PAS3 Case Study Exercises 1-7 for Chapters x-x

Appendix II

Appendix II

Instructions and

Case Studies for Exercise 5

Readings: Chapters 14-16

INTRODUCTION

The intent of this exercise is to illustrate an ethical framework that provides practical guidance for researchers in publishing responsible and trustworthy research. Seven case studies are presented, each dealing with an important ethical dilemma. If there is not enough time to do all seven cases, faculty should select those cases that are most likely to be of interest to the participants. Workshop participants should be assembled into small groups, with at least one workshop faculty member present to provide instructions, distribute the cases, and lead the discussion. It is strongly recommended that workshop faculty read Chapters 14-15 carefully. These chapters deal with ethical issues. Chapter 14 describes the "seven deadly sins," their consequences and their prevention. Chapter 15 has case studies that can be analyzed using the handouts included here. The first is a "Checklist for Analysis of Critical Incidents." Its use is explained in the chapter. It can be filled out once the trainees have read the case studies. The case studies, the cases and the case interpretations are all included below. They have been used in numerous workshops to provide trainees with an opportunity to read the chapters and apply its contents to the analysis of the cases. They can be used before or after students have read the chapters, or after a lecture explaining the principles of moral reasoning.

Didactic Lecture: This lecture will review the "Seven Deadly Sins in Scientific Publishing and How to Avoid Them", as described in Chapter 14 of Publishing Addiction Science. The lecture describes a problem-solving approach to moral reasoning that can be used to evaluate moral dilemmas, based on work by White and Popovits (2001).

A set of case studies will be discussed in small group sessions, each dealing with one of the "seven deadly sins." After discussing each case, participants will be asked to apply the moral reasoning approach using a checklist for analysis of critical incidents that is explained in Chapter 8 of Publishing Addiction Science (McGovern, Babor and Stenius, 2004). The case studies are: 1) Selective reporting of the literature; 2) Redundant publication; 3) Authorship Credits; 4) Undeclared conflict of interest; 5) Human subjects violations; 6) Plagiarism; 7) Scientific Fraud.

It takes about 20 minutes to review and discuss each case, so cases should be selected to fit the available time and the particular interests of faculty or participants. Following each case are a series of discussion questions that draw attention to the moral reasoning issues covered in Chapter 8 of the book, <u>Publishing Addiction Science</u>. After considering these questions, the moderator should follow the outline shown in Box 8.2, which is organized according to the three questions. Then compare the group's responses to the ethical analyses that are excerpted here from Chapter 8. Below are the ethical analyses that provide an ethical

interpretation of each case. This is followed by the cases themselves, which can be printed and distributed at the beginning of the exercise.

ETHICAL ANALYSIS: Case I:

The responsibility for providing a complete account of the literature and research pertaining to Addiction Reflection therapy rests with both authors, with Ann Dorphin shouldering most of the responsibility because of her supervisory position. Selective reporting of the literature to support a particular point of view is a significant ethical infraction. It clearly deviates from accepted standards of citation, as described in Chapter 4. Using the White-Popovits grid (see Box 8.2) for the analysis of critical incidents as a guide, this ethical violation has significant moral implications for the authors, their institution, the addiction field, and society as a whole. The reprimand that the authors received from the editor, together with the rejection of the manuscript and the accompanying professional embarrassment, are minor inconveniences compared to the greater harm that might have resulted from the publication of their work. Consider how their faulty research might have harmed the well-being of clients being treated by service providers who, in good faith, followed the researchers' clinical recommendations.

The authors' actions, probably motivated by self-interest, violated the ethical principles of non-maleficence and justice. There is a clear mandate to 'do no harm' enshrined in the principle of non-maleficence. Lective and Dorphin's lack of honesty in espousal of self- interest has the potential to endanger the well-being of all clients and institutions involved with the new therapy. In addition, the principle of justice (fairness) becomes relevant when one considers the fruitless expenditure of scarce resources on a futile mode of treatment. In addition, Prof. Dorphin is clearly in a position to violate the student's autonomy (self-determination) by bringing undue pressure on him to publish his research in a manner supportive of her original theory. This form of coercion, which is clearly unethical, is often ignored in research situations, with consequences for everyone involved when this is uncovered. Much of the harm, real and potential, involved in this situation could have been avoided by following the established standards of citation practice i.e., to present all sides of the related literature.

ETHICAL ANALYSIS: Case 2:

As noted in Chapter 7, the Second Circle Of Hell houses those guilty of promoting their own self-interest in the practice of redundant publication, in violation of accepted ethical norms. Salame Science and her three collaborators find themselves in this unholy situation by submitting material that is (partially) under consideration by another journal, and by using verbatim material without quotation marks or attribution. By signing the journal's ethical statement, they have blatantly lied about the existence of the other papers and their relationship to the rave drug study.

Thus, however inadvertent it initially appears, the deception involved in failing to disclose the relationship between the papers has serious ethical implications. Referencing again the White-Popovits Analysis grid (see Box 8.2), several types of harm can result at professional, clinical, and societal levels. First, if all 16 articles were in fact published (as opposed to one or two comprehensive articles) the authors would be in effect denying as many as 15 competing and perhaps equally worthy authors of the opportunity to publish in the same journals, given the fact that many journals have limited space and must reject a high proportion of submitted papers. Second, the task of reviewing and processing these redundant papers creates unnecessary work for reviewers and editors, most of whom volunteer their time as a service to the peer review system. Whether the possible harm rises to the level of 'significant' in the White-Popovits grid is debatable; it is certainly 'moderate,' in terms of harm inflicted by any standard of ethical analysis. Clearly, violations of the standards of honesty, candour, fidelity, and diligence are involved in the authors' actions. Self-interest trumps

all other ethical considerations. The decision of the authors to lie in their ethical declaration attacks the basic trust which undergirds the scientific enterprise and has the capacity to inflict the type of 'irreparable damage to scientific investigators, editors and the community' described in Chapter 7.

The authors, by following established standards for citing the interrelationships involved in their collaborative studies, and by responding honestly to the statement required by journal editors and publishers, could have avoided both the ethical and legal censure, and the opprobrium resulting from their deception and dishonesty.

ETHICAL ANALYSIS: Case 3

One could argue that this situation has significant ethical implications for Drs. Doogood and Stringalong on an individual basis, and moderate implications for the scientific director and the research assistant. Stringalong is violating Mary Doogood's autonomy as first author by insisting on the addition of the extra names, although he would not be violating it if he merely suggested it. This is all the more egregious because of the implications of the duress deriving from his position of authority. There are also issues of 'doing no harm' and of fairness, understood as distribution of credit according to merit. Tamanger, the research assistant, may have some claim to be considered as an author from a fairness perspective, but does not really meet the criteria for authorship described in Chapter 5 of this book. Of course, both could be included in the acknowledgment section without violation of the rule of appropriate attribution of authorship credit. Should the names be included as co-authors, an argument could be made that the damage to the profession, the field, and to society could result at a moderate level of concern.

Stringalong might counter, from a utilitarian viewpoint, that assuring the publication of the data, through the inclusion of the scientific director's name, would work towards the betterment of individuals and society, and thereby outweigh the harm involved by including the additional authors. He might likewise remind us that names are regularly added to the list of authors without being seen as a major ethical violation.

The counter-argument points to the damage, certainly moderate and possibly significant, inflicted on the field by the violations of honesty, equity, fidelity, and loyalty involved in this practice of gift authorship. It is clearly contrary to the practice guidelines enshrined in the ISAJE Ethical Guidelines (see Appendix B), and as such violates the fiduciary relationship between authors and journal editors. In summary, the issues raised in this case involve ethical violations at the individual, institutional, and societal levels and therefore cannot be justified.

ETHICAL ANALYSIS: Case 4

Dr. Greedy has many personal, professional, and financial interests embedded in the promotion of Payola. His ability to influence a wider public and to advance the acceptance of the new drug are closely tied to the publication of his review article. A real conflict of interest exists and a host of ethical concerns arise at the individual, institutional, and societal levels.

At the outset, it is important to establish the stakeholders, i.e., those who are likely to benefit or lose from the publication of a review article that fails to acknowledge the author's financial stake in Payola's development. First, the author stands to profit in many ways from the publication of the review piece, although the extent of this benefit depends partly on the prestige of the journal and its influence on readers. Second, patients experiencing addiction stand to gain if knowledge of the efficacy of the new medication becomes widespread knowledge following the article's publication.

In his defence, Dr. Greedy might say that the promotion of the new product was the province of the advertising arm of Chemical Therapeutics Inc., and that neither he nor the company would benefit unduly from the publication of the review article itself. He might even add that his ownership of the patent and his financial ties to the company were matters of public record and these activities are perfectly legal and ethical (accepted even in academic circles) in his role an entrepreneur-scientist. His decision to publish his findings was made solely out of respect for the editor, Dr. Naïve. If the journal had a disclosure policy about conflict of interest, he would have had the option of complying with it or declining the invitation to publish his data.

Another important set of stakeholders in this case includes the journal itself, its editor, and the publisher. An objective bystander might question the professional and ethical judgment of the editor, Dr. Naïve, in inviting Dr. Greedy to submit an article without first consulting the editorial board. Here Dr. Naïve has failed in his fiduciary responsibilities to the author, the publisher, the journal, and the readers. Even if Dr. Greedy's review was valid and clinically significant, deserving of the broadest possible dissemination, the integrity of both the journal and the field are nonetheless called into question by Naïve's lack of responsibility. The absence of a conflict of interest disclosure policy excuses neither the editor nor the author. In a like vein, neither Dr. Greedy nor Dr. Naïve should claim that the possible good resulting from the publication of the review article outweighs the harm done. One could further argue that if this practice of non-disclosure became widely accepted, irreparable harm could result for patients, the publishing field, and society as a whole.

This case gives us pause when we acknowledge a certain reluctance on the part of the entire scientific community - in its individual, academic, and research components - to provide full disclosure. The relationship among research, industry, and publishing outlets is a necessary one, but ethical standards are needed to manage conflicting interests between self-interest and concern for the common good.

ETHICAL ANALYSIS: Case 5

In this case, it is appropriate to emphasize the vulnerability of persons with addictions in all aspects of their well-being, including treatment and research, and the intensification of such vulnerability in particular environments such as correctional facilities. Such concerns are central to Dr. Ploit's research, which describes the response of parolees to an innovative treatment programme. Even though the participants were originally assigned to the new treatment because of limited resources, ethical review is very important to make sure that coercion was not a factor. These questions arise in the presence or absence of a research protocol.

The question of ethical approval, requested by the editor as a condition for accepting this piece for review, is an important one. Ethical review gives some assurance that the research itself meets basic ethical standards, and also includes the expectation to provide oversight of the ongoing research in terms of participant well-being in a research environment. The Ethical Review Board, if it was involved in the discussion of this research, could have decided that the research enjoyed exempt status under the rubric of quality assurance and chart review. On the other hand, it may have required full compliance with all the requirements of a regular research protocol. In addressing a journal's ethical concerns about compliance with ethical review committees or other supervisory bodies, the nature of Dr. Ploit's work changes when it becomes research. The editorial board could reasonably restrict Dr. Ploit's research to data gathered subsequent to approval.

Compliance with regulatory bodies generally satisfies legal requirements in research undertakings; there is also a guarantee that basic ethical standards are in place. The regulatory research bodies share with journal editors a concern with the promotion of good and the avoidance of harm at the individual, institutional, and societal levels. The author has a fiduciary relationship with the ERB and with the editor, and all parties are mutually dependent on each other acting in good faith and in compliance with a commonly accepted ethical framework that promotes the common good. Compliance standards in and of themselves guarantee minimum protection for stakeholders in research undertakings; ethical standards often espouse a higher standard.

ETHICAL ANALYSIS: Case 6

The students' plagiarism has important implications, with the possibility of harm for the students themselves, the original author, the research institution, the addiction field and for society as a whole. The students, according to the White-Popovits grid, exposed themselves to the risk of possible dismissal from their doctoral programme as punishment for their violation of accepted ethical norms. It is conceivable, however, that they acted out of ignorance, and that they had not received appropriate ethics training from their professors or their institution. Had the individual professors and the institution been remiss in providing appropriate direction for the students, then the institution and its representatives should be as culpable as the students.

The actions of the students obviously involved a form of theft where Dr. Id's work is concerned, but any damage to her reputation will be moderate or minimal according to the White-Popovits scale. Their transgressions have the possibility of injuring the professional field and society as a whole, especially if such actions became commonplace in the publishing field. According to the White-Popovits scheme of universal values, the students violated the values of justice, honesty, and diligence in their failure to acknowledge the work of the original author. They acted out of selfinterest, with lack of regard for established ethical and professional guidelines. They might be accused of violating the original researcher's autonomy by denying her the opportunity to control her own work through appropriate citations. If the students failed to receive appropriate ethical formation and direction from their institute, then the administrators and professors at the institute would be in violation of the principles of beneficence and nonmaleficence. Institutions have a moral responsibility to provide an environment in which integrity and honesty are an essential part of their research undertaking (Institute of Medicine 2002). Stewardship also enters into the equation because, from a societal perspective, institutions have a responsibility to society to use resources wisely.

ETHICAL ANALYSIS: Case 7

The good espoused by Dr. Frank N. Stein's research is the enhancement of the addiction field through the advancement of knowledge about the effects of brain transplants. Appropriate institutional approval has been granted for the research. In addition, the research enjoys societal approval through funding which provides appropriate

resources for good scientific work. The stakeholders are the recipients, the scientists, the medical school, and society as a whole. Whether or not to continue this research depends on outcome studies, largely dependent on the findings of Stein and Numbers. The researchers are convinced that the minor changes in their statistical analysis are not significant or unethical. They feel that the continuation of their work will confer immense benefits on all involved and especially people with addictive disorders. Their decision to use the new statistical analyses, together with their justification of this approach in their response to the review process, shows an unqualified acceptance of an ethical approach in which the end justifies the means. After all, this is new cuttingedge enquiry where data trimming on a minor scale may be considered no more than a minor peccadillo.

The researchers, despite their idealism and good intentions, are blinded to the implications of honesty, stewardship, and fairness in their decisions. Their dishonesty impinges on the well-being and safety of the recipients of brain transplants. In addition, they are not being good stewards of the funds that supported this research. Furthermore, it is a disservice to the other, unfunded scientists whose requests for funding are based on honest and responsible findings.

Our tongue-in-cheek response to this fanciful and imaginative scenario uncovers many ethical pitfalls resulting from what might appear prima facie as minor adjustments in one's statistical approach. Rigorous honesty must inform the research itself, and transparency around methods and outcomes must inform the dialogue between authors and editors. The relationship between the two parties is a fiduciary one, and the engendered trust touches the basic integrity of scientific publishing. Using the White-Popovits grid, one could award this case a perfect score of 'significant' on all the interests and vulnerability items.

CASE STUDIES

CASE 1. SELECTIVE REPORTING OF THE LITERATURE

Mr. C. Lective is a graduate student in clinical psychology at Orgone University who has just finished his doctoral dissertation under the direction of his mentor, the prominent clinical psychologist Prof. Ann Dorphin. The dissertation topic was based on Professor Dorphin's Theory of Addiction Reflection, which proposes that drug users' brainwaves give off an aura of escaping endogenous opiates that can be captured by perceptive therapists and re-cycled to form a therapeutic alliance. After several promising quasiexperimental studies and case reports of Addiction Reflection therapy, all published by Prof. Dorphin or her students, two independent randomized trials produced negative

results. A review paper was then published questioning the validity of the theory as well as the unorthodox research methods used at Orgone University. Consistent with previous studies at Orgone U, Mr. Lective's dissertation has produced positive but unimpressive results in support of the theory. Prof. Dorphin strongly suggests that the results be published, and collaborates in the drafting of a paper that recommends that Addiction Reflection therapy be adopted widely in routine clinical practice. The paper is submitted to a small psychotherapy journal. After receiving the reviews, the editor of the journal writes the following letter to Mr. Lective:

'I have now received two reviews of your manuscript. The first reviewer liked the paper and has few recommendations for revision. The second reviewer, however, notes that your literature review fails to describe recent studies of Addiction Reflection therapy, including a highly critical review paper, and thereby presents an inaccurate and misleading characterization of the current status of the theory. Although your study does not seem to contain any fatal flaws, I have decided not to accept the paper because of the reviewer's criticism that the background, rationale, hypotheses and discussion are all in need of major revision, and the level of scholarship reflected in the paper's introduction suggests that the authors are either unfamiliar with recent research on the topic, or are being unusually biased in their reporting of the background to their study.'

DISCUSSION QUESTIONS

1 What could Mr. Lective and Prof. Dorphin have done to avoid this situation? 2 Who is responsible for the selective reporting of the literature, the first author (Mr. C. Lective), the second author (Prof. Ann Dorphin), or both?

CASE 2. REDUNDANT PUBLICATION

A junior faculty member, Dr. Salame Science, is approaching tenure review at a large university that places great emphasis on the number of first-authored publications as the main criterion for promotion. Dr. Science, who has been working with three other investigators on a large collaborative survey study, suggests that the investigators report their findings separately for each of 16 drugs, thereby giving each of the investigators four first-authored publications. Dr. Science develops a template in which the literature review, methods, and statistical analyses are practically the same for each article, with only the name of the drug being changed for the 16 articles. When one of the papers dealing with a new rave drug is submitted to a journal for review, the authors fail to advise the editor of the other 15 papers under review at different journals, and do not cite any of these papers in their report. Moreover, the co-authors all sign an ethical statement required by the journal indicating that the paper has not been published in whole or in part by another journal, and is not under consideration by another journal.

- 1 What should Dr. Science and her co-investigators have done with the reporting of the survey findings?
- 2 What, if anything, should they have told the editor at the time they submitted the manuscript?

CASE 3. AUTHORSHIP CREDITS

Mary Doogood is a post-doctoral fellow at the prestigious National Addiction Research Centre (NARC). She is conducting research on prescription drug addiction under the direction of her mentor, Dr. Arthur Stringalong. After a preliminary analysis of the findings, Dr. Stringalong (who helped design the study, secure grant funding, and analyze the data) suggests that they prepare an article for submission to the Journal of Irreproducible Results.

When Dr. Doogood finishes the first draft, Dr. Stringalong insists on two additions to the list of authors: 1) the scientific director of NARC, who had nothing to do with the study or the writing of the manuscript; and 2) the research assistant who conducted the interviews, entered the data, and did a literature search, but who otherwise had little involvement in the study design, data analyses, interpretation of findings and drafting of the manuscript. Dr. Stringalong tells Mary that with the NARC director as last author, the paper would have a better chance of being accepted by the Journal of Irreproducible Results. He also suggests that the research assistant, Ms. Day Tamanager, deserves to be listed as a reward for her hard work; a publication credit will help her with her application for admission to graduate school.

- 1 What should Mary do about the suggestion to add the name of the scientific director of NARC?
- 2 What should Mary do about the suggestion to add the name of the research assistant?

CASE 4. UNDECLARED CONFLICT OF INTEREST

Dr. Boyam I. Greedy was asked by the editor of the Journal of Neuropsychopharmacoepidemiology (NPPE), Dr. Tom Naïve, to submit a review paper on the subject of anti-dipsotropic medications. The invitation was based on Dr. Greedy's expertise in the pharmacological treatment of craving and his widely cited articles on a new anti-craving drug called Payola. Dr. Greedy prepared the review and submitted it to the journal editor. In the article Dr. Greedy cited both published and unpublished reports to support his contentions that:

- anti-craving drugs like Payola reduce drug craving and substance abuse;
- a large multi-center clinical trial of Payola is currently underway by the manufacturer, Chemical Therapeutics, Inc.;
- methods to deliver Payola via patch technology have been developed.

Because the Journal of NPPE has no formal policy, Dr. Greedy was not asked to declare any real or apparent conflicts of interest. Additionally, in the acknowledgements section of the article, Dr. Greedy included pertinent information about the people who helped him prepare the article. But neither his communications with the editor nor the acknowledgements section revealed the following information:

- Dr. Greedy holds US Patent 6,375,999 on 'Methods and Devices for Transdermal Delivery of Payola'.
- Dr. Greedy is a member of the Scientific Advisory Board of Chemical Therapeutics, Inc., and as such was given an option to purchase 7,000 shares of stock at 5 cents per share. When the projected initial public offering of shares by Chemical Therapeutics occurs in the near future at the corporation's estimated share price of \$25.00 per share, Dr. Greedy's equity will be valued at more than \$250,000.
- Dr. Greedy received substantial consulting payments from Chemical Therapeutics, including first class airfare to numerous international meetings, where he spoke about his research on Payola.

- 1 What ethical issues could arise in this convergence between Dr. Greedy's role as a scientist writing a review paper and his connections with the drug company, Chemical Therapeutics, Inc.?
- 2 To what extent does Dr. Greedy stand to gain financially by gratuitously promoting his patented Payola patch?
- 3 To what extent does Dr. Greedy stand to gain financially from the interest that his positive assessment of Payola might generate for Chemical Therapeutics in advance of a public stock offering?
- 4 What are the real or apparent conflicts of interest in this case?
- 5 What are Dr. Greedy's ethical obligations in this case?

CASE 5. HUMAN SUBJECTS REQUIREMENTS

A clinical psychologist, Dr. X. Ploit, who is working at the Department of Parole, hears about a dataset consisting of clinical records, demographic information, and rearrest data for parolees (i.e., convicted criminals who are released to the community under close supervision) who were exposed to a new substance abuse treatment programme. Since the programme could not accommodate all parolees, only people being released from prison on alternate weeks were assigned to the programme. The others received no treatment. When Dr. Ploit learns of this 'natural experiment', he concludes that the data could comprise a very valuable contribution to the literature, as the parolees were in effect randomly assigned to treatment and control conditions, and were not pre-selected for participation in a research project. Because of his lack of ethical training, Dr. Ploit is unaware of the need to obtain Ethical Review Board (ERB) approval to access these kinds of records for research purposes, even though he has legitimate access to the same records because of his clinical responsibilities. Thus, he obtains the names of the selected paroled prisoners, looks up their remand records, and conducts a statistical analysis. The analysis reveals that the parolees who were exposed to treatment were significantly less likely to return to prison for parole violations associated with alcohol and drug use. Dr. Ploit writes up the results and submits them to the Journal of Drug Criminalization.

When the paper is submitted, Dr. Ploit is asked to sign a form stating that the study had received all necessary human subjects approvals by an Ethical Review Board. Although Dr. Ploit feels conflicted about signing the statement, he decides to lie about his failure to seek ethical approval, reasoning that 1) the results do not identify individual prisoners; and 2) the ERB would probably have given him permission to access the data anyway. Dr. Ploit also hesitates to seek post-hoc permission from the ERB at this point, as they might now deny permission. He reasons that the value of the findings for society and the prisoners far outweighs his minor ethical transgression.

- 1 Why was Dr. X. Ploit required by the editor to submit documentation that he had met ethical review requirements for the study?
- 2 What is the function of institutional and editorial requirements regarding the treatment of human participants?
- 3 Do compliance standards in themselves assure ethical behaviour in research?

CASE 6. PLAGIARISM

Hans Besserwisser and Gretchen Schnell have both just started as doctoral students on a project at the University of Freudberg, exploring the impact of the therapist-patient relationship in psychoanalytic treatment for female abusers of prescribed psychotropics. Reading the background literature, they find a very good article by Professor Eve N. Id in one of the big US-based psychoanalytic journals. In the article, Dr. Id explores how the angle of the analyst's sofa can influence the level of subconsciousness that the patient is able to reach in therapy. The article establishes the so-called Divanaltitude theory.

The two ambitious students decide to submit an article to the Bayerische Zeitschrift für Psychoanalytische Alkoholstudien to demonstrate that they are on the cutting edge of current research. Their article, written in German, presents the Divanaltitude theory along with some findings from a small, local survey that the students conducted to learn what alcohol and drug therapists think about the design of sofas in therapeutic settings. Besserwisser and Schnell inform the editor that they consider their text to be an overview and not a piece of original research.

The editor, who is not familiar with the Divanaltitude theory, sends the text to a referee. The referee's critique comes back after two weeks. She has discovered that the introduction is a direct translation of Professor Id's abstract. Several subtitles and the structure of the first part of the article are identical with Dr. Id's. The fact that the authors have one reference to Dr. Id's article in the second paragraph of the text is obviously not enough; the referee considers this to be a case of plagiarism.

The editor subsequently sends a letter to the young authors stating that he cannot accept the article for publication since large sections of the text are identical with an already published article. He states that their submission breaches internationally accepted ethical rules of publishing and demands of an explanation. The editor also informs the authors that he will send a copy of the letter to the head of their department at Freudberg.

- 1 How could the students have avoided the reprimand of the journal editor and the possible censure of their chair and university?
- 2 What harm, real or potential, could result from the students' action?
- 3 Could the students claim that they were unfamiliar with the ethical rules of publishing? If they were unfamiliar, whose obligation was it to inform them?

CASE 7: SCIENTIFIC FRAUD - 'DATA TRIMMING'

Dr. Frank N. Stein is a junior faculty member in the Department of Anatomical Protuberances at a large Transylvanian medical school. His latest research project deals with the effects of brain transplants on addiction careers. Preliminary analysis of the data on the first 10 transplants show an interesting trend, but the p value is just shy of statistical significance. Dr. Stein's statistician, Igor Numbers, suggests they conduct a few more transplants to increase statistical power and then add an equal number of cases to the control group (without the benefit of random assignment). Igor also suggests they conduct a one tailed test to get a more favourable alpha level, and drop some of the covariates to increase the degrees of freedom. After all these protocol changes have been made, the paper is submitted for publication as a true random assignment study with significant differences between groups. One of the reviewers questions the use of a one tailed test, suggests that the authors include more covariates in their analyses, and asks the editor to obtain more detailed information from the authors (Stein and Numbers) about the way the samples were assembled.

- 1 Was it ethical for Dr. Stein to use the one tailed-test?
- 2 How should Stein respond to the editor?

Checklist for Analysis	of Critical Incidents*		
Case Number			
I. Whose interests are inv Science, Society, all of the	1 5	vorkers, their institution,	the Professional Field,
How much harm will res	ult?		
Interests and Vulnerabilities	Significant	Moderate	Minimal / Non
Yourself			
Co-workers			
Institution			
Professional Field			
Science / Society			
Obedience (Obey Conscientious Re Beneficence (Do Gratitude (Pass g Competence (Be Justice (Be fair; o Stewardship (Use Honesty and Can Fidelity (Keep yo Loyalty (Don't al Diligence (Work Discretion (Response Self-improvement Nonmaleficience Restitution (Mak Self-interest (Pro Other Culture-special	bandon) hard) ect confidence and privacy) t (Be the best that you can be) (Don't hurt anyone) e amends to persons injured) tect yourself)	cal directives)	his situation?
*Adapted from White an	d Popovits (2001)		