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POLICIES AND PROCEDURES OF THE UNIVERSITY HOPITAL OF ANTWERP

RELATING TO ALLEGATIONS OF MISCONDUCT IN RESEARCH

Research in the Antwerp University Hospital is grounded upon the principles of academic freedom and mutual trust. High ethical standards in the conduct of research and other academic pursuits are maintained. The "code of ethics for scientific research" as published by the Royal Academy of Science, the Royal Flemish Academy of Belgium for Science and Arts and the Royal Academy of Medicine in Belgium form the basic principles following which research is conducted (see addendum). Misconduct in research is a fundamental violation of this trust and represents an assault upon the integrity of the University Hospital community.

Acts of misconduct are fortunately rare, but explicit procedures must be provided for dealing with instances of alleged misconduct. It is the purpose of this document to outline the policies and procedures that will be followed in the investigation and reporting of allegations of research misconduct at the Antwerp University Hospital.

The best strategy for dealing with misconduct is to prevent it. Thus, it is imperative that those who participate in research reaffirm their responsibility for the ethical conduct of all research activities with which they are associated. Principal investigators, laboratory supervisors and others who lead research must recognize their ultimate responsibility for the authenticity of research conducted and published in their names and that of the University Hospital. They should realize that they must provide adequate supervision for their trainees and research teams. It is also their responsibility to see that all persons who have contributed to the research receive appropriate credit for their work. It is incumbent upon collaborators and other contributors to research to understand that the inclusion of their names as co-authors of publications reflects a genuine contribution to the work, and signifies that they have approved the publication and are prepared to accept responsibility for the work reported.

In order to respond to allegations regarding the integrity of any published report, adequate records of the original protocols and research records, including all raw data, must be preserved for at least 15 years, so they can be made available for inspection.

This policy is applicable to any research misconduct arising from research conducted at the Hospital, and/or conducted by Hospital employees, including misconduct involving: (1) Applications or proposals for support for extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information; (2) Supported extramural or intramural research; (3) Supported extramural or intramural research training programs; (4) Supported extramural or intramural activities that are related to research or research training, such as the operation of tissue and data banks or the dissemination of research information; and (5) Plagiarism of research records produced in the course of supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported or any research record generated from that research, regardless of whether an application or proposal for funds resulted in a grant, contract, cooperative agreement, or other form of extramural or intramural support.

This policy applies only to research misconduct occurring within six years of the date the Hospital receives an allegation of research misconduct, unless (1) the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use, for the potential benefit of the respondent, of the research record that is alleged to have been fabricated, falsified, or plagiarized, or (2) the Hospital, following consultation with the Belgian Advisory Committee on Bioethics, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse

effect on the health or safety of the public. In the event the alleged misconduct occurred outside the time limit described above, the matter should be referred to the Medical Council.

Definitions

Research means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research). Research, as used herein, includes all basic and applied research in all disciplines. This includes, but is not limited to, research in economics, education, the humanities, linguistics, medicine, nursing, psychology, the natural and social sciences, engineering, mathematics and statistics, and includes any research involving human subjects or animals.

Research misconduct means 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. Plagiarism may also include self-plagiarism. Self-plagiarism refers to the author's re-use of their earlier work and passing it off as new or original material. Research misconduct does not include honest error or honest differences of opinion.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, chapters, books, audio or video tapes, CDs, internal reports, journal articles, and any documents and materials provided to the Hospital or to a Hospital official by a respondent in the course of the research misconduct proceeding.

Research support means funding, or applications or proposals, for research, research training, or activities related to that research or training, that may be provided through: (1) funding for intramural or extramural research by grants, cooperative agreements, or contracts; or (2) subgrants or subcontracts under those funding instruments; or (3) salary or other payments under those grants, cooperative agreements, or contracts.

The Committee to Investigate Misconduct in Reseach

The Committee to Investigate Misconduct in Research (hereinafter referred to as the Committee) is charged with the responsibility of investigating allegations of research misconduct by members of the community of the Antwerp University Hospital. It is the Committee's responsibility to determine if allegations of research misconduct can be substantiated, to make a final report on the findings of investigations, and to recommend appropriate action to the Medical Council and to the Medical Director of the Hospital. The Medical Council and the Medical Director will inform relevant authorities of the existence, progress and outcome of any formal investigations,

The Committee shall be drawn from a standing body (the "pool") consisting of members of the Medical Council of the Hospital, the Medical Ethical Committee, internal or external experts as deemed appropriate. The President of the Medical Council shall select six members from that pool to serve as the Committee for each investigation. Members of a Committee shall continue to serve for the duration of that matter. The members of the Committee will elect a chair to conduct the proceedings. Additional *ad hoc* members of the Committee with special expertise in the area of investigation may be appointed to the Committee from within or outside the Hospital at the request of the Committee or by the Medical Council. Only those *ad hoc* members who are full-time Hospital employees may vote. In accordance with Belgian legislation, reasonable steps shall be taken to ensure an impartial and unbiased

investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation. Members of the Committee whose participation in the investigation of allegations against a specific individual could be construed as inappropriate or who are involved in the research in question will be expected to recuse themselves from such proceedings. In case of doubt, the President of the Medical Council , or the Medical Council by majority vote, may require a member to recuse himself or herself.

In the event the President of the Committee has a conflict of interest related to an allegation, he or she will recuse himself or herself. The President will appoint an appropriate individual to act as the President of the Committee under these circumstances.

Procedures for the Investigation of Alleged Misconduct

The goal of the procedures is to investigate and resolve allegations of research misconduct in an expeditious, responsible and fair manner. The responsibility of protecting the rights and reputations of all who are involved in any investigation of research misconduct is recognized as very important. For this reason, disclosure of the identity of respondents and complainants in research misconduct proceedings shall be limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as required or allowed by statute or regulation. The Hospital shall protect, to the extent possible, the privacy of those who in good faith report apparent research misconduct and shall undertake all reasonable and practical efforts to protect the positions and reputations of any complainant, witness, or Committee member and to prevent potential or actual retaliation against these complainants, witnesses, and Committee members. Individuals responsible for carrying out any part of the research misconduct proceeding must not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses. The Hospital and Committee shall afford the respondents, complainants and research subjects, identifiable from research records or evidence, confidential treatment to the extent possible. Persons accused of misconduct may consult with legal counsel, but legal counsel for neither the accused nor for the Hospital may participate in any hearing or interview.

Steps in an investigation:

1. **Allegation –** Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional official. Allegations of misconduct should normally be directed to the President of the Medical Council or designee, who shall determine if an inquiry is warranted. Others who receive an allegation of misconduct should immediately forward it to the President of the Medical Council.

2. An inquiry is warranted if the Medical Council determines that the allegation (1) falls within the definition of research misconduct and (2) is sufficiently credible and specific so that potential evidence of possible research misconduct may be identified.

3. **Inquiry -** An inquiry is an information gathering and initial fact finding process to determine if a formal investigation of misconduct should be undertaken. An inquiry will be conducted by an Inquiry Panel, made up of three tenured Hospital or University members chosen by the President of the Medical Council. Members who serve on the Inquiry Panel may not serve on the Investigation Committee for the same matter. At the time of or before beginning an inquiry, the President of the Medical Council must make a good faith effort to notify in writing the presumed respondent. If the Inquiry Panel subsequently identifies

additional respondents, the Inquiry Panel will notify the President of the Medical Council who in turn will notify them in writing.

To the extent it has not already done so at the allegation stage, the Hospital must, on or before the date on which the respondent is notified or inquiry begins, whichever is earlier, promptly take all reasonable and practical steps to (1) obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, (2) inventory the records and evidence, and (3) sequester them in a secure manner, except that, where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent in evidentiary value to the original data or evidence on the instruments. The Hospital shall, where appropriate, give the respondent copies of, or reasonable, supervised access to, the research record. The Hospital shall undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding.

An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A draft written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the Inquiry Panel as to whether an investigation is warranted. An investigation is warranted if there is (1) a reasonable basis for concluding that the allegation falls within the definition of research misconduct and (2) preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

The individual(s) against whom the allegations were made shall be given a copy of the draft report. If they wish to comment on that report, their comments must be submitted in writing to the Inquiry Panel within 14 calendar days of the date on which the individual(s) received the draft report and will be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

The final report of the Inquiry Panel, including any comments received from the individual(s) against whom the allegations were made, shall be sent to the President of the Medical Council. The reasons for the decision whether an investigation is warranted should be documented in that report.

The President of the Medical Council shall maintain sufficiently detailed documentation of inquiries to permit a later assessment of the reason for that decision. Such records shall be maintained in a secure manner for a period of at least seven years after the termination of the inquiry, and shall, upon request, be provided to authorized government personnel as may be required by law.

Within 30 days of finding that an investigation regarding research involving government support, either Flemish, national or international, is warranted, the Hospital shall provide the relevant governmental agency with the written findings and a copy of the report of the Inquiry Panel which shall include the following information: (1) The name and position of the respondent; (2) A description of the allegations of research misconduct; (3) The government support, including for example, grant numbers, grant applications, contracts, and publications listing federal agency support; (4) The basis for recommending that the alleged actions warrant an investigation; and (5) Any comments on the report by the respondent. The Hospital shall provide the following information to the relevant governmental agency upon request: (1) The institutional policies and procedures under which the inquiry was conducted; (2) The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) The charges for the investigation to consider.

4. **Formal investigation of misconduct -** If findings from the inquiry provide a sufficient basis for conducting an investigation by the Committee, the President of the Medical Council will initiate an investigation within 30 days following receipt of the Inquiry Panel report. An investigation means the formal development of a factual record and the examination of that record leading to a decision either to make a finding that research misconduct was not shown or to recommend a finding of research misconduct; the latter finding may include a recommendation for appropriate actions, including administrative actions. The President of the Medical Council will inform the respondent and any collaborators promptly, in writing, of the allegations, of the decision to initiate a formal investigation, and of the procedures that will be followed. The Committee shall give the respondent and the President of the Medical Council written notice of any new allegations of research misconduct within a reasonable amount of time after deciding to pursue any such allegations not addressed during the inquiry or included in the initial notice of investigation.

The Committee is empowered to call for and examine all relevant documentation, including, but not limited to, research data and proposals, laboratory notebooks, grant applications, publications, correspondence, memoranda of telephone calls and computer data, files and programs. These materials may relate to any research with which the accused is involved. To the extent the Hospital has not already done so at the allegation or inquiry stages, the Committee shall take all reasonable and practical steps to (1) obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, (2) inventory the records and evidence, and (3) sequester them in a secure manner, except that, where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent in evidentiary value to the data or evidence on the instruments. Whenever possible, the Hospital shall take custody of the records (1) before or at the time the President of the Medical Council notifies the respondent; and (2) promptly thereafter, whenever additional items become known or relevant to the investigation. The Hospital shall, where appropriate, give the respondent copies of or reasonable, supervised access to, the research record.

A first round of hearings will be conducted in which those who have brought the charges, those alleged to have committed research misconduct, and any others who might have knowledge relevant to the alleged misconduct will be interviewed individually in closed-door sessions. A transcription or recording of these interviews shall be prepared and given to each interviewed party for comment or revision, and included as part of the investigatory file. Comments by any interviewed party or the accused must be made within 30 days of receipt of the transcription or recording. The Committee shall consider and address any comments of the interviewed parties and the respondent before issuing a final report. The Committee shall use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research, records and evidence relevant to reaching a decision on the merits of the allegations. The Committee shall pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

At the conclusion of these hearings, the Committee will review the evidence and apprise all those who may bear some responsibility for the alleged misconduct of the results of the investigation to that point. These individuals will then be granted the right of rebuttal and the opportunity to present additional evidence to the Committee. Following this, the Committee may recall earlier witnesses for re-examination, call new

witnesses, or close the investigative phase. In any case, before the Committee moves toward final deliberations, those bearing potential responsibility will always be given an opportunity to review and comment upon any new evidence uncovered subsequent to their last appearance before the Committee.

The Committee must complete within 120 days all aspects of investigation, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to the appropriate Hospital officials in order that the final report can be submitted to relevant authorities where required. If unable to complete the investigation in 120 days, the Committee must provide the reasons for the delay to the President of the Medical Council who must ask the relevant authority for an extension in writing, where required.

Committee Report and Recommendations

The Committee will evaluate all evidence and testimony in order to determine if the allegations of misconduct are substantiated and, if so, who must bear responsibility. Because of the negative impact of charges of misconduct, whether ultimately substantiated or not, on the research career of an individual, it is important that the Committee's final decision be rendered in clear terms. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the Hospital establishes by a preponderance of the evidence that the respondent had research records and intentionally, knowingly, or recklessly failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community. In determining whether the Hospital has carried the burden of proof imposed by this part, the Committee shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent. The respondent has the burden of going forward with and proving by a preponderance of the evidence any and all affirmative defenses raised and any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

A finding of research misconduct requires a determination by the Committee by an eighty percent (80%) majority vote that (1) there was a significant departure from accepted practices of the relevant research community; (2) the misconduct was committed intentionally, knowingly, or recklessly; and (3) the allegation was proven by a preponderance of the evidence. Preponderance of the evidence means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not. If the Committee cannot reach this conclusion, then it will report that the individual(s) under investigation have been exonerated. A minority report by a Committee member may be written which will be included with the final report. The Committee may make other relevant recommendations for action to be taken by the Hospital.

At the close of its investigation, the Committee will prepare a draft written report, and make that draft report available for comment by the respondent(s). The comments of the respondent(s), if any, must be submitted in writing to the Committee within 30 days of the date on which the respondent(s) received the draft report. If they can be identified, the complainant(s) should be provided with those portions of the report that address their role and opinions in the investigation. The comments of the complainant, if any, must be submitted in writing to the Committee within 30 days of the date on which the complainant received the draft investigation report or relevant portions of it. The Committee will submit the final report including any comments received from the respondent(s) or the complainant to the President of the Medical Council and the Medical director of the Hospital.

The final Committee report must be in writing and must:

(1) Describe the nature of the allegations of research misconduct;

(2) Describe and document the funding support, if any, including for example, any grant numbers, grant applications, contracts, and publications listing funding support;
(3) Describe the specific allegations of research misconduct for consideration in the investigation;
(4) Include the institutional policies and procedures under which the investigation was conducted;
(5) Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed;
(6) For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so,
    (a) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard.
    (b) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
    (c) Identify the specific funding support, if any,
    (d) Identify whether any publication needs correction or retraction;
    (e) Identify the person(s) responsible for the misconduct; and
    (f) List any current support or known applications or proposals for support that the respondent has pending with national or international funding agencies.
(7) Include and consider any comments made by the respondent and complainant on the draft investigation report.

The Hospital must maintain and provide to the relevant governmental funding agency upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

All recommendations of the Committee shall be considered as advisory to the President of the Medical Council and to the Medical Director of the Hospital, who shall be responsible for coordinating further action consistent with Hospital policy. In principle, anyone found to have committed research misconduct should, in the absence of extenuating circumstances, be recommended for dismissal from the Hospital. If it is found that misconduct was committed by a collaborator or other member of a research team, and the supervisor of the research is found to have failed to make reasonable and periodic inquiry as to the authenticity of the data, and if this inquiry would have been likely to prevent or uncover the fraudulent research, the supervisor should be recommended for appropriate sanction. The Medical Director of the Hospital will, in discussion with the board of directors and the medical council, determine what sanctions and/or corrective action will be taken in accordance with Hospital policy and ensure that the report is submitted to any appropriate agencies.

If the Committee determines that the allegations of misconduct were made in bad faith, the Committee may recommend sanctions be imposed against those making bad faith allegations. This recommendation will be forwarded to the appropriate human resource department and to the Medical Director.

Notification During Inquiry or Investigation

The relevant governmental authority or funding agency will be notified by the President of the Medical Council or designee when the Hospital determines that an investigation involving federal or governmental funded research is warranted. For all research, a determination of the need to inform other interested parties will also be made at this time. A determination as to whether other interested parties, such as collaborators, supervisors, and

officials of sponsoring or funding agencies or institutions, shall be notified will normally be made only after a formal investigation is initiated.

The President of the Medical Council or designee is responsible for immediately notifying the relevant governmental agency if it is ascertained at any stage of the inquiry or investigation of research misconduct that there is reason to believe that any of the following conditions exist, or are likely to exist:

(1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
(2) There is reasonable indication of possible violations of civil or criminal law.
(3) Federal action is required to protect the interests of those involved in the research misconduct proceeding.
(4) The research misconduct proceeding may be made public prematurely and government authorities should be enabled to take appropriate steps to safeguard evidence and protect the rights of those involved.
(5) The research community or public should be informed.

In such circumstances, consideration may be given to the advisability of notifying a funding agency as well.

For studies funded with governmental or public money, the President of the Medical Council will keep the relevant (governmental) agency apprised of any developments during the course of the investigation which disclose facts that may affect current or potential agency funding for the individual(s) under investigation or that the agency needs to know to ensure appropriate use of public money and otherwise protect the public interest as may be required by Flemish and (inter)national law or regulations.

Interim Action

If at any time during the formal investigation, the Committee feels that interim action by the administration is needed in order to safeguard the interests of any of the involved parties or funding agencies or to expedite the investigation, it may recommend appropriate measures to the President of the Medical Council. It will be the responsibility of the President of the Medical Council to consult regularly with the Committee during the investigation and to apprise appropriate agencies of any developments material to their interests, and take appropriate action to protect sponsoring agency funds.

Notification of Third Parties after Investigation

The Committee shall identify and advise the President of the Medical Council of all parties who should be notified of its findings; these may include the Hospital Board Members, editors of journals or officers of societies where research papers or abstracts related to the research have appeared or are pending, and the officials of current or past granting agencies involved in funding or otherwise sponsoring any compromised research. The President of the Medical Council shall notify the Belgian Advisory Committee on Bioethics where appropriate. The Committee may also recommend actions concerning the release of information regarding the incident to the media and corrective actions to prevent further instances of misconduct in light of the experience gained from the investigation.

In the event the research is funded by a government agency, the Hospital shall comply with the funding agency rules and reporting requirements.

If the charges of misconduct are not substantiated, those under investigation shall be so notified in writing, and the Hospital shall undertake diligent efforts to ensure that the reputations of those involved are restored as fully as possible. This may require, with approval of the accused, notification of collaborators, granting agencies, and any others who might have become aware of the investigation.

The Hospital agrees to cooperate fully with relevant national and foreign governmental authorities and agencies during its oversight review or any subsequent administrative hearings or appeals as may be authorized by existing regulations. This includes providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

Dissemination of This Statement of Policies and Procedures

The Medical Council, its constitution, regulation and procedures, are posted on the website of the Antwerp University Hospital. The hospital employees shall be notified through posting on the Hospital website.

Addendum: Code of Ethics for Scientific Research in Belgium