



Good Scientific Practice

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BREAKTHROUGH OF THE YEAR: Breakdown of the Year: Scientific Fraud Jennifer Couzin

... A shadow was creeping across one of this journal's [*Science*] landmark papers, in which a team of South Korean and American researchers, led by Woo Suk Hwang at Seoul National University, claimed to have created the first-ever human embryonic stem cell lines that matched the DNA of patients. After anonymous allegations of irregularities in that paper appeared on a Korean Web site, South Korean authorities launched an investigation.

... inquiries discredited two papers Hwang published in *Science* in 2004 and 2005, which claimed some of the greatest accomplishments to date with human embryonic stem cells. The papers were retracted. But the scientific fraud, one of the most audacious ever committed, shattered the trust of many researchers and members of the public in scientific journals' ability to catch instances of deliberate deception.



Busted. The unraveling of Hwang's stem-cell papers was the first and worst of the year's research scandals.

As it turned out, the Hwang debacle marked the beginning of a bad year for honest science.....

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Why this lecture????

- ▼ What does „Good Practice“ mean in science?
- ▼ Who sets the standards?
- ▼ Do's and Dont's in scientific work

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What are the aims of scientific work?

- ▼ ..to answer scientific questions through research (gain knowledge)
- ▼ international acknowledgement through publications and defence of research results
- ▼ academic degree

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How are these aims reached?

- ▼ Ensuring the quality of scientific work!!
in
 - preparation
 - execution
 - documentation
 - evaluation
 - publication

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Quality ensurance: Good Practice Standards

- ▼ Good Laboratory Practice
- ▼ Good Manufacturing Practice
- ▼ Good Clinical Practice
- ▼ Good Veterinary Practice
- ▼


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Standards for Quality Ensurance

- ▼ „Good Laboratory Practice“ (GLP): Formal framework für safety tests for chemical products. Required by law in many countries. *“Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals (only preclinical studies), agrochemicals, cosmetics, food additives, feed additives and contaminants, novel foods, biocides, detergents etc.... GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments”.* (Wikipedia)
- ▼ GLP: Good Laboratory Practice according to ISO 9000 / Organisation for Economic Co-operation and Development (OECD) (www.oecd.org)....
- ▼ GCP: Good Clinical Practice, EU-directives (2001/20/EG und 2005/28/EG) , : ICH Guidelines for Good Clinical Practice (European Medicines Agency **EMA**)
- ▼ GCPV: Clinical Trials for Veterinary Medicinal Products in the European Union
- ▼ **VICH**: International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Products of the FDA (<http://www.fda.gov/cvm/vich.html>)

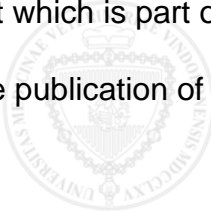
How to set Good Practice Standards

- ▼ Legal frameworks
 - e.g., in production of drugs
- ▼ Self-control
 - E.g., in academic research at universities
- ▼ **GSP**: Principles of the VUW for the ensurance of Good Scientific Practice (intra.vu-wien.ac.at/unileitung/ethikkommission/GoodScientificPractice.pdf)



Internal Guidelines for Doctoral Theses at the VUW
Interne Richtlinien zur Erstellung einer Dissertation an der VUW

- The requirements of Good Scientific Practice must be met in all points.
- A Thesis at the VUW is an innovative, hypothesis-based study in the framework of the doctoral study programme.
- It is a scientific project which is part of the research at the VUW
- It includes appropriate publication of the results.



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Good Scientific Practice
Ethik in Wissenschaft und Forschung
 Richtlinien der Veterinärmedizinischen Universität Wien

Gemäß Vorlage der Ethik- und Tierschutzkommission der Veterinärmedizinischen Universität
 Wien nach Befassung des Senats am 04.05.2005 vom Rektorat am 24.05.2005 beschlossen

Einleitung

Die Veterinärmedizinische Universität Wien verpflichtet sich den höchsten Ansprüchen der Wissenschaftsethik. Diese beinhalten das Streben nach Wahrheitsfindung, Genauigkeit und Ehrlichkeit im Umgang mit Daten und Publikationen, Verlässlichkeit, freie wissenschaftliche Meinungsäußerung und Gedankenaustausch sowie den tierschutzkonformen Umgang mit und die größtmögliche Schonung der zu wissenschaftlichen Zwecken herangezogenen Tiere. Die folgenden Richtlinien dienen dazu, diese Werte unter den geltenden gesetzlichen Rahmenbedingungen in einer immer komplexer werdenden Forschungsumgebung und in einem kompetitiven finanziellen Umfeld zu bewahren.

Zielsetzung

1. Verbindliche Festschreibung von allgemein gültigen und verbindlichen Richtlinien für alle MitarbeiterInnen an der Veterinärmedizinischen Universität Wien.
2. Festlegung von Evaluierungsmechanismen im Sinne des Qualitätsmanagements.
3. Festlegung der Vorgangsweise bei vermutetem wissenschaftlichem Fehlverhalten.

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Good Practice from the beginning to the end




What is important for GSP in

- preparation
- execution
- documentation
- evaluation
- publication

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1. Preparation: The planning process



Prior to the start of the practical work a **Project Outline** has to be prepared:

- ▼ - name of the student and the supervisor
- ▼ - work title/running title
- ▼ - Scientific question and work hypothesis
- ▼ - time frame
- ▼ - study structure
- ▼ - statistical evaluation including responsibilities (!)
- ▼ - source of patients/samples?
- ▼ - external cooperation partners
- ▼ - critical points/milestones
- ▼ - cost estimation
- ▼ - type of publication (desirable: oral presentation, publication)
- ▼ - further use of additional results

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Work Hypothesis

- ▼ Hypothesis = preliminary answer to a scientific question!
- ▼ "Scientific hypothesis is a hypothesis (a testable conjecture) used as a tentative explanation of an observation, but which has not yet been fully tested by the prediction validation process for a scientific theory. A hypothesis is used in the scientific method to predict the results of further experiments, which will be used either to confirm or disprove it.
- ▼ Hypothesis reg. the relation of variables:
 - directed hypothesis (...is higher/lower than...)
 - undirected hypothesis (...changes...)
- ▼ A hypothesis must be falsifiable. One cannot regard a proposition or theory as scientific if it does not admit the possibility of being shown false.. You cannot prove „That's how it is!", only that the likelihood of it being wrong is very small.

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Work Hypothesis

- ▼ On the basis of known = published results
- ▼ Where do I find publications on my research topic?
- ▼ „uncensored/unrated“, e.g. via Google
- ▼ „peer-reviewed“, i.e. refereed by an expert in the field*
- ▼ s. course „literature search“
 - PubMed: <http://www.ncbi.nlm.nih.gov/sites/entrez/>

*A peer group is a group of approximately the same age, social status, and interests. Generally, people are relatively equal in terms of power when they interact with peers (Wikipedia)


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Important Steps in the Planning Process

- ▼ Responsibilities
 - Who is the student, are there other (diploma) students/postdocs working in that area?
 - Who are the respective supervisors?
 - Conflicts of interest?
 - Who is responsible for quality assurance?
- ▼ Time frame
 - work contracts, deadlines
- ▼ Legal framework
 - approval/permission for animal experimentation, clinical material...
 - laboratory and work safety (radiation, GM technology...)

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Planning and Ethics

- ▼ Data with inadequate statistical preparation are often useless.
- ▼ Work with patients: often additional stress; consent, appropriate education?
- ▼ Animal experimentation: stress, pain, consume of animals
- ▼ Disregard/violation of legal framework and safety issues: Danger for oneself and others
- ▼ Use/waste of lab/clinic resources (equipment, time, manpower...)

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Planning of Experiments for Drug Registration



- ▼ Documentation of legal framework
 - Contract (development, approval, signing)
 - Payment Plan
- ▼ Protocol
 - Responsibilities: Sponsor, Monitor, Auditor, Principal Investigator, Statistician; Animal Technician, Technical Staff....
 - Time Frame (preparation, in-life part, evaluation, documentation, reporting)
 - Schedule of Activities
 - Documentation of all steps in the procedure
 - Documentation of relevant parameters
 - Protocols
 - Signature list

CONTENTS

<u>1</u>	<u>STUDY CONTACTS</u>	
<u>2</u>	<u>STUDY TITLE</u>	
<u>3</u>	<u>STUDY NUMBER</u>	
<u>4</u>	<u>STUDY OBJECTIVES</u>	<u>7.1</u> Type of Study
<u>5</u>	<u>JUSTIFICATION</u>	<u>7.2</u> Randomisation
<u>6</u>	<u>STUDY SCHEDULE</u>	<u>7.3</u> Experimental Unit
<u>7</u>	<u>STUDY DESIGN</u>	<u>7.4</u> Study animals and housing
<u>8</u>	<u>TREATMENT</u>	<u>7.4.1</u> Animal details
		<u>7.4.2</u> Justification
		<u>7.4.3</u> Fate of study animals
<u>8.1</u>	<u>Investigational veterinary products</u>	<u>7.5</u> Test facility
<u>8.2</u>	<u>IVP accountabilities</u>	<u>7.5.1</u> Husbandry
<u>8.3</u>	<u>Concomitant veterinary care and ther</u>	<u>7.5.2</u> Maintenance
		<u>7.6</u> Inclusion/exclusion of study animals
		<u>7.6.1</u> Inclusion criteria
		<u>7.6.2</u> Exclusion criteria
		<u>7.6.3</u> Post-inclusion removal criteria
		<u>7.7</u> Infection
		<u>15.1</u> Study protocol amendment
		<u>15.2</u> Study protocol deviation

16 APPENDICES

SCHEDULE OF EVENTS/AKTIONSPLAN
SIGNATURE LIST
ERROR CODES /FEHLERKODEX
LITTER RECORD
RANDOMISATION LIST
BODY WEIGHT
PREPARATION OF INFECTION DOSES
GENERAL HEALTH OBSERVATION
DOSE ADMINISTRATION FORM
FAECAL SCORE
DETERMINATION OF OOCYST NUMBERS
FAECAL OOCYST COUNTS
DOSE CALCULATION CHART
VETERINARY REPORT
REPORT OF ANIMAL REMOVAL FROM THE STUDY
STUDY PROTOCOL AMENDMENT
STUDY PROTOCOL DEVIATION
NOTE TO FILE
DATA ENTRY, VERIFICATION AND LOCKING

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2. Execution of Research

- ▼ „state of the art“ (lege artis)
- ▼ equipment and methods need to be sufficiently accurate and correctly used
- ▼ check if equipment is ready for use (pH-meter!)
 - instructions, manuals, test protocols, failure protocols....
 - use protocols, document deviations

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Supervision

- ▼ What do you expect from your supervisor?
- ▼ What can your supervisor expect from you?

- ▼ contract for supervision
- ▼ communication
- ▼ appropriate support
- ▼ appropriate conduct

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The work environment

- ▼ Working in a team
- ▼ Shared responsibilities
- ▼ Working with other people (students, postdocs/assistants, technical staff...)
- ▼ General rules not noted anywhere:
 - Book of etiquette (Labor-"Knigge")
 - Invisible hierachy
- ▼ Individuals outside teams

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A few tips...

Kathy Barker, *At the Bench. A Laboratory Navigator*. Cold Spring Harbour Laboratory Press (2005)

- ▼ Getting Oriented
 - General Lab Organization and Procedures
 - ▶ The Big Picture
 - ▶ Laboratory Personnel
 - ▶ Lab Routines
 - ▶ What to Expect the First Week
 - ▶ What To do the First Week
 - ▶ What Not to Do the First Week
 - ▶ Survival Through Common sense and Courtesy
 - ▶ Nonnegotiable Safety Rules
- ▼ Plotting a Course
- ▼ Navigating

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3. Documentation



What is appropriate Documentation?

- ▼ complete
- ▼ correct
- ▼ up to date
- ▼ permanent and durable
- ▼ comprehensible for others

Documentation



- ▼ ... of the used equipment
- ▼ ... of the used materials, samples and animals
- ▼ ... of the applied methods (including deviations from standard methods)
- ▼ ... of the evaluated parameters
 - s. protocol!
- ▼ ... of the obtained data
 - **PRIMARY DATA!**
- ▼ ... of the evaluation
 - e.g., protocol of the statistical programme

Methods

- ▼ applied methods (including deviations!)
 - Manufacturer's instructions (for test kits etc.)
 - Standard Operating procedures (SOPs) from the lab
 - own documentation



1. Ziel, Zweck, Geltungsbereich:
Diese Arbeitsanleitung legt dar, wie FIMC's gewonnen werden sollen. Diese Vorschrift gilt nur für die Gewinnung von FIMC's aus Vollblut.

2. Begriffe, Definitionen und Abkürzungen:
FIMC: Fragment of Membrane Invariant Cells (Stützplasmagemein)
EL: Erythrocytes-Lysis-Puffer

3. Geräte und Material:

Geräte:	Ständer
Eisbadbehälter ca. -4 °C:	AA57B21
Gelbehälter ca. -20 °C:	AA57B21
Centrifuge GS-11R, Beckman:	AA57B17
Fachkühlboxen SF 30, Siemens:	AA57B11
Material:	Ständer
Eppendorf Epipette (1000 µl):	AA57B21
evaku. polypropylen. System, Eppendorf:	AA57B21
Reaktionsgefäß (1,5 ml), Eppendorf:	AA57B21
Plastikbechler für Reaktionsgefäße:	AA57B21
Platzier:	AA57B21
Einschleifschleife, Pflanzsch. peroxidfrei, Hartmann:	AA57B21
Gelbeinle:	AA57B21
Alu-Folie:	AA57B21
Ethanol, Eppendorf:	AA57B21
Erythrocytes-Lysis-Puffer (EL), Qiagen:	AA57B21

Genehmigt/überprüft:	Freigegeben/überprüft:	Freigegeben/überprüft:
Dr. A. Joachim	Dr. A. Joachim	Dr. A. Joachim
Datum: 12.02.2009	Datum: 12.02.2009	Datum: 12.02.2009

Raw Data




- =primary data
- ▼ primary (first!!!) documentation
 - ▼ ... by hand into a protocol sheet
 - ▼ ... by hand into the lab book
 - ▼ ... in an electronic lab book
 - ▼ ... electronically (by a device)

To be kept for 5 (10) years, at least until publication of data!

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The lab book

- ▼ Different versions:
 - loose sheets in folder
 - bound, with numbered pages
 - electronic
- ▼ => rules of the respective lab!
- ▼ e.g., patent rights!



z. B. Formulator®, Regulator®

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Advantages and Disadvantages of Different Types of Documentation

- ▼ bound book:
 - + no lost pages, good proof against fraud allegations
 - order not logical, but according to date
- ▼ loose pages/folder:
 - + can be sorted according to experiments
 - pages can get lost, proof of authenticity?
- ▼ Electronic notebook:
 - + easy to read, good preparation for evaluation
 - backup necessary, authenticity difficult, wear during use?

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What is written in the lab book?



- ▼ **EVERYTHING!! AT ONCE!!** Directly writing in the lab book ensures a minimum of transfer errors!
- ▼ Protocols (glued into the lab book) manual records, photos, printouts, references to other archives (x-ray collections, TIS...)
- ▼ Date, title of the experiment
- ▼ Use permanent pen! Corrections must be readable
- ▼ Write down everything that is easy to forget: dilutions, animal numbers, batch numbers, incubation times, measured values, buffer receipts, temperatures....
- ▼ Experiments that went wrong and mistakes that you have made should also be described
- ▼ Thoughts on interpretations of data and further experiments can be included
- ▼ Don't worry about your handwriting and the quality of your drawings – it's the contents that count!

Who owns the lab book?



- ▼ The lab book belongs to the workplace (lab/clinic), not you. This is where it should be kept.
- ▼ A lab book is not a public document!
- ▼ It is the basis of all your discussions with your supervisor on your work.
- ▼ It represents your scientific work, in cases of doubt it supports the authenticity of your data and therefore your own credibility!

4. Evaluation

- ▼ Consequent questioning of the results = Pillar of scientific work!
 - ▼ ... therefore ALL data must be evaluated!
Omission of data must be justified („doe not fit“ is not enough!!!)
 - ▼ Discuss critically with others. Make notes about it.
 - ▼ Read the relevant literature thoroughly.
 - ▼ Consult a specialist*.
- *The statistician should already be involved in the planning.

5. Publication

- ▼ Types of publications:
 1. written:
 - Original publications in peer-reviewed scientific journals
 - Review journals in Übersichtsartikel in peer-reviewed scientific journals (for established scientists)
 - Articles in journals for popular science
 - Book articles, books
 - Thesis (monography)

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Publication

2. oral:

- Dissertantenseminar
- Public defense
- Seminar presentation
- Presentation at national/international scientific meetings or conferences

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The Review system...

- ▼ „true“ scientific publications are ALWAYS peer-reviewed (journal publication, Thesis)
- ▼ Reviewer: peer in the field or a related discipline
- ▼ Review process on the basis of scientific criteria
- ▼ NEVER IGNORE THE
- ▼ IGNORIEREN SIE NIEMALS DIE BEMERKUNGEN DER GUTACHTER!!!

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... and the Impact-Factors



- ▼ The importance of a publication (*impact* on the field) is evaluated along different criteria (frequency of citation, cited half-life...). The impact factor of a journal is determined by all articles published there.
- ▼ The higher the impact factor, the more submissions a journal will receive (and the more difficult publication will be there!)

What can go wrong?



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What can go wrong?

... in the initial phase:

- ▼ poor preparation
- ▼ poor supervision/support (written contract?)
- ▼ poor planning (no permissions...)
- ▼ no specific/definitive arrangements reg. time schedule , expectations, workload, goals....
- ▼ insufficient access to lab space, equipment...
- ▼ no contact person for questions and problems

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What can go wrong?

... in practical phase:

- ▼ poor working conditions
- ▼ Poor working climate
- ▼ Too much frustration (difficult project)
- ▼ overload
- ▼ underload
- ▼ poor definition of aims
- ▼ No control over technical problems
- ▼ POOR DOCUMENTATION

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What can go wrong?

... in the phase of evaluation and publication

- ▼ lack of orientation („how do I start?“)
- ▼ language problems
- ▼ poor data documentation
- ▼ Conflicts of interest student-supervisor
 - results \leftrightarrow expected (anticipated) results
 - Finalisation of Thesis \leftrightarrow Publication
 - Publication of own results \leftrightarrow Publications of other students
 - (co)authorship, order of authors
 - workload, deadlines
 - delay in compiling data
 - Delay of corrections



Ethics in Publications – Important Points



- ▼ (co-) authorship
- ▼ Multiple publications
- ▼ Confidentiality, data protection/patent rights, privacy protection
- ▼ plagiarism
- ▼ incomplete literature search and literature quotations

Authorship



- ▼ usually >1 author, most important positions: first author, last author (for *seniors*)
- ▼ Who can be an author?
 - Everone who has substantially contributed to the work: „Minimum requirement for authorship would be participation in conceiving and/or executing and/or interpreting at least that part of the publication in a co-author's field of expertise, sufficient for him/her to take public responsibility for it.“ (<http://www.deakin.edu.au/education/rads/guidelines/scientific.php>)
- ▼ Who cannot be author?
 - “honorary authorships” eg., for an expert in the field for short advice = taboo!
 - ...as is mutual coauthorship in order to increase the number of papers of single members of a group without substantial contribution

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Authorship

- ▼ Missing of contributions, author's contribution not acknowledged
 - Leads to mistrust, damages one's reputation, cooperations can break up
 - Coauthorship vs. acknowledgement, esp. for technical assistance!
- ▼ Author order?
 - Rules can vary, should be made clear beforehand!
 - "Writer=first author" ⇔ „major contributor = first author“
 - Conflict of interest between postdoc (Habilitation) – PhD student (Thesis)
- ▼ Responsibilities
 - Each authors is responsible, at least for his own contribution – first and last authors are responsible for the whole publication!
 - Formally, the corresponding author is responsible towards the Editor of the journal.
 - All authors should agree upon a final version.

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Multiple Publications

- ▼ ... are not acceptable except
 - with a complete description of previous uses (*cross-referencing*)
 - in simultaneous publications: only when the editors of both journal are informed

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Confidentiality, Data protection, Patent right



Confidentiality/privacy protection relates to

- ▼ ... all activities in the project team/in the lab
- ▼ ... all unpublished results and project plans of the group (for staff as well as referees!)

- ▼ protected data:
 - ... personal data of patients (patient owners)
 - ... unpublished data prior to publication
 - ... data relevant for a patent before patenting
 - ... unpublished data/data under review of other scientists

Violation can lead to a lawsuit!

Plagiarism



Plagiarism is the use or close imitation of the language and ideas of another author and representation of them as one's own original work. (Wikipedia)

- ▼ =use of text/graphs without naming the source (but not infringement of copyrights*)
- ▼ at VUW all Diploma and Doctoral Theses are checked electronically for plagiarism
- ▼ Note: Copyrights for graphs in books are usually with the publisher (even for our own work)

* Plagiarism is not copyright infringement. While both terms may apply to a particular act, they are different transgressions. Copyright infringement is a violation of the rights of a copyright holder, when material protected by copyright is used without consent. On the other hand, plagiarism is concerned with the unearned increment to the plagiarizing author's reputation that is achieved through false claims of authorship (Wikipedia)

Literature Search and Literature Quotations



- ▼ incomplete citations and references:
- ▼ ... annoy the left-out authors
- ▼ ... may lead to an incomplete overview of the status quo of a scientific hypothesis
- ▼ ... means that you have not properly elaborated the topic!

1. Older publications are not automatically out of date!
2. Literature outside PubMed, Medline/Scopus... does exist!

Omission of Quotations



- ▼ Deliberate omission of references
 - ... because you don't like the presented results
 - ... because you don't like the authors
 - ... because it is a competing research group
 - ... because you don't want them to receive credit for being quoted
 - ... because you are too lazy to get the paper

- ▼ Is unethical!

(It is different if you find that the methodology of the paper is flawed or poorly presented. Even though, it should be quoted, although critically.)

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Spinach Stories...

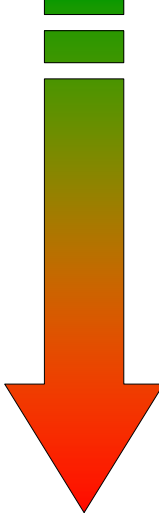
- ▼ a quote from a quote must be described as one!
=> obtain and read the original paper or quote from secondary literature and reference appropriately (Meyer, 1956, cited in: Schmidt et al., 1996)
- ▼ The documentation of literature searches (electronically or in paper) is also part of the research documentation!

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Scientific Misconduct

Corrupt or just sloppy?



No scientific misconduct:
Unnoticed mistakes
misinterpretations/differences in interpretations

Grey Area:
poor documentation
trade speculations as facts
omission of data without (statistical) justification

**Breach of Good Scientific Practice
(scientific misconduct)**
abstraction or concealment of data
data theft
data forgery

Every 3rd scientist??

every 100. scientist??

K. Powell, Misconduct mayhem, Nature 2006, 441, 122-123.

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Ethics in Science



The VUW commits herself to the highest standards of scientific ethics.[....] Pursuit of truth, exact and honest handling of data and publications, reliability, freedom of scientific expression and exchange of ideas... [.....]

What Can You Do When Things Go Wrong?



Univ. Prof. Dr. Anja Joachim
Parasitologie und Zoologie

Univ. Prof. Dr. Peter Schmidt
Pathologie

- Confidential conversation
- Further steps only with your consent



„Whistleblower!“

- ▼ When others infringe Good Practice Principles...
- ▼ ... it is your personal decision whether you want to tell on her/him!!!

**„It is an honour system“
Mortimer Litt, Harvard Medical School**