SEN15D015

Title:	**UEA Research Integrity Report 2014-15**
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Issue

The Concordat to Support Research Integrity encourages employers of researchers to present a short annual statement to their governing body providing a summary of activities and issues relating to the support and implementation of research integrity, and processes relating to allegations of misconduct in research.

Recommendation

Recipients are invited to receive and accept the attached report, which has been reviewed by the University Research Exec and the University Research Ethics Committee.

Resource Implications

Support for Research Integrity is provided by REN and by the Schools which are responsible for the sub-committees of the University Research Ethics Committee. Time and financial provision for all levels of Research Integrity training need to be incorporated into future plans.

Risk Implications

Failure to accept this report would compromise the annual financial report to the Higher Education Funding Council for England (HEFCE), which now requires a statement of compliance with the Concordat to Support Research Integrity as part of its ongoing financial support.

Equality and Diversity

No equality and diversity issues are associated with this report.

Timing of decisions

Acceptance by Senate will support the annual financial return to HEFCE which is currently being compiled.

Further Information

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Background

This report summarises UEA activities and issues relating to Research Integrity in the period 1 January 2014 to 31 July 2015, in order to align it with the end of the university's academic and financial years.

The Concordat to Support Research Integrity encourages research active institutions to make an annual report to their governing bodies which:

"provides a summary of actions and activities that have been undertaken to support and strengthen understanding and application of research integrity issues

provides assurance that the processes that they have in place for dealing with allegations of misconduct in research are transparent, robust and fair and that they continue to be appropriate to the needs of the organisation

provides a high-level statement on any formal investigations of research misconduct that have been undertaken"

Discussion

No discussion is anticipated.

Attachments

The report is attached.

UEA Research Integrity Report

1 January 2014 to 31 July 2015

This report summarises UEA activities and issues relating to Research Integrity in the period to 31 July 2015, in order to align it with the end of the university's academic and financial years.

The term Research Integrity has been adopted internationally to describe "the core principles and responsibilities that should be common to all good research"[1]

Governance arrangements in support of research at UEA include the Guidelines on Good Practice in Research, the Research Ethics Policy and Procedures for Dealing with Allegations of Misconduct in Research. We are also required to comply with UK legislation relating to research, as well as Concordats and codes of practice issued by funding bodies and collaborating organisations.

The Research Ethics domain is the responsibility of the University Research Ethics Committee (U-REC), which is constituted from the Chairs of the REC subcommittees (S-RECs), lay members and co-opted experts, led by a Chair appointed by the Pro-Vice-Chancellor (Research and Enterprise). Oversight of Research Integrity across UEA rests with the Pro-Vice-Chancellor (Research and Enterprise), supported by the University's Research Executive.

This report will be produced annually for the University Research Executive, and consists of three main sections – a summary of activities, developments to the UEA research integrity framework in the period, and arising issues or areas for further development and consideration.

1. Activity

Activity	**Number**	**Comment**
REC Subcommittees (S-RECs) Proposals reviewed Proposals approved	 396 384	Numbers have reduced since previous report as more UG research is being reviewed by module leaders
University REC (U-REC) Proposals reviewed Proposals approved	 21 21	U-REC reviews surveys by Central Services, and complex reviews from S-RECs
Alleged misconduct in research (stage 1) Staff	 1	Member of ATS staff was not aware of the University Research Ethics Policy and so had not received training on obtaining REC approval.
Student	0	
Alleged misconduct in research (stage 2) Staff	0	
Student	5	1 referred to SSDC – not guilty of MiR 1 referred to SSDC – not upheld

[1] The Concordat to Support Research Integrity 2012

SSDC = Senate Student Disciplinary Committee

MiR = Misconduct in Research

		1 referred to SSDC – guilty of MiR but no action taken due to extenuating circumstances 2 investigation in progress
Number of Serious Adverse Events for UEA sponsored healthcare studies	36	2 studies both involving patients in poor health. None of the SAEs were assessed as being related to study. All SAEs reported to NNUH/UEA Joint Research Governance Committee
Number of breaches of Good Clinical Practice for UEA sponsored healthcare studies	1	False reporting of work carried out by Research Assistant at a study site. Handled by employing organisation and reported to funder.(R21049) No routine audit or monitoring of sponsored studies carried out by UEA in this period. Clinical Trials Unit will undertake this in future for complex or high risk studies.

2. Development of UEA's Research Integrity Framework

During the period the framework in support of Research Integrity has been developed as follows:

1. The Guidelines on Good Practice in Research have been reviewed with a version date of July 2015 and have been presented to Senate.

2. A scoping exercise has been undertaken to gather feedback from researchers and members of U-REC to inform the review of the University Research Ethics Policy and Terms of Reference. The proposal for the review was presented to the Pro-Vice-Chancellor for Research and Enterprise, at a meeting of Research Exec in May 2015. It is expected that the revised policy will be ready in May 2016.

3. The Research Data Management Policy and the Procedures Guidance were updated in July 2015.

4. The NNUH/UEA Joint Research Governance Operations Group working with the Norwich Clinical Trials Unit has developed additional Standard Operating Procedures for healthcare research:

SOP 350 Case Report Form Development
SOP 600 Creating a Statistical Analysis Plan
SOP 605 Sample Size Calculation
2.9b/14 Pharmacy Management of IMPs outside Pharmacy

and reviewed:

SOP 210 Breaches of Good Clinical Practice
SOP 310 Development of a Participant Information Sheet and Informed Consent Form
SOP 315 Obtaining Written Informed Consent from Competent Adults in Clinical Trials
SOP 505 Creating and Maintaining Training records

5. Training and workshop activities have been undertaken with staff, students and Research Ethics Committee members, on Research Integrity, Research Ethics and Governance, and the Joint Standard Operating Procedures for healthcare research. Training has been provided as part of the CSED programme, and in response to requests from specific courses.

3. Issues and future development

1. Compliance with the Concordat to Support Research Integrity is a status that needs to be maintained, and this requires training and development of staff, students and members of Research Ethics Committees. UEA now has a subscription to the UK Research Integrity Office (UKRIO) and among other benefits it has produced a Concordat Self-Assessment Tool which enables universities to approach compliance in a structured way.

2. Care and Respect for the Environment and Cultural Objects is already included in the Guidelines on Good Practice in Research, but the challenge in the coming year will be to incorporate this in the revised Research Ethics Policy in a way which facilitates good research.

3. Training provision. Time and financial provision for all aspects of Research Integrity training need to be incorporated into future plans.

4. The Procedure for Dealing with Allegations of Misconduct in Research has been required for two cases since July 2015 which have provided valuable experience of translating a procedure from paper to implementation, and the Procedure will be reviewed with the benefit of these cases.

5. The Health Research Authority has begun the roll out of a substantially revised process for obtaining NHS Research Governance and Research Ethics permissions, involving a single point of application, and these changes will affect all researchers starting healthcare studies after December 2015.

6. The Concordat on Openness in Animal Research Discussions have been held between REN and UEA researchers involved in animal research, and the results will be used to inform UEA's decisions relating to openness on this subject.

7. Clinical Trials Regulation EU no 536/2014
The new EU law takes the form of a Regulation, meaning that it will apply directly in each member state of the EU without the need to be transposed into national law, and thereby will ensure the rules are consistent throughout the EU. This will apply no earlier than 28 May 2016.

8. Data Protection Act. The European Commission plans to unify data protection within the European Union (EU) with a single law, the General Data Protection Regulation (GDPR) which will take account of globalisation and developments in computing and social media. The Regulation is timetabled for 2016/17 and is expected to address current disparities in data protection relating to research, between countries.

Sue Steel
v. 1.2 22 October 2016