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PUBLIC HEALTH WALES RESEARCH MISCONDUCT PROCEDURE

Introduction and Aim

This procedure provides a definition of research misconduct and outlines the process for reporting, investigating and responding to such allegations when allegations of misconduct in research are brought against any present or past member of staff in respect of research undertaken while in the employment of Public Health Wales.

Linked Policies, Procedures and Written Control Documents

All corporate policies and procedures are available on the Public Health Wales website

This procedure should be read in conjunction with, but does not replace, the following documents:

- Research Misconduct Policy
- UK Policy Framework for Health and Social Care Research
- All Wales Raising Concerns (Whistleblowing) Policy
- PHW Respect and Resolution Policy
- PHW Counter Fraud, Bribery and Corruption Policy and Procedure
- The concordat to support research integrity

Scope

This procedure applies to NHS research studies, as defined in the UK Policy Framework for Health and Social Care Research, where Public Health Wales has responsibility for their management.

It provides guidance on reporting observations of suspected research misconduct in line with organisational requirements.

Equality and Health Impact Assessment	An Equality, Welsh Language and Health Impact Assessment has been completed and can be viewed on the policy webpages.
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Summary of reviews/amendments				
Version number	**Date of Review**	**Date of Approval**	**Date published**	**Summary of Amendments**
1	2019	06/02/2020	02/2020	Previously this content had been covered within TP08 Counter Fraud, Bribery and Corruption Policy and Procedure. The Counter Fraud, Bribery and Corruption Policy and Procedure was reviewed in March 2019 and the need for a separate policy and procedure was identified.
2	2023	13/09/23	17/10/23	Change of titles of a number of job roles, including the Head of Information Governance

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1. Introduction

Research misconduct is characterised as behaviour or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld. It is a problem because it can cause harm (for example to patients, the public and the environment), damages the credibility of research, undermines the research record, and wastes resources.

The purpose of this procedure is to outline the process to follow in instances where research misconduct is alleged and to describe the process for investigating allegations of research misconduct. This document provides a definition of research misconduct and outlines when this procedure applies.

Public Health Wales expects all research undertaken within the organisation, involving participants, staff and resources to be conducted according to the highest standards of research practice and in accordance with the UK Policy Framework for Health and Social Care Research. This applies whether the organisation concerned is acting as the host and/or the sponsor of the research. As outlined in the UK Policy Framework for Health and Social Care Research '*Employers are expected to: take proportionate, effective action in the event of errors and breaches or if misconduct or fraud are suspected*' (page 27).

In addition to ensuring that all regulatory requirements are met, researchers may wish to refer to more general guidance on good research practice such as:

1) Code of Practice for Research. Version: 3.0 (UK Research Integrity Office, 2023)

2) Guidance on Good Research Practice (Welcome Trust April 2022)

3) Good Research Practice: Principles and guidance (Medical Research Council, July 2012)

While it is expected that an allegation of research misconduct will be a very rare event, research misconduct is unacceptable and this procedure outlines the process for reporting, investigating and responding to such allegations against staff undertaking research studies in Public Health Wales. This is to ensure that the process is fair and protects all the parties concerned. The aim of this procedure is to protect the safety, well-being, dignity and rights of research participants and to support staff responsible for investigating allegations of misconduct in a thorough and fair manner.

2. Roles and responsibilities

2.1 Who should use this procedure

This document should be used by anyone wishing to make an allegation of research misconduct against a member of staff in Public Health Wales and by staff who are responsible for investigating such allegations.

2.2 Definitions

2.2.1 Research Misconduct

The UK Research Integrity Office (UKRIO) defines research misconduct as including, but not limited to:

i) Fabrication;
ii) Falsification;
iii) Misrepresentation of data and/or interests and/or involvement;
iv) Plagiarism;
v) Failures to follow accepted procedures or to exercise due care in carrying out responsibilities for:

a. avoiding unreasonable risk or harm to
- humans;
-animals used in research;
- the environment;

b. the proper handling of privileged or private information in individuals collected during the research.

It goes on to say:
'…misconduct in research includes acts of omission as well as acts of commission. In addition, the standards by which allegations of misconduct in research should be judged should be those prevailing in the country in question and at the date that the behaviour under investigation took place' (p 29).

In order to reach the conclusion that misconduct has taken place, it must be judged that there was an intention to commit the misconduct and /or recklessness in the conduct of the research.

2.2.2 Complainant(s)

The complainant is the person making the allegation of research misconduct. A complainant may be anyone with a concern i.e. the individual does not have to be a member of staff (past or present) of the organisation concerned.

2.2.3 Respondent(s)
The respondent is the person against whom the allegation is made.

2.2.4 Named Person
The named person is the individual nominated by Public Health Wales with responsibility for:
i) Receiving allegations of research misconduct
ii) Initiating and supervising the process for investigating the allegation
iii) Maintaining information about the allegation and its investigation and making the necessary reports within the organisation and the appropriate external organisations
iv) Taking decisions at key stages of the procedure

2.2.5 Sponsor
The individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance the study.

The responsibilities of the employing organisation and/or Sponsor and all Public Health Wales staff involved in research are outlined in the table below.

Role	Responsibilities
Employing organisation and or Sponsor	Have robust systems and processes in place to prevent or detect research misconduct. Any delegation must be in writing, the sponsor retains legal responsibility and must therefore have adequate oversight procedures and communication channels.
All Public Health Wales staff involved in research	Reporting observations of suspected research misconduct in line with organisational requirements.

3. Procedure

The procedure for investigating allegations of research misconduct follows the model procedure recommended by the UK Research Integrity Office (UKRIO) at **http://www.ukrio.org/publications/misconduct-investigation-procedure/**

All allegations of research misconduct will be treated seriously and fairly and their merit investigated with integrity, confidentiality and sensitivity.

Throughout the procedure, due regard will be given to the need to:

- protect researchers against malicious or ill-founded allegations,
- protect the position and reputation of those alleged to have engaged in fraud or misconduct when such allegations are not confirmed,
- protect the position and reputation of those who make allegations in good faith, i.e. in the reasonable belief on the basis of any supporting evidence that misconduct may have occurred,
- observe the principle of no detriment such that neither the person making the allegation (complainant) nor the person against whom such an allegation is made (respondent) should suffer as a consequence of the fact that an allegation was made in good faith.

So far as is possible, Public Health Wales shall throughout its enquiries and investigations take all reasonable measures to preserve the anonymity of the complainant and the identity of the complainant will not be made known to the respondent without obtaining the complainant's prior written consent. The respondent shall be fully informed about what they have to answer and shall have full opportunity to reply.

3.1 Personnel to Involve

Public Health Wales has in place nominated key individuals to assist in investigating allegations of research misconduct, should they arise. These are,
i) A 'Named Person' (and an alternate) and
ii) Senior individuals from the relevant Personnel and Finance departments.

3.1.1 Named Person

The UKRIO advise that the 'Named Person' (NP) should be a person within the organisation with significant knowledge and experience of research but should not be:
i) the Chief Executive Officer of the organisation
ii) the Head of Research or
iii) the Director of People and Organisational Development

For the purposes of this procedure, the NP is the Head of Information Governance in Public Health Wales. In the event of the NP having a conflict of interest, the designated 'alternate' would act in place of the NP in keeping with the UKRIO's procedure.

3.1.2 Human Resources and Finance
In addition, the HR and Finance Managers associated with research and development should assist the NP in investigating any allegations where appropriate. Where a possible conflict may exist, alternative HR and Finance representatives will be identified by the NP, ideally with some experience in research.

3.2 Receiving and Investigating an Allegation or Research misconduct

The procedure below describes the process to be followed when an allegation has been received in writing by the NP. An initial enquiry from a complainant might be anonymous but in order for the allegation to be investigated it should be submitted in writing. Some situations may not require formal investigation but might be resolved by informal discussion and / or arbitration e.g. those that are not regarded as serious in nature. UKRIO will offer advice as to whether an informal resolution might be appropriate for a specific allegation.

There are four stages to the procedure for investigating an allegation:
i) the preliminary stage,
ii) the pre screening stage,
iii) the screening, and
iv) the formal investigation.

The NP should follow the detailed procedure for each of these stages as set out in Part C (pages 11 – 20) of the UKRIO's 'Procedure for the Investigation of Misconduct in Research' (2008). A summary of the whole procedure is outlined below.

Preliminary stage

- An allegation of research misconduct should be submitted in writing to the NP in the relevant organisation. Receipt of the allegation should be formally acknowledged, as appropriate. If the NP has any involvement or potential conflict of interest in the case, the matter should be dealt with by the NP's designated alternate.
- The NP reviews the allegations to judge if the reported behaviour falls within the definition of research misconduct. Even at this stage it may be necessary to take immediate action to protect participants, staff etc and to inform the relevant regulatory authorities. It may also be necessary to implement the organisation's disciplinary process. If so, this will continue in parallel with the investigation of the allegation of research misconduct.
- If the allegation falls outside the definition of research misconduct the NP (or alternate) will write to the complainant to inform them of the reasons why the research misconduct investigation process is not appropriate, advise which process might be appropriate for

handling the allegation and to whom it should be reported.

- If the allegation is deemed to fall within the definition of research misconduct, the NP informs the following people within the member organisation(s):

- Chief Executive Officer
- Director of People and Organisational Development
- Deputy Chief Executive and Executive Director of Finance and Operations
- The Head of Research & Evaluation

- If the member organisation is the respondent's primary employer the investigation proceeds. If the respondent has a different primary employer, the allegation will be referred on to that employer.
- If contractual obligations apply, the NP informs other organisations involved in the research e.g. the funding body.
- The NP informs the respondent about the allegations made against him/her. The respondent receives a summary of the allegations in writing and information about the procedure for investigating the allegation(s).

Pre screening Stage

- The NP ensures that relevant information and evidence is protected, especially if there is concern of risk to individuals or that evidence may be destroyed or tampered with. Such action may include securing medical records and research materials, temporary suspension of the respondent, limiting their access to parts of the Organisation's premises. The respondent must be informed of the reasons for these actions in writing by the NP.
- The NP may consider it appropriate to carry out additional investigations if related but separate issues of research misconduct come to light.

The Preliminary and Pre Screening stages should normally be completed within 10 working days of an allegation being received in writing.

Screening Stage

- The NP completes an initial investigation to determine that there is a case to answer i.e. the allegation is not mistaken, malicious, vexatious, or frivolous. If it is found to be any of the latter, the allegation will be dismissed. Under such circumstances a decision will be taken about the need for disciplinary action against the complainant.
- If the allegation cannot be discounted at this point, a Screening Panel will be convened. The purpose of the Panel is to decide if there is a prima facie case of misconduct (see Annex 4 of the UKRIO's document for guidance about the composition and

operation of the Screening Panel).

- The Screening Panel should aim to issue draft findings to the NP within 30 working days of being convened. The NP should forward the draft findings to the respondent and claimant. A final report will be issued when any factual errors have been corrected.
- Allegations then considered to be mistaken, frivolous, vexatious and/or malicious will be dismissed. It may be necessary to take action to uphold the reputation of the respondent and the relevant research project(s). Under these circumstances, a decision will also be made regarding the need for disciplinary action against the complainant.
- When the allegations have some substance but are considered to be relatively minor and / or there was no clear intent to deceive, a formal investigation will not be required and the matter will be dealt with through the relevant education and training processes, or other non disciplinary mechanisms, within the member organisation. The needs of staff and or students working with the respondent should also be considered.
- When there is considered to be substance to the allegations and they are sufficiently serious, a formal investigation will be implemented.

Formal Investigation

- The NP informs the following people that a formal investigation is taking place:
    - o Respondent
    - o Complainant
    - o The Chief Executive Officer
    - o Director of People and Organisational Development
    - o Deputy Chief Executive and Executive Director of Finance and Operations
    - o The Head of Research & Evaluation
    - o Personnel in relevant external organisations e.g. funding bodies
- The NP convenes a formal Investigation Panel (see Annex 5 of the UKRIO's guidance for advice about the composition and operation of the Investigation Panel).
- The Panel reviews the evidence and interviews the respondent and complainant.
- Having reviewed the evidence, the Investigation Panel concludes whether the allegation of research misconduct is:
    - o upheld in full
    - o upheld in part
    - o not upheld
- The NP, Director of People and Organisational Development and other appropriate senior members of the Organisation decide what action should be taken.

- The NP informs the respondent, complainant, Heads of the Organisation and relevant departments and relevant external bodies of the outcome and what actions are to be taken.
- The actions are implemented.

When a serious allegation of fraud is made and is supported by credible evidence, then the NP will report this to the NHS Counter Fraud Policy lead who will advise in deciding how the investigation should proceed.

4. Monitoring compliance

It is the responsibility of the Named Person to notify the Knowledge, Research and Information Committee in Public Health Wales of any allegations of research misconduct received, in order that this committee can monitor the use of this procedure and related policy.

5. References

Research Misconduct and Fraud SOP01, 02/10/2017, Abertawe Bro Morgannwg University Health Board

Standard Operating Procedure for Fraud or Misconduct in Research (SOP B04) version 2, 09/12/2014, Betsi Cadwaladr University Health Board and Bangor University