of the need for additional procedures to protect whistle blowers, the accused research institutions, the public, science, and human research participants' (Mishkin and Ariand 1998). Reports from such meetings generally reach the same consensus: Research Ethics Committees should not be expected to monitor and investigate research after protocols have been approved (Mishkin 1999)

One reason for this is that the overall aim of a REC is to protect human participants in research. To add investigating misconduct to its responsibilities could divert it from its basic focus (Wigodsky 1984: 1-5). Another consideration is because RECs lack both human and financial resources. In addition, it is argued that RECs function to advise and educate researchers and the public as opposed to acting as a vehicle for enforcement. As such, it is not well-suited in its organizational style for the job. Rather than mutual discussions between RECs and researchers, the possibility is that if RECs take on the role of monitors or investigators that inquiries and proceedings could become adversarial. This would defeat the educational aspects of REC aims

Sensitive inquiries and difficult technical issues may emerge about the accused researcher which REC members may not be capable of handling because of their knowledge-base, organizational structure, politics and place within the institution or organization (Vaughn 1989: 196-200). It remains a truism that scientific misconduct investigations become unpleasant and easy to mishandle (Gunsalus 1998; Bozeman and DeHart-Davis 1999; Sox and Rennie 2006:146-153).

Moreover, it is generally (if arguably) assumed that there are institutional norms or policies in place which serve the function of monitoring research activities (Lemmons and Freedman 2000: 547-562). These are the major reasons RECs are not considered as the proper structures to attend to allegations of research misconduct. At the same time, one may ask why in most of their terms of reference the monitoring of research is included.

In South Africa as well in other countries, there are measures in place which provide at least a minimal oversight for research participants. This is usually in the way of the name and contact details of the researcher or Principal Investigator (PI) and authorising REC Chairperson (or equivalent) which are included on the Participant's Information Form (or Study Information Sheet). The purpose of this is to provide research participants with a way of contacting those involved in a research activity to ask questions or raise concerns. While the importance of this information may not be

highlighted well enough by RECs or researchers, it does nonetheless provide some measure of oversight.

In addition, telephones numbers are present on certain websites such as the South African Human Research Council which aims to provide for anonymous reporting of misconduct. The problem is that such mechanisms of monitoring are not readily known or explained to research participants and the public (much less researchers, employees of institutions, research organizations, pharmaceutical and other businesses).[24] This becomes an issue when held to whistle blowing which as we know arises from an employee within an institution or organization.

One suggestion concerning a way in which a whistle blower could be protected from retaliation by his or her organization or employer is by way of a "hotline" telephone system to preserve anonymity. A whistle blowing hot line was established in the UK to serve as a point of reporting misconduct. The hotline called "Safecall" was established to provide a means of communication for organizations wanting to inform other members of their organization of current affairs in their company in the hope of promoting transparency and openness. The hotline also provides a means of having employees reporting what they considered as untoward incidences in a discreet manner without fearing victimisation (Safecall,2006)

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[24] (Note) This is aside from the fact that many research participants in developing countries do not have access to the internet.

The British Medical Association (BMA), in response to a National Health Service (NHS) consultation regarding the protection of whistle blowers argued that whistle blowing policies must be strengthened so employees have an avenue in which to report concerns (BMA,2011). Equally, they point out that there should be a change or shift in organizational culture. Because employees need to feel supported when voicing their alarms, the responsibility for raising, investigating and resolving concerns should be shared by both employers and employees. This idea has also been highlighted when considering aspects of whistle blowers and justice within institutions and organizations (Martinson, et al. 2006).

The Global Fund (GF), in at its annual report of 2005, summarised the activities of their Ethics Committee and proposed that it should explore the development of a whistle blowing policy. It was envisaged that such a policy could serve as a mechanism or “hot line” for reporting fraud and abuse. However, some Ethics Committee members argued that the development of such a policy would be complex and would have to involve the expertise of ethics advisors and legal consultants.

The BMA (2011) responded saying that that such concerns should not be left to reach a critical point and only considered when patient safety is thought to be at risk. In that response, we can also identify a similar problem in reporting research misconduct. The idea of taking

a proactive approach to prevent scandals and publicity fall away when no scandal is currently in the public's attention.

The reasons why RECs should not take on the additional burden of attending to authentic, perceived, or false claims of scientific misconduct is understandable. However, because good clinical practice in scientific research falls within the moral directives of RECs, the idea of developing an institutional or even broader anonymous 'hotline' where scientific misconduct can be reported, I suggest, should at least be initiated from RECs.

Admittedly, this would not be an easy task. It would require the institution or organization to understand and support such an initiative. To do so, the institution would have to understand the different ways in which they may be contributing to potential scientific misconduct e.g. in distribution of research funding, grants and awards and support for researchers in all fields. It would require taking a serious look at their system of institutional organization, which may represent the greatest impediment. Yet, a case could be made that this is a part of the duty RECs and institutions have to the public

In the end, if scientific research is considered institutionalized as a moral enterprise, then there remains a social responsibility on the part of structures such as RECs, institutions and organizations to maintain integrity in science. One way of doing this, as I have

argued, is to protect whistle blowers and in so doing, safeguard the public from harm.

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