Amsterdam UMC
University Medical Centers

Research Meeting Scientific Integrity
March 2, 2021 4-5 pm

Program

16.00	Introduction and In Memoriam Hanneke de Haes	Jan Heimans
16.05	How to get the Amsterdam UMC Research Code into our system	Peter Hordijk
16.20	How to deal with suspected falsification and fabrication	Ed van Bavel Carlie de Vries
16.30	Role of the Academic Integrity Committees	Noam Zelcer
16.35	How to coach our Ph.D. students	Jan Heimans Kirsten Douma
16.50	Discussion	Ed van Bavel
17.00	End of meeting	

Hanneke de Haes (1949 - 2020)

Peter Hordijk
Prof Physiology, Amsterdam UMC

member of the editorial board for the new Research Code

Editorial committee:
Prof. Hanneke de Haes, PhD
Prof. Peter Hordijk, PhD
Prof. Marja Boermeester, MD, PhD
Michel Paardekooper, PhD
Esther Stoop, PhD

We are grateful to Lex Bouter, Marij Hillen and Louis Ates for their critical review of the draft text and constructive comments, which substantially improved the contents.

We thank Nienke Dikkers for her valuable contributions, and Jessika van Kammen, Miriam van Strien, Janine Stolwijk, Marlies Stouthard, Ed van Bavel, Henriette Griffioen, Leonie van Rijt, Selma Camic, Rudy Scholte, Karien Stronks, Yvo Smulders, Jan Hol, Joris Bod, Simone van der Heijden, Zsofia Ottoway, Jeroen van Leur, Désirée de Lange, Joris Heus, Nicole Burger and Yvonne Donselaar for their insightful input.

Part 1

Why a (new) Amsterdam UMC Research Code?

This new version is an updated, shortened and more easy-to-read Research Code

Is it boring? No

Is it important? Yes

Is it important for me (PhD students) or only for PI's? For both!

Why a (new) Amsterdam UMC Research Code?

- we compared the existing code with those of KNAW, UMCG, LUMC, EUR etc

- we also looked back at older doc's for reference:

NFU – "naar een goede waarde" (on valorisation)

LERU (The League of European Research Universities) position paper 2016 on Citizen science

Why a (new) Amsterdam UMC Research Code?

Mode of action:

- Basis was the existing Research Code
- Chapter content and order was evaluated and adapted
  (including merging of previously exisiting chapters)
- Tekst was significantly shortened and revised, with the help of the (original) ‘owners’
- All URL’s were checked and updated
- Final draft was commented on by (young) researchers and by Lex Bouter

New ‘smoel’ and icon’s

Table of contents

1 Expectations regarding supervisors and junior researchers

2 General research and laboratory practice

3 Dealing with laboratory animals

4 Dealing with human subjects involved in research

5 Research data management

6 Authorship

7 Peer review of research proposals and manuscripts

8 Research collaboration agreements

9 Valorization

10 Dealing with the media

11 Conflicts of interest

12 Research misconduct: bad practices, prevention and dealing with suspected violations

New ‘smoel’ and icon’s

1 Expectations regarding supervisors and junior researchers

Scientific research is a team effort. Scientists at different career levels (and from different disciplines) cooperate in research. Mutual trust and respect are vital for responsible research conduct. Supervisors have the overriding responsibility for coaching junior researchers. They are expected to create the necessary conditions for good research and to lead by example rather than referring to the power they represent. They should be committed to supporting and mentoring less experienced researchers through good scholarship and research integrity. Cooperation and dedication to this process are obviously needed from the junior researchers as well. An interesting study amongst PhD candidates and supervisors in the Netherlands showed that both supervisors and junior researchers regard personality, knowledge, skills and communication as important for a successful PhD trajectory. The expectations regarding supervisors and junior researchers are described separately below.

1.1 What is expected of research supervisors

Good supervision is required for PhD candidates, and also for junior researchers, MDs, postdocs, master’s and bachelor’s degree candidates. Supervisors may be PhD students, postdocs, or (assistant, associate or full) professors. Some supervisory responsibilities may be divided among members of the supervisory team. If so, this must be made explicit to the junior researcher. The guidelines given here apply to all forms of supervision of research activities. We focus on three elements of the working environment that lead to an optimal research and learning experience for the junior researcher.

1.1.1 Research climate

Good research thrives in a positive research and learning climate. Building and maintaining such a climate is

New ‘smoel’ and icon’s

4 Dealing with human subjects involved in research

An absolute prerequisite for research involving human subjects—both patients and healthy volunteers—is that they are treated with respect, and have their health and rights protected. Researchers have a responsibility to ensure the well-being of research subjects and their voluntary participation in research. Moreover, researchers must be aware of the potential conflict between the interests of the research subjects and the interests of the research.

4.1 Regulatory framework

The interests of human subjects involved in medical research are protected by a number of (supplementary) laws, decrees, regulations, directives and codes of conduct [3]. Applicable legislation depends on the specificities of the research (such as research using a medicinal product or medical device, trials with embryos, population screening, or research involving children or incapacitated subjects). A comprehensive list of all requirements for all types of research is presented on the website of the Central Committee on Research Involving Human Subjects (*Centrale Commissie Mensgebonden Onderzoek*; CCMO).

Currently, the main legislation governing clinical research conducted in the Netherlands is the Medical Research Involving Human Subjects Act (*Wet Medisch-wetenschappelijk Onderzoek met mensen*; WMO), which is based on the Nuremberg Code, the Declaration of Helsinki and the ICH Good Clinical Practice guideline (ICH-GCP). ‘Medical research that includes subjecting persons to interventions or imposing a particular course of conduct upon them’ is subject to the WMO. The main purpose of the WMO is to protect those who participate in medical scientific research while ensuring the integrity of research data. The WMO is designed to protect human subjects in various ways:

[3] For an overview of relevant laws, decrees, regulations and codes of conduct, see the website of the CCMO or the Appendix of the VSNU, Netherlands Code of Conduct for Research Integrity, 2018, p. 28.

New ‘smoel’ and icon’s

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12 Research misconduct: bad practices, prevention and dealing with suspected violations

1

Expectations regarding supervisors and junior researchers

topic	*For example:*
Research climate	*Creating room for open discussions; giving feedback*
Attitude & communication	*PhD student takes responsibility for her/his research;*
	is transparent about problems or potential errors

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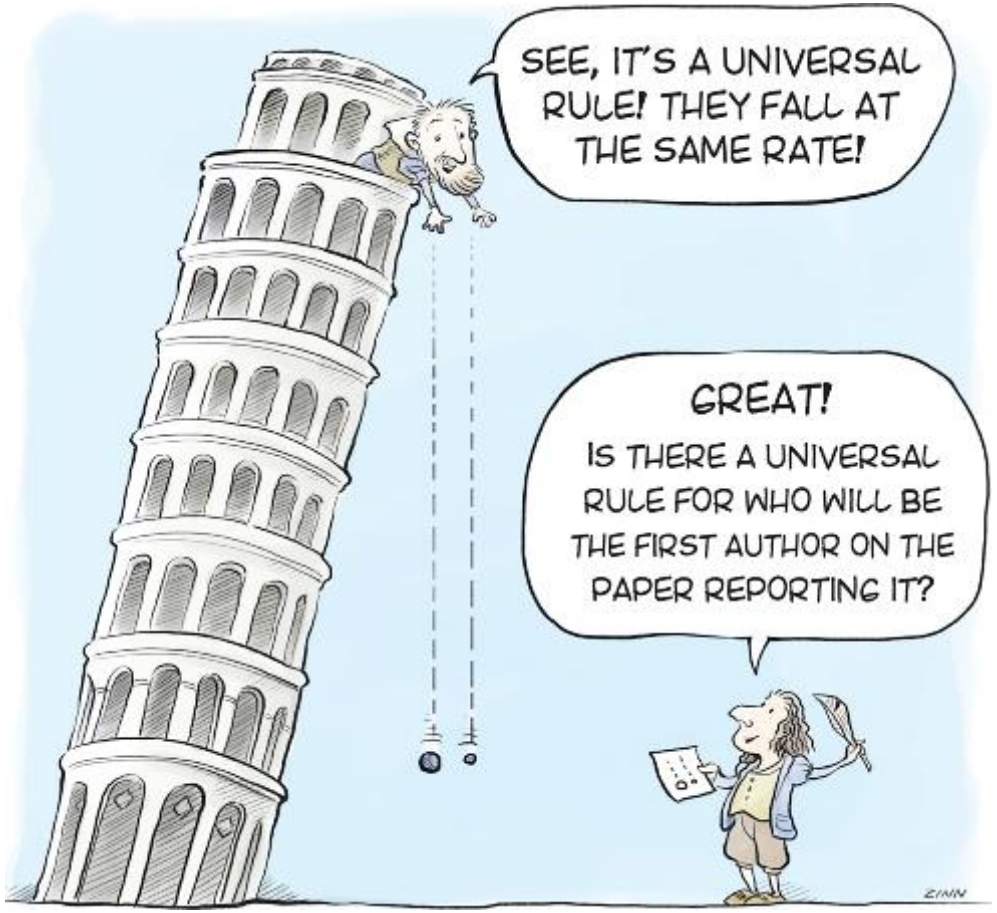
Authorship



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Authorship

topic

For example:

Authorship - types

First, last, corresponding authors: roles and responsibilities;

Also: who qualifies as an author and why?

Acquisition of funding or general supervision of the research group (e.g. head of dept.) does not justify authorship

Demanding an unqualified authorship or leaving a qualified author from the manuscript is a breach of research integrity

Etc.

12

Research misconduct: bad practices, prevention and dealing with suspected violations

topics

Types of misconduct

Researcher & research group

Dealing with suspected misconduct

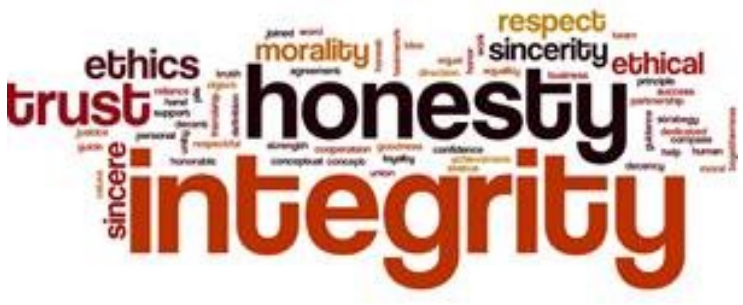
For example:

Fabrication, falsification, plagiarism

Responsibility, transparency, open discussions
Organizing regular work discussions, creating a safe environment

(inter)national 'codes of conduct'

Confidential councellors
(Ed van Bavel-AMC / Jan Heimans -Vumc)



So, the Amsterdam UMC Research code provides

- Information
- Framework and guidelines
- Lots of url’s

For researchers young and old, to improve their research

Read it and use it!

Part 2

Now, how to get the message across?

Part 2

Now, how to get the message across?

- introduction and discussion on research code as part of Master program and during PhD – events or courses

- make Research code part of the PAV (praktijkstage acad. vorming) for GNK students

- research code as part of the intro package of new employees (pre-clinical and clinical research), including mandatory reading

- choose an annual event/day on which to ask attention for research integrity

- introduce a Research Integrity check when finalizing a research paper for submission

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Dealing with suspected falsification/fabrication of research data

Ed van Bavel — Scientific integrity counselor AMC

Carlie de Vries — Chair of the ‘audit F/F’ committee

FFP: The clearest and most severe examples of research misconduct

“Fabrication: the invention of data or research results and reporting them as if they are fact”

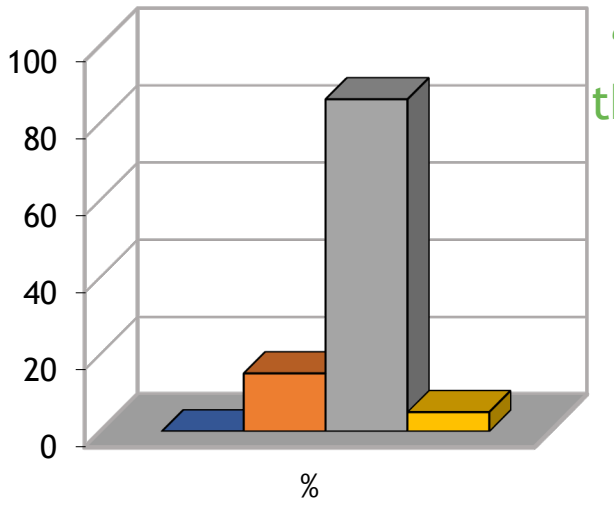
“Falsification: the manipulation of data or research material, equipment or processes to change, withhold or remove data or research results without justification”

“Plagiarism: the use of another person’s ideas, work methods, results or texts without appropriate acknowledgement”

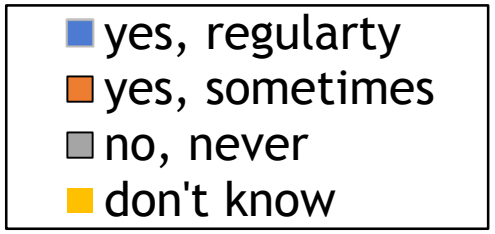
https://www.vsnu.nl/files/documents/Netherlands%20Code%20of%20Conduct%20for%20Research%20Integrity%202018.pdf

Frequency of suspected F/F at Amsterdam UMC

- ~ once-twice a year for AMC
- None reported for VUMC



"I have seen in my surroundings that data were made up." (N=78) (approve 2012, AMC/Vumc)



"A pooled weighted average of **1.97%** (N = 7, 95%CI: 0.86-4.45) of scientists admitted to have fabricated, falsified or modified data or results at least once--a serious form of misconduct by any standard--and up to **33.7%** admitted other questionable research practices."

Fanelli, Plos One 2009

Fabrication and falsification discussion issues

- How to prevent?
- How to uncover?
- How to act?

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Aanpak en aandachtspunten bij vermoeden en/of vaststellen van falsificatie / fabricatie van data of onderzoeksresultaten

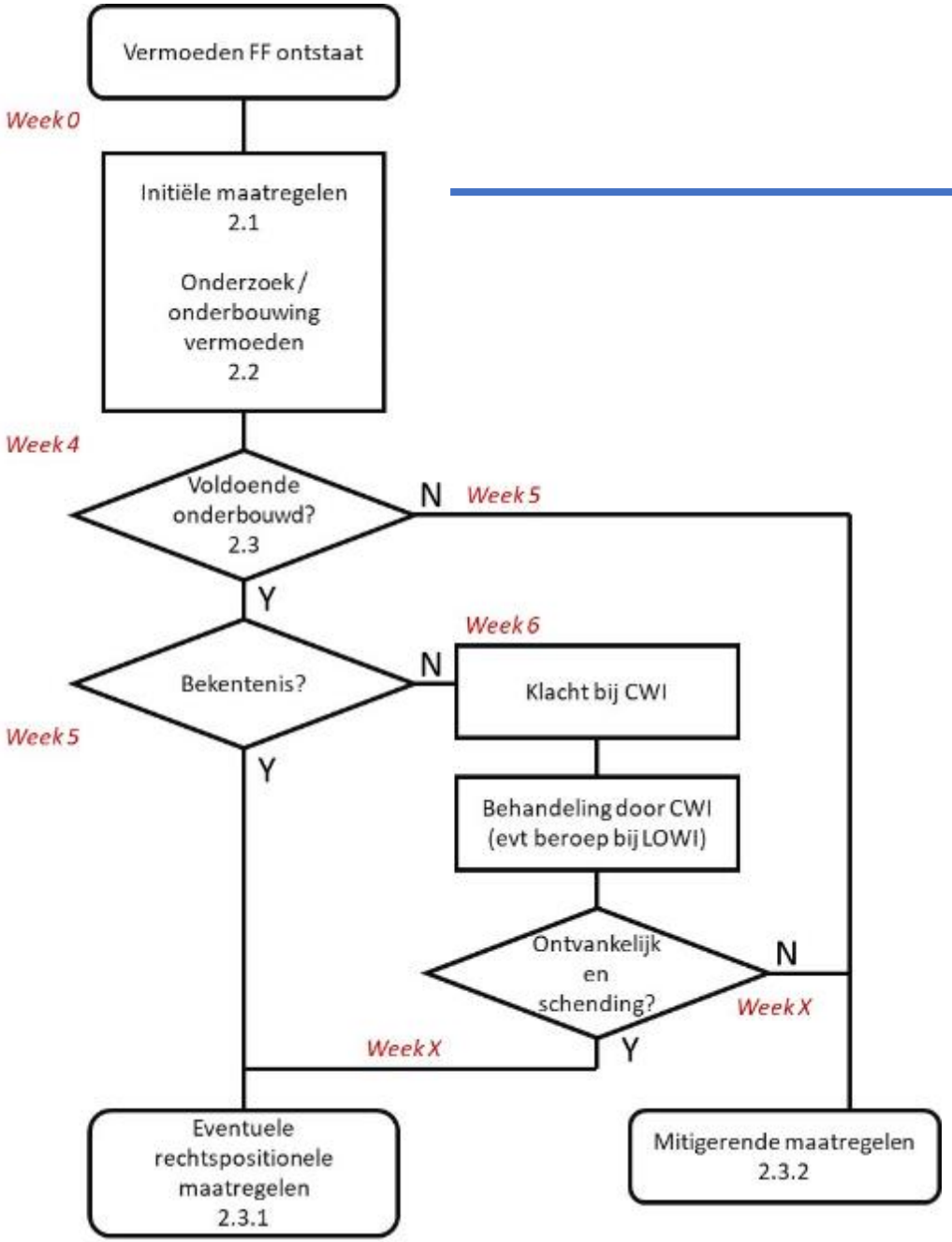
Hanneke de Haes, Ed van Bavel, Jan Heimans[1]

versie 23-10-2020

https://www.amsterdamumc.org/research/integrity.htm

Why a guide for specifically F/F?

- Most serious manifestations of research misconduct
- Severe consequences for suspect (‘beklaagde’), research group, Amsterdam UMC, the research field and patients
- Suspicion on F/F generally occurs acutely
- Emotional event
- Lack of independency of complainant (‘klager’)
- High risk of wrong actions in notably first days
    - Accusations based on insufficient evidence / misunderstanding
    - Accusation of the wrong person
    - Public accusations
    - Lack of respect for suspect
    - Cover-ups
    - Insufficient safeguarding of data and F/F evidence



Initial measures:

Complainant:

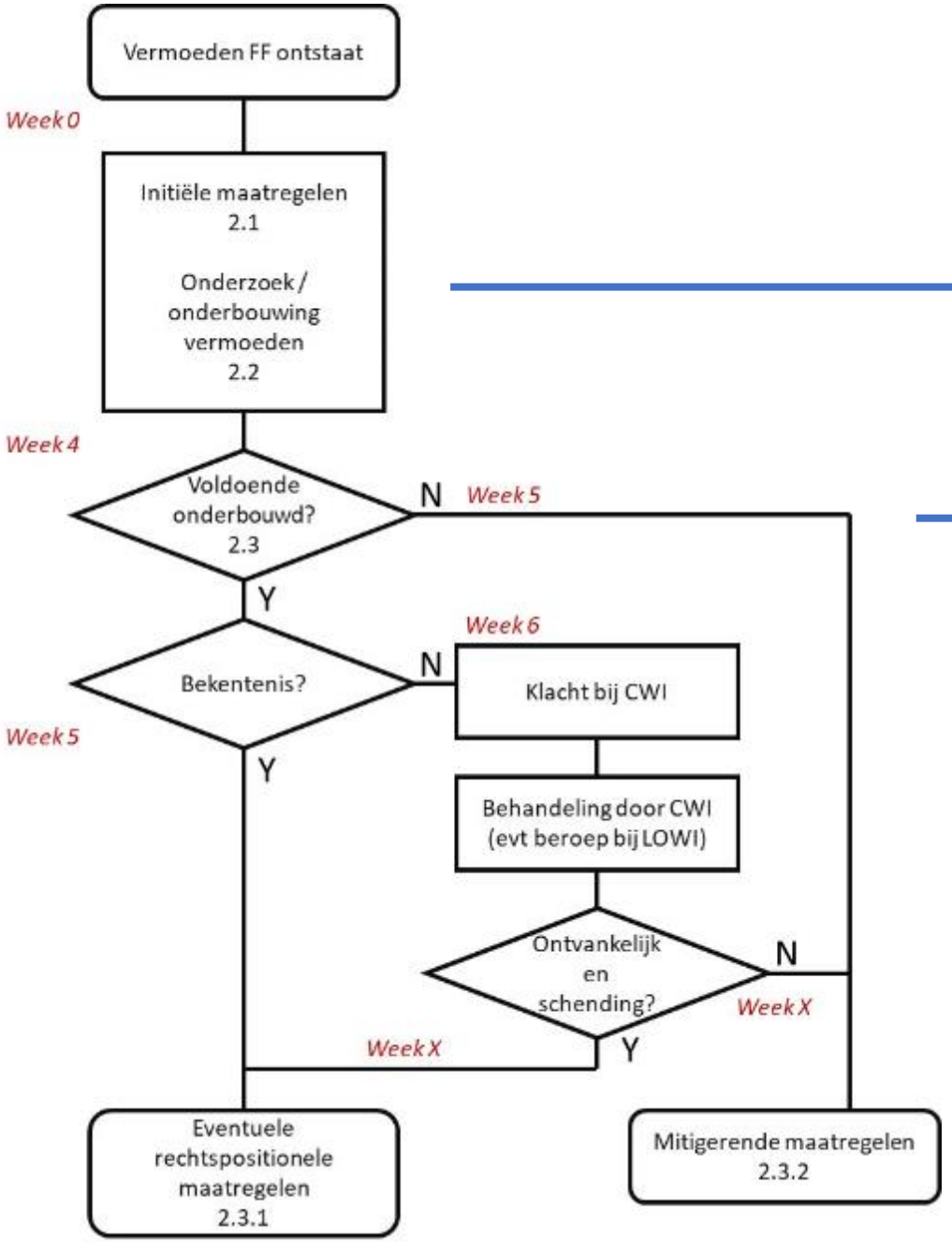
- Inform the Scientific Integrity Counselor
- Inform the PI and/or Head of Department
- Ensure that serious suspicion becomes known to all management layers
- Consider when to inform the suspect.

Head of Department:

- Block access of suspect to ALL data, labjournals, the lab, biobanks…
- Discuss the concerns with the suspect
- Involve the Dean
- Involve HRM / legal if needed
- Ensure that submissions / promotions are put on hold

Dean:

- Discuss the needed measures with the Head of Department
- Activate the Committee ‘ audit F/F’

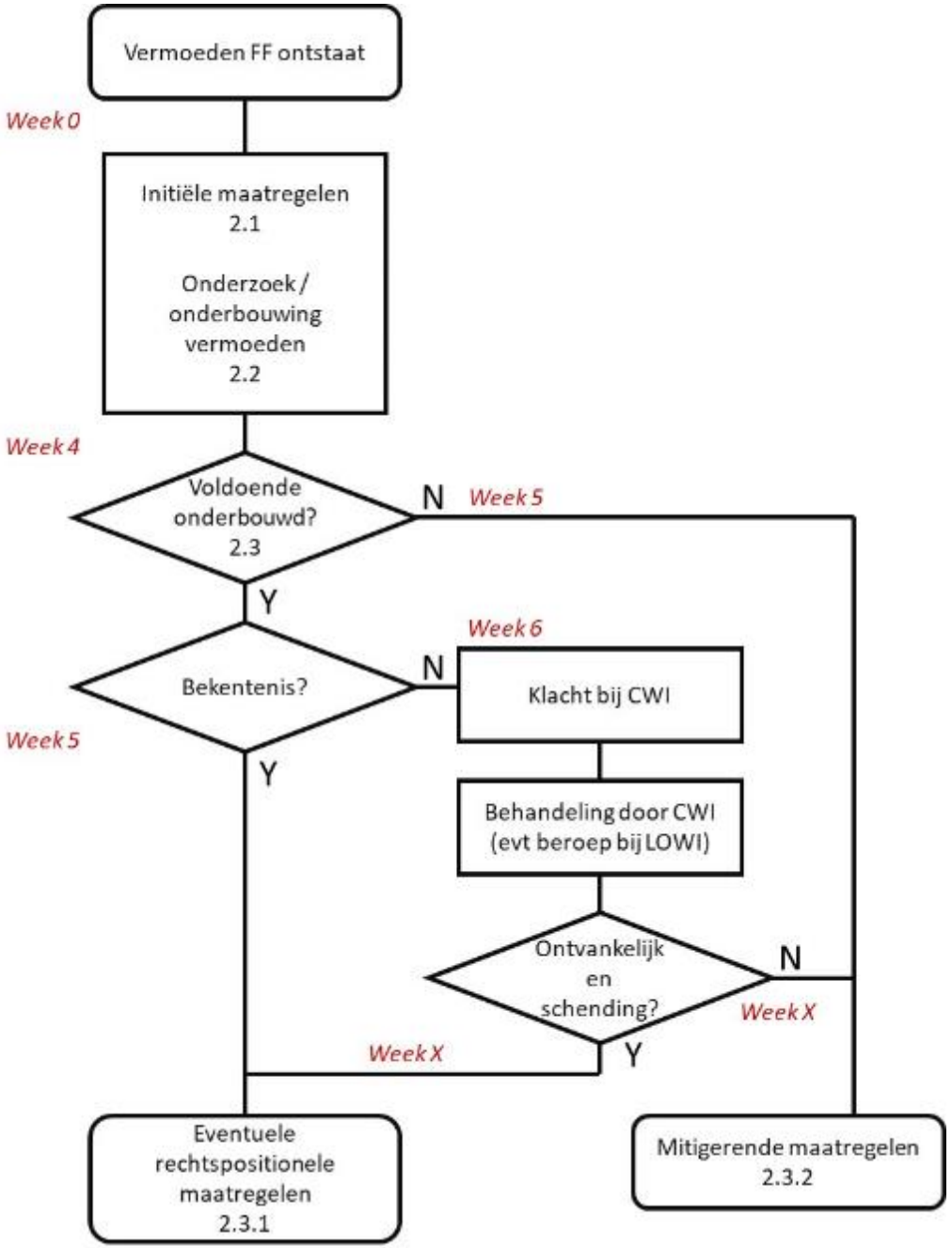


Collect and review evidence for suspected F/F

PI and Head of Department:
- Collect data of ALL studies that involved the suspect.

Committee ‘audit F/F’ reviews evidence and comes to advice and recommendations (Carlie de Vries)

Dean makes judgment and files complaint to CWI if needed



Whom and how to inform that there are serious concerns?

Depends strongly on case, possible actions by Head of Department:

During these weeks, for those closely involved:
- Be open, explain procedure, stress confidentiality, discuss concerns, …

After the final judgment, for e.g. the department:
- Share conclusions and measures taken
- Evaluate how this could have happened, how to prevent this in future

If F/F could not be shown or did not happen:
- ‘Resocialize’ the accused person, if at all possible.

Commissie Audit Fabricage & Falsificatie

Prof. dr. Carlie de Vries	Molecular Cell Biology / chair
Prof. dr. Arjan van de Loosdrecht	Internist-Hematology
Prof. Koos Zwinderman	Epidemiology
Mr. Elcke Kranendonk	Legal / secretary

Addition *ad hoc* of experts




Commissie F&F - Procedure

Acts fully confidential and independent

Alert of F&F to Board of Directors

Request to Commissie F&F

Commissie F&F - Procedure

- Collect information
- Hearing and rebuttal involved individuals
- Research
  - Adequate substantiation of suspicion of F&F and extent?
  - Careful approach to the defendant and truth-finding?

- Report to the Dean
- Advice
  - Actions with regard to journals, co-authors, subsidy providers, collaborating parties
  - Submission of case to the CWI
  - Improvement for science integrity within the department or in Amsterdam UMC

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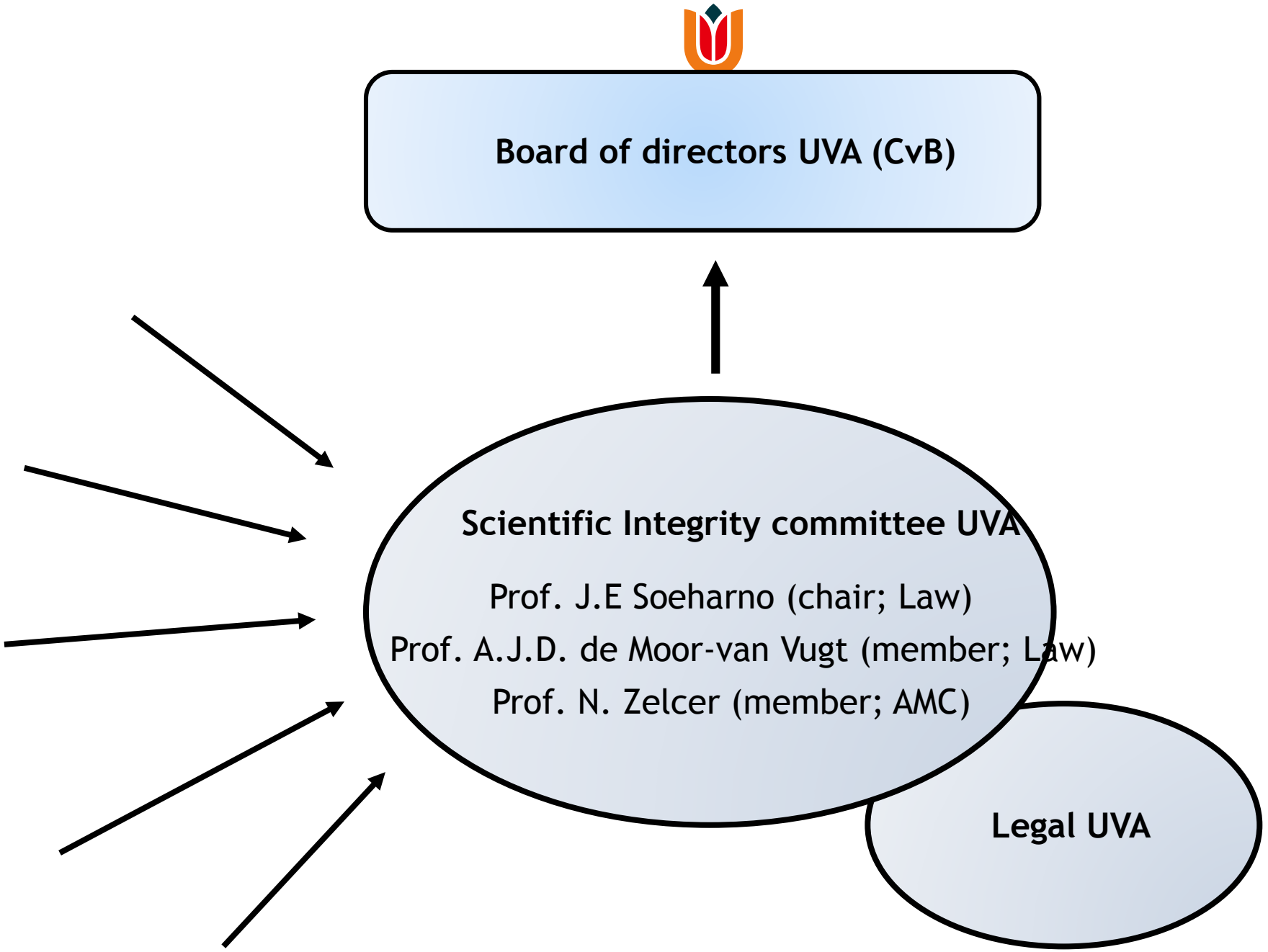
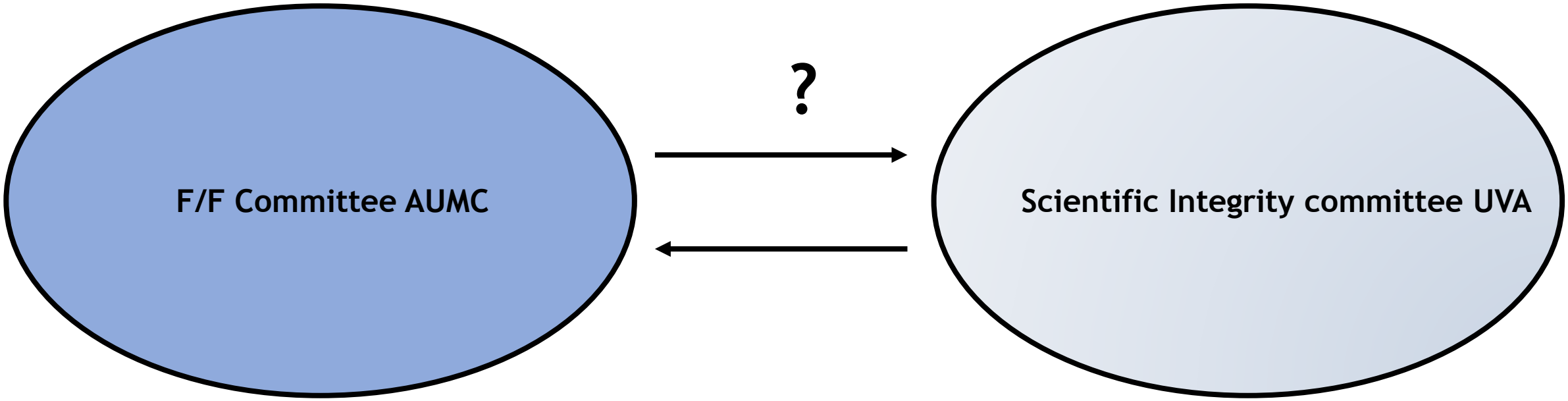
The Academic Integrity Committees

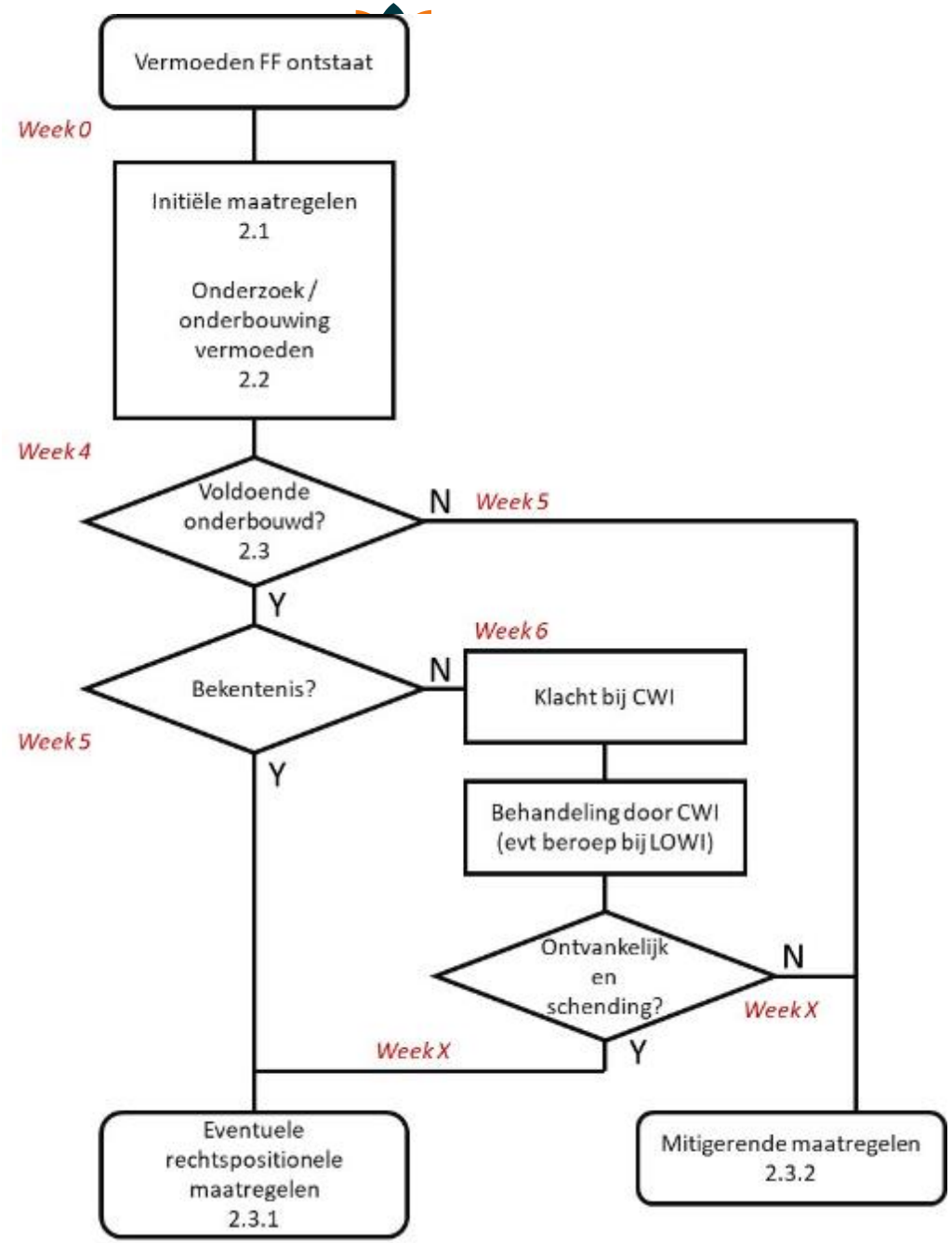
Noam Zelcer


Board of directors UVA (CvB)
Scientific Integrity committee UVA
Prof. J.E Soeharno (chair; Law)
Prof. A.J.D. de Moor-van Vugt (member; Law)
Prof. N. Zelcer (member; AMC)
Legal UVA



- Under which regulations does the F/F committee operate?
- Can cases investigated by the F/F be passed on to the UVA WI Cie?
- Can the UVA Wi Cie handle cases from the VUMC?
- Where can one appeal a decision?

....


Vermoeden FF ontstaat
Week 0
Initiële maatregelen
2.1
Onderzoek /
onderbouwing
vermoeden
2.2
Week 4
Voldoende
onderbouwd?
2.3
N
Week 5
Y
Week 6
Bekentenis?
N
Klacht bij CWI
Week 5
Y
Behandeling door CWI
(evt beroep bij LOWI)
Ontvankelijk
en
schending?
N
Week X
Week X
Y
Eventuele
rechtspositionele
maatregelen
2.3.1
Mitigerende maatregelen
2.3.2

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How to coach our PhD candidates

Vertrouwenspersonen/Confidential counselors

Kirsten Douma

Ed van Bavel

Jan Heimans

Background

- AMC:
  - Confidential counselor Scientific Integrity (Prof. dr. Ed van Bavel)
  - Confidential counselor for PhD Candidates, of the AMC Graduate School (dr. Kirsten Douma)
- Vumc:
  - Confidential counselor Scientific Integrity (Prof. dr. Jan Heimans)
  - No special confidant for PhD Candidates. They approach prof. Heimans or to a confidential counselor of the ‘Bureau Ombuds-en vertrouwenszaken’

Supervision of PhD Candidates and Scientific Integrity

- In the Netherlands Code of Conduct for Research Integrity (VSNU, 2018; 1.1.4):
- “There are other forms of integrity besides research integrity. The researcher must treat subordinates, students and colleagues with respect, for example, and must refrain from committing fraud with expense statements. Insofar as these forms of integrity are not directly related to the research practice, they fall outside the scope of this Code. The boundary is not always clearly defined, however, so this Code also includes some ‘borderline’ cases..”

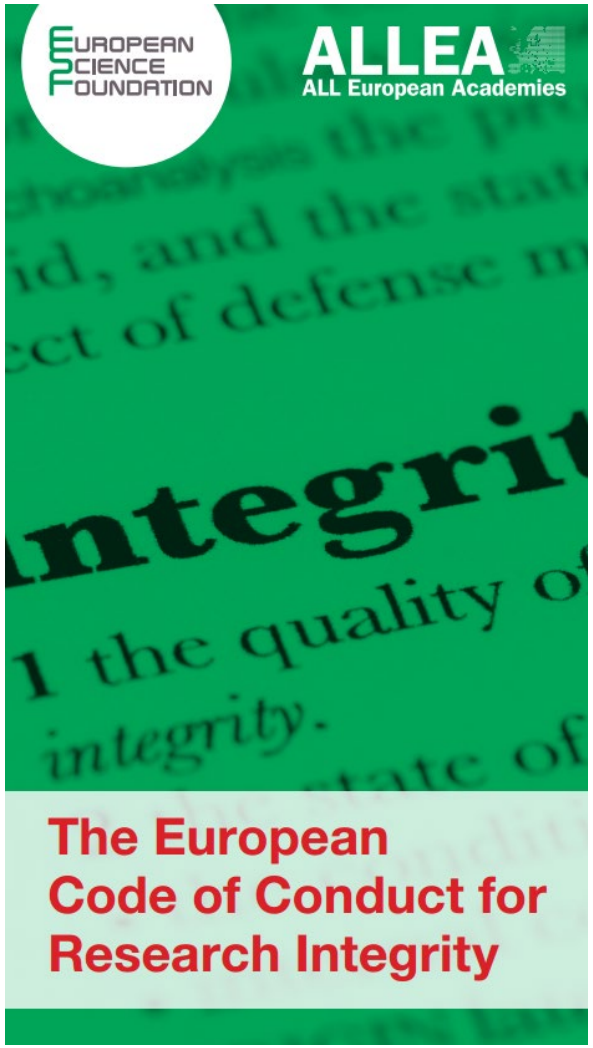
§ 4.2 Training and supervision

1. Raise awareness about research integrity within the organization and, where necessary, provide or facilitate training courses for researchers, support staff, research leaders and research managers.
2. Embed a focus on research integrity firmly in educational activities of higher education institutions.
3. Provide a working environment in which responsible research practices are facilitated.
4. Ensure that new researchers and PhD students are supervised by suitably qualified persons.
5. Ensure transparent and fair procedures for appointments, promotions and remuneration.

§ 3.7.56 & 57 Norms for all phases

- As a supervisor, principal investigator, research director or manager, provide for an open and inclusive culture in all phases of research.
- As a supervisor, principal investigator, research director or manager, refrain from any action which might encourage a researcher to disregard any of the standards in this chapter.

To conclude: Scientific integrity goes hand in hand with a broadly carried and well-founded professional supervision culture



These principles include:

- honesty in communication;
- reliability in performing research;
- objectivity;
- impartiality and independence;
- openness and accessibility;
- duty of care;
- fairness in providing references and giving credit; and
- responsibility for the scientists and researchers of the future.

Experiences:
problems of supervisors

- **Insufficient motivation and/or initiative** of PhD Candidate
- **Doubt about the own input** of the PhD Candidate
- Strongly **distorted work relation** between PhD Candidate and supervisor(s).

Experiences: problems of PhD Candidates

- Insufficient **financial means** (and thus appointment) for the complete duration of the trajectory
- Slow or no **progress of research**, which makes it hard to finish in time
- Insufficient **supervision**
- Disproportionate **pressure to perform** which might lead to ‘sloppy science’
- Seriously **distorted work relation** between PhD Candidate and supervisor(s).

Financial means

- Insufficient **financial means** (and thus uncertainty about appointment) for the complete duration of the trajectory. Only vague promises for the remainder of the trajectory.
- Frequently proposed ‘solutions’:
  - Part time appointment, while working fulltime
  - Lower salary
  - Last months PhD in own time and at own expenses
  - Appointment elsewhere and finishing PhD in evening hours (own time)
  - Unemployment benefits (WW-uitkering) while working on PhD
  - Parents have to guarantee finances (garant staan)

Progress of research

- Causes:
  - Wrong expectations about: extent and duration of experiments, METC procedure, inclusion rate etc.
  - Lack of realistic work plan with time schedule
  - Research partners not included in time
  - Lack of time of supervisors: no regular or missed research meetings, very slow feedback on manuscripts
  - Difference of opinion or conflicts between supervisors or institutes

Supervision

- Causes:
  - Insufficient expertise, knowledge or time of supervisors
  - Too many tasks unrelated to PhD
  - Only 1 supervisor; adding (co-)supervisors is postponed as long as possible
  - Supervisors leave without replacement being arranged
  - Conflicts within the supervisory team with PhD Candidate lost in the middle
  - Responsibilities within the supervisory team and/or project unclear
- Consequences:
  - No or insufficient structured work meetings
  - No regular progress meetings

Pressure to perform

- Structural overlabour
- Not allowed to take leave
- Pressure on more and more publishing “…it is never enough…” (changing the rules during the game)
- Lack of time: sloppy science or even messing with data as an ultimate consequence

Distorted work relation

- Lack of mutual trust
- Mutual expectations are unclear
- Insufficient involvement of supervisors
- Unclear responsibilities for the PhD trajectory

International PhD Candidates

- Vulnerable Scholarship PhD Candidates
- Curious financial constructs
- Assigned to failed projects or projects with unreachable goals
- Cultural differences:
  - Dealing differently with hierarchy
  - Failure is unacceptable
  - Loneliness

Conclusion

Scientific integrity and good conduct of science is inseparable from professional and dedicated supervision of PhD Candidates

Recommendations

- Further enhancement of a professional culture of supervision.
- Obligatory training on good supervision for supervisors
- Improve quality within the whole chain
- A confidential counselor for all PhD Candidates of the Amsterdam UMC. In close cooperation with the PhD Candidate Advisors of the Amsterdam UMC Doctoral School (in formation).
- Improve funding situation of PhD trajectories
- Attention for undesirable behavior versus problematic behavior, e.g. in line with www.zouikwatzeggen.nl

Discussion