

LEEDS BECKETT UNIVERSITY

RESEARCH ETHICS SUB-COMMITTEE

Wednesday 16 May 2018

at 2pm in Room G07, Old Broadcasting House
City Campus

Governance and Legal Services

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AGENDA for the Wednesday 16 May 2018 meeting

The fifty third meeting of the Research Ethics Sub-Committee will be held at 2pm in room G07, Old Broadcasting House, City Campus.

14:00	Part A: Preliminary Items	Paper	Led by
	A1 Apologies		K Spracklen
	A2 Declarations of interest		K Spracklen
	A3 Minutes of the last meeting held on 07 March 2018	REE-2017-062	K Spracklen
	A4 Matters arising	REE-2017-063	S Morris
14:15	Part B: Items for Information & Monitoring	Paper	Led by
	B1 Research Ethics Audit outcomes: Film, Music & Performing Arts	REE-2017-064	P Thompson
	B2 Research Ethics Audit outcomes: 2017/18 action plan monitoring:		
	(a) Art, Architecture & Design	REE-2017-065	A Simson
	(b) Built Environment & Engineering	REE-2017-066	N Evans
	(c) Computing, Creative Technology & Engineering	REE-2017-067	E Abbott-Halpin
	(d) Carnegie School of Education	REE-2017-068	J Sharp
	(e) Carnegie School of Sport	REE-2017-069	J O'Hara
	(f) Cultural Studies & Humanities	REE-2017-070	H Shore
	(g) Leeds Business School / Leeds Law School	REE-2017-071	L Yeomans / J Guth
	(h) Clinical & Applied Sciences	REE-2017-072	R Brooks
	(i) Health & Community Studies	REE-2017-073	D Fox
	(j) Social Sciences	REE-2017-074	J Willot
	(k) Events, Tourism, & Hospitality	REE-2017-075	A Kenyon
	B3 PREVENT update	REE-2017-076	K Spracklen

15:00	Part C: Items for discussion / decision	Paper	Led by
	C1 Research Ethics Procedures	REE-2017-077	K Spracklen
	C2 Research Ethics Audit process 2017/18	REE-2017-078	S Morris
	C3 Research Data Management	REE-2017-079 CONFIDENTIAL	K Spracklen C Barnes
	C4 Ethical Data Sharing	REE-2017-080	A Wilson K Spracklen
15:30	Part D: Other Business	Paper	Led by
	D1* Schedule of meetings & business 2017/18	REE-2017-081	K Spracklen

■ *Shaded items indicate that the Board / Committee is being asked to make a decision.*

**Starred items will be taken without discussion unless a member notifies the Chair or Secretary in advance that she or he wishes the item to be open for debate*



RESEARCH ETHICS SUB-COMMITTEE

MINUTES of the 07 March 2018 meeting

Present:

Professor Karl Spracklen (Chair)

Antonis Elia

Dr Jessica Guth

Dr Heather Shore*

Dr Niall William Richard Scott

Dr Liz Yeomans

Dr Neil Evans

Dr John O'Hara

Professor Alan Simson

Martin Watson

Dr Debbie Fox

Dr John Sharp

Dr Paul Thompson

Dr John Willot

In attendance:

Stuart Morris (Secretary)

Dr Angela Murphy

Apologies:

Professor Eddie Abbot-Haplin

Dr Rob Brooks

Dr Alex Kenyon

Dr Andrew Wilson

**Attended the meeting as indicated in the proceedings.*

Part A: Preliminary Items

Terms of reference and membership

- 041.2017.REE (a) The Committee received a report from the Secretary presenting the current terms of reference and membership (paper reference REE-2017-043).
- (b) It was **reported** that nominations were currently being sought for a Research Student representative for the 2018/19 academic year and elections for this position on the Sub-Committee would be concluded by the end of March 2018. The name of the successful candidate would be presented at the next meeting of the Sub-Committee.

Declaration of interest

042.2017.REE No declarations of interest were made.

Minutes

043.2017.REE The Committee **AGREED** that the minutes of its meeting held on 06 December 2017 were an accurate record (paper reference REE-2017-044).

Matters arising

- 044.2017.REE
- (a) The Secretary presented a report on the matters arising from the minutes of the previous meeting of the Committee held on 06 December 2017 (paper reference REE-2017-045).
 - (b) *Arising from minute 023(b).2017.REE:* A guidance document on the reporting of research ethics activity to the School Academic Committees was currently being put together by the Chair and would be provided to Schools as soon as possible.
 - (c) *Arising from minute 025(b).2017.REE:* It was reported that review had been undertaken of a sample of staff research that had been granted ethical approval in the online system. It was confirmed that there did not appear to be any that should have answered in a positive manner to the questions related to PREVENT. Nevertheless, work that was currently being undertaken to update and revise the Research Ethics Procedures and associated online ethical approval system would incorporate improved guidance for researchers on completing the ethical approval process, particularly concerning the questions relating to PREVENT to ensure that staff and/or students were left with no ambiguity over how they should respond to the questions. Training for staff and students, in particular research supervisors, concerning research ethics would also contain further guidance on how to address the questions related to PREVENT in the ethical approval questionnaire. It was also noted that in the latest PREVENT update report, that would be considered later in the agenda, there had been an instance where one staff project had declared that their research was being undertaken in a sensitive area and had registered a positive response to the PREVENT questions. It was confirmed that, in accordance with the current procedures, this research proposal had been approved by the Chair of the Research Ethics Sub-Committee.
 - (d) *Arising from minute 028.2017.REE:* The Chair of the Research Ethics Sub-Committee would be meeting with the Director of Research & Enterprise in an effort to provide clarity on how the administration of research ethics would be co-ordinated across the University and, in particular, who would be responsible for re-drafting the research ethics procedures and testing the new version of the online ethics approval system. A further update would be provided at the next meeting of the Sub-Committee.
 - (e) *Arising from minute 031(b).2017.REE:* The research ethics audit report for the School of Film, Music & Performing Arts would be presented later in the agenda for consideration.

- (f) *Arising from minute 031(C).2017.REE:* Further investigation had taken place to determine how oversight of research ethics was being managed in for the Department of Languages and it was confirmed that the Department was currently setting up a Departmental Academic Committee, with similar terms of reference and membership to a School Academic Committee, to maintain oversight of this work.
- (g) *Arising from minute 035.2017.REE:* A fuller mapping of the European Code of Conduct for Research Integrity would be presented at the May 2018 meeting of the Sub-Committee.

Part B: Items for Information & Monitoring

Film, Music & Performing Arts

- 045.2017.REE (a) The Sub-Committee received a report from the School of Film, Music and Performing Arts, addressing the action plan that had been formulated following the 2016/17 research ethics audit (paper reference REE-2017-046).
- (b) The report had identified a number of issues concerning data collection, in particular how the School categorised research, and the guidance being given as to what should be submitted via the ethical approval process.
- 046.2017.REE It was **AGREED** that the Chair of the Research Ethics Sub-Committee would carry out further work with the School to provide guidance on the ethics procedures and further support would also be provided to ensure that the School's data was correct. An update on progress would be submitted at the next meeting of the Sub-Committee.

Research Ethics Audit outcomes: 2017/18 action plan monitoring:

- 047.2017.REE (a) The Committee received reports from the Schools on how they had been addressing the actions arising from the 2017/18 research ethics audits.
- (b) The Sub-Committee noted the progress being made by the following Schools in addressing the action plans:
- (i) Art, Architecture & Design (paper reference REE-2017-047)
 - (ii) Built Environment & Engineering (paper reference REE-2017-048)
 - (iii) Carnegie School of Education (paper reference REE-2017-050)
 - (iv) Carnegie School of Sport (paper reference REE-2017-051)
 - (v) Cultural Studies & Humanities (paper reference REE-2017-052)
 - (vi) Leeds Business School / Leeds Law School (paper reference REE-2017-053)
 - (vii) Clinical & Applied Sciences (paper reference REE-2017-054)
 - (viii) Health & Community Studies (paper reference REE-2017-055)
 - (ix) Social Sciences (paper reference REE-2017-056)
 - (x) Events, Tourism, & Hospitality Management (paper reference REE-2017-057)

- (c) It was confirmed that completion of the action plans for all of the above Schools remained on track.

048.2017.REE It was **noted** that the inconsistencies in the availability of administrative support for the processing of research ethical approvals via the online system had emerged as a consistent theme across all Schools. It was highlighted that the discussions between the Chair of the Research Ethics Sub-Committee and the Director of Research & Enterprise concerning the central support for the Research Ethics Procedures and the administration of the online system would hopefully resolve some of the issues the Schools had been facing.

049.2017.REE

It was **AGREED** that:

- (a) An update on the action plan for the School of Computing, Creative Technology & Engineering (paper reference REE-2017-049), which had not been received due to staff absence due to sickness, would be circulated to members of the Sub-Committee as soon as it was available.
- (b) The Chair of the Research Ethics Sub-Committee would meet with academic staff from the School of Art, Architecture and Design to provide some further guidance on how project-based research activity should be progressed through the research ethics application procedure as it had been identified that some staff in the School were not always aware that some of their small scale project work would be classed as research and would require ethical approval.

Secretary's Note: Dr Heather Shore left the meeting.

PREVENT update

- 050.2017.REE (a) The Sub-Committee received a report from the Chair providing an overview of research ethics applications made on the on-line system for approval to undertake research that fell under the PREVENT duty since the last meeting of the Sub-Committee in December 2017 (paper reference REE-2017-058).
- (b) It was reported that in the period 22 November 2017 to the 20 February 2018 there had been thirteen research applications that had registered a positive response in relation to the PREVENT questions in the ethical approval process:
- (i) Twelve applications had been made from undergraduate students from a range of courses across the University, ten of which were considered to have been correctly submitted and to have fallen under the auspices of the PREVENT duty. All ten had been low-risk applications and had received approval by the Chair of the Research Ethics Sub-Committee.
- (ii) Two applications had been submitted by mistake and were rejected on those grounds.

- (iii) One application had been made by a member of staff and, in accordance with the Research Ethics Procedures, had been approved by the Chair of the Research Ethics Sub-Committee.

Part C: Items for discussion/decision

Research Ethics Procedure

- 051.2017.REE (a) The Committee received a report from the Chair providing an overview of the progress made on the new Research Ethics procedures, including the new version of the on-line application and approval system (paper reference REE-2017-059).
- (b) The Sub-Committee was informed that Information Technology (IT) Services had nearly completed the revised online system and were currently adding a few final updates following feedback gained at the Research Ethics away morning.
- (c) It was confirmed that the re-drafting of the written procedures continue to be delayed as a decision on how research ethics could be supported by the Research & Enterprise Office still needed to be made. The Sub-Committee expressed concern that this matter needed to be resolved as soon as possible as in order to implement a new / revised set of procedures in September 2018 then they would need to be written and then approved by the Research & Enterprise Committee in June 2018. The Chair of the Sub-Committee would be discussing this matter with the Director of Research & Enterprise in an effort to resolve this matter and ensure that it was clear how the administration of research ethics would be co-ordinated across the University. A further update would be provided at the meeting of the Research & Enterprise Committee.

Update on the development of a Protocol for Research being undertaken abroad

- 052.2017.REE (a) The Committee received a verbal report from the Insurance & Risk Officer and the School Research Ethics Co-ordinator from the School of Social Sciences providing an update on the development of a protocol for research being undertaken abroad. This replaced the written report (paper reference REE-2017-060) which had originally been due to be presented.
- (b) The Sub-Committee was informed that following a review of the guidance already provided in the research Ethics procedures it was proposed that a separate protocol would not be required and that a checklist would instead be added as an addendum to the procedures providing useful guidance on matters to consider for researchers undertaking research overseas.
- 053.2017.REE It was noted that it was important that guidance on the stage at which the University's Insurance & Risk Officer should be contacted regarding overseas research should be included in the checklist. It would also be important that a prompt was included for researchers to keep up-to-date with the current Foreign

Office advice on travel to the country they would be conducting research in as this advice could change on a daily basis to some higher risk countries.

054.2017.REE The Sub-Committee **AGREED** with the proposal to develop a checklist to accompany the revised Research Ethics Procedures rather than develop a separate protocol.

Feedback from away-day for research ethics

055.2017.REE (a) The Committee received a verbal report from the Chair providing feedback from the Research ethics away morning which was held on 23 February 2018.

(b) It was **reported** that during the morning an update had been provided concerning the development of the new version of the online research ethics approval system where it was confirmed that this was now at the final stages of development. Attendees at the away morning also provided some further feedback that would be incorporated in the new version of the system.

(c) The University's Insurance & Risk Officer provided colleagues with an overview of the insurance implications of undertaking research, in particular for research being undertaken overseas. And

056.2017.REE It was **noted** that the morning had been a success and attendees had reported that it had provided them with an opportunity to carry out more informal discussions concerning research ethics with colleagues from other Schools.

Part D: Other Business

Schedule of meetings and business for 2017/18

057.2017.REE The Committee received its schedule of meetings and business for 2017/18 (paper reference REE-2017-061).

Date of next meeting

058.2017.REE The next meeting of the Research Ethics Sub-Committee would be held at 14:00 on 16 May 2018 in Room G07, Old Broadcasting House, City Campus.

Other business

059.2017.REE No other business was raised.

Confirmed by the Committee/Board as a correct record and signed by the Chair:

Signed: _____ Date: _____

Matters Arising

Executive Summary

This report summarises the matters arising from the last meeting on 07 March 2018 that are not covered elsewhere in the papers.

- (a) *Arising from minute 043(b).2017.REE:* Following elections held between March and April 2018 Kay Nacto was elected as the new Research Student representative for the 2018/19 academic year. Kay's term of office will begin on 01 September 2018.
- (b) *Arising from minute 035.2017.REE:* A fuller mapping of the European Code of Conduct for Research Integrity would now be presented at the October 2018 meeting of the Sub-Committee once the administrative support in the Research Office was in place to support this piece of work.
- (c) *Arising from minute 049(a).2017.REE:* An update on the action plan for the School of Computing, Creative Technology & Engineering (paper reference REE-2017-049), which had not been received due to staff absence due to sickness, would be provided at the meeting.
- (d) *Arising from minute 049(b).2017.REE:* An update would be provided at the meeting by the Chair concerning his meeting with the academic staff from the School of Art, Architecture and Design to provide some further guidance on how project-based research activity should be progressed through the research ethics application procedure.

Action Requested

The report is **for information**. The Sub-Committee is invited to note the matter arising from its last meeting on 07 March 2018.

Appendices

n/a

Author

Name: Stuart Morris
Job title: Senior Governance Co-ordinator
Date: 08 May 2018

Approval Route

n/a

School of Film, Music and Performing Arts School Research Ethics Audit Report 2016-17

Executive Summary

The report appraises the overview of the research ethics audit for 2016-17 for the School of Film, Music and Performing Arts, noting that some data is missing and that much-needed staff development for the SREC and LRECs is scheduled to be delivered in May.

Action Requested

The report is **for decision**. The Sub-Committee is invited to consider the outcomes of the audit and that research ethics is being managed by the School and that practice is compliant with the University's Policy and Procedures.

Appendices

None

Author

Name: Dr Paul Thompson

Job Title: School Research Ethics Co-ordinator

Date: 26 April 2018

Approval Route

n/a

Research Ethics Audit Report Covering 2016/17

Name of School:	SCHOOL OF FILM, MUSIC & PERFORMING ARTS
Author of School Report:	Dr Paul Thompson, School Research Ethics Coordinator

Outcomes / Actions carried over from the last audit undertaken via the previous faculty structure:			
	Issue in 2015-16	Action in 2016-17	Progression
1.	No Data	No Data	No Data

2016/17 Applications and Statistics

Undergraduate Students

Course Title	Number of Students on Course 2016/17
BA (Hons) Music Production & Performance	104
BA (Hons) Music Production	188
BSc (Hons) Music Technology	180
BA (Hons) Animation	11
BA (Hons) Filmmaking	450
BA (Hons) Dance	28
BA (Hons) Performance	13
BSc (Hons) Audio Engineering	57
<i>Total</i>	<i>1031</i>

Undergraduate Projects

Risk Category 1	No Data
Risk Category 2	None
Risk Category 3	None
<i>Total</i>	<i>0</i>

The overall UG profile indicates that application data is missing, as there should be significantly more C1 and C2 data. For example, ALL final year projects in music are submitted through the online ethical approval process. Further work is needed here to gather the necessary data.

PG Students

Course Title	Number of Students on Course 2016/17
MA Music and the Moving Image	9
MA Music Production	25
MA Popular Music and Culture	3
MA Sound Design	5
MSc Music Technology	1
MSc Audio Engineering	3
MSc Sound & Music for Interactive Games	19
MA Performance	5
MA Filmmaking	33
MA Documentary Filmmaking	9
MFA Filmmaking	2
<i>Total</i>	<i>114</i>

Risk Category 1	No Data
Risk Category 2	0
Risk Category 3	0
<i>Total</i>	<i>N/A</i>

The overall PG profile also indicates that application data is missing, as there should be significantly more C1 and C2 data. For example, ALL final MA projects in music are submitted through the online ethical approval process. Further work is needed here to gather the necessary data . After which, it is hoped that by assessing best practice across other schools, the school of FMPA will develop a more transparent ethics process across the School.

FMPA Staff Applications 2016/17

Number of applications	Name	Ethical Risk category	Date of approval
1	Larra Anderson	C2	March 2016

FMPA PhD level Ethics Applications 2016/17

Number of applications	Name	Ethical Risk category	Date of approval
6	Jodean Sumner	C2	July 2015 (research then carried out within 2016)
	Jodean Summer	C2	February 2016
	Natasha Parcei		November 2016
	Danielle Millea	C2	February 2017
	Aletia Badenhurst	C2	March 2017
	Danielle Millea	C2	July 2017

The previous report noted the inconsistency of some of the data and data that was clearly missing. Further work is still needed here to gain a better understanding of ethics within the school of FMPA. After consulting Course Directors in Music, it was determined that the majority of ethics approvals are Category 2 and these are clearly missing from the data set. The admin support for accessing the data in FMPA was recently withdrawn due to change in staff but it is hoped that the data can still be captured by the new member of staff to gather more definitive ethics data.

Overview of Staff Development and Attendance at Staff Development

The previous report noted that no formal staff development sessions have been held and there appears to be some ambiguity around the role of SRECs, LRECs and supervisors within the ethics application process. Staff development sessions are now in development with the UREC (Karl Spraklen) who has proposed to offer training to LRECs and the SREC within the school towards the end of May. This will hopefully reduce the amount of ambiguity around each of the roles and ensure active and appropriate engagement with the ethics process across the school.

As the number of applications that require review by LRECs (Local Research Ethics Coordinators) may grow, as a result of a review and encouragement, the academic workload of SRECs and LRECs will need to be carefully monitored.

Research Ethics Audit Outcomes / Action Plan: School of Built Environment and Engineering

Executive Summary

This report provides a second update on progress on completing the 2017/18 Research Ethics Action Plan. It indicates that there is still one action that is ongoing and one that is not yet applicable.

Action Requested

The report is **for information**.

Appendices

Not applicable

Author

Name: Dr Neil Evans

Job title: Course Director BA Human Geography / Human Geography and Planning

Date: 1 May 2018

Approval Route

Not applicable

2017/18 Research Ethics Audit Action Plan Monitoring Report for School of Built Environment and Engineering

Introduction

The 2016/17 BEE Research Ethics Audit was completed in September 2017. It included an action plan for 2017/18. This report is an update on progress towards addressing the actions contained therein since the first update of 1st March.

School of Built Environment and Engineering Research Ethics - Action Plan 2017/18

Issue	Action	Responsibility	Deadline
1. Some non-compliance in Surveying Group	Liase with CD and Dissertation Module Leader to increase compliance	SREC	Oct 2017 and throughout 2017-18
2. Different degrees of comprehensiveness in relation to information on non-compliance in module handbooks	Liase with CD and Dissertation Module Leader to improve clarity and consistency of this information	SREC	Oct 2017
3. Apparent non-compliance of most franchise students	Liase with CD responsible for Franchise courses to explain need for compliance	LREC	Oct 2017 and Semester 1
4. Need for staff training for new research ethics procedures	Hold training event(s) in course groups	SREC	2016-17 Semester 1
5. Unreliable data for MA students	Raise this at URESC meeting to liase with IT Services to improve quality of data	SREC	4/10/17

Actions taken since 1st March

1. Action 3 is still ongoing.
2. Action 4 has been put back until the new research ethics procedures come into place.

Conclusions and recommendations

Action 3 is ongoing and Action 4 is not yet applicable.

Research Ethics Audit Outcomes / Action Plan: Carnegie School of Education

Executive Summary

The report contains a brief update of ethics audit outcomes and actions for the Carnegie School of Education since the last reporting period.

Action Requested

To receive and note progress.

Appendices

None.

Author

Name: Professor John Sharp
Job title: Director of Education (Unit 23)
Date: 1 May, 2018

Approval Route

n/a

Audit outcomes and actions: Carnegie School of Education

Introduction

A brief update on ethics audit outcomes and actions for the Carnegie School of Education since the last reporting period.

Issue	Action	Responsibility	Deadline	Progress
1. Sampling and scrutiny	To note that the sampling and monitoring of research ethics activity will be tabled and minuted with actions as required at Academic Committee as part of the standing item for research.	Professor John Sharp	Raised October, 2017, completed June, 2018	Underway with all new professors having received ethics training. Completed by June/July, 2018 as anticipated. Sampling and scrutiny event to be organised.
2. Research projects outside of the UK	All supervisors will be required to monitor, report and confirm compliance to the Director of Research who will, in turn, report in subsequent audits.	Professor John Sharp	Raised October, 2017, completed June, 2018	Ongoing. The School has now appointed a new Director of Research Degrees in Dr Shona Hunter (also at Readership). Dr Hunter has been updated.
3. Professional development for staff	Research ethics update lunchtime CPD session: policy and practice, updates, changes.	Professor John Sharp	October 11, 2017	Session delayed. This will be incorporated into next sessions staff research and development seminar series.

Conclusions and recommendations

The Carnegie School of Education will continue to comply with all ethics monitoring and reporting procedures required, through Academic Committee and the School's own Research and Enterprise Committee.

References and further information

Not applicable.

Professor John G. Sharp

Director of Education (Unit 23)
1 May, 2018

Research Ethics Audit Outcomes / Action Plan: Carnegie School of Sport

Executive Summary

An update on the 2017 / 2018 Research Ethics Action Plan from the Carnegie School of Sport. There are no additional progress updates, since the last committee meeting.

Action Requested

The report is **for information**.

Appendices

Appendix 1. Action Plan and Progress to Date

Author

John O'Hara

Professor of Sport and Exercise Physiology

8th May 2018

Approval Route

Not applicable

RESEARCH ETHICS SUB-COMMITTEE

16 MAY 2018

Appendix 1: School of Sport: Research Ethics - Action Plan 2017/18

Issue	Action	Responsibility	Original Deadline	Progress
1. Increase staff and student's awareness of research ethics policy and procedures in preparation to make all staff LRECs.	Provide training on research ethics policy and procedures for staff including all new LRECs (formerly known as MiS Supervisors). This should be a pre-requisite of staff supervising student research.	Chair/LRECs	30/10/17	Training has been delivered by the 'Super' LREC's to the staff who are supervising dissertations this year in their discipline areas.
2. To support staff/LRECs with resources	Provide exemplar ethics applications, especially UG applications	Chair/LRECs/ Supervisors	30/12/17	This is an on-going item, but the advisory group now has some UG exemplars to share with staff.
3. Provide suggestions on how research ethics training can be integrated into the University staff development and PDR process	Provide recommendations to Dean/HoR on increasing staff student preparedness for research ethics	Chair	30/11/17	<p>It was proposed that research ethics training was mandatory for all staff prior to dissertation supervision this year. As per point 1 above, staff have engaged with the necessary training.</p> <p>Increasing student preparedness for research ethics is an on-going item, which the advisory group are now turning their attention too.</p>

4. Valuing the contribution of the LREC in upholding sound ethical practice and promoting adherence to the University policy	Written communication to the Head of Research, Prof Susan Backhouse on the important contribution of LRECs to this role.	Chair	20/07/17	Completed by the previous Chair.
5. To continue to provide feedback to URESC on the University Policy, Procedures and Online system	Written communications to the Chair of URESC	Chair	30/07/18	On-going
6. Recruitment of the Chair of School of Sport Research Ethics review Group.	Written communication to the Director of Research on roles and responsibility of Chair and the recruitment of a replacement Chair.	Chair/Director of Research	25/09/17	Professor John O'Hara was appointed as the new Chair in September 2017.
7. Sampling procedure for UG/PG ethics applications.	To discuss the sampling procedure for auditing applications per Subject Group at the November 22 SREG	Chair/SREG	30/11/17	The sampling procedure has been agreed, with 'Super' LREC's. In the first instance they are reviewing one ethics submission from each member of staff within their subject area. This is presently underway for the UG applications. PG audit will happen later in the year, once all the students have submitted their applications.
8. Provide training to Subject Group LREC Leads to operationalize new research ethics procedures	Provision of detailed plans/briefing for how LREC Leads will operationalize the new procedures.	Chair/Dean	30/10/17	This was delivered by the Chair of URESC in September 2017.

Research Ethics Audit Outcomes / Action Plan: School of Cultural Studies & Humanities

Executive Summary

The report provides an update on Ethics compliance within the School of Cultural Studies and Humanities, since 13.02.18

Action Requested

The report is **for information.**

Appendices

None

Author

Heather Shore

Professor of History, CSH

01/05/18

Approval Route

n/a

Ethics Update for School of Cultural Studies and Humanities

Introduction

This report outlines compliance and developments in Ethics policy since February

Report

Since my last report, Professor Karl Spracklen has addressed the School meeting about staff research ethics compliance. I have continued to communicate with Course Directors and dissertation tutors across the School to ensure UG and PG compliance. The audit will demonstrate whether that has had the desired impact. I also addressed the PG Social History students about Research Ethics compliance for their dissertation.

Action Plan:

1. Refreshing staff engagement with system	Chair of RESC Prof Karl Spracklen addressed colleagues on research ethics compliance for staff research	LREC/ Prof Spracklen	Completed 10.04.18
2. Non-compliance by students	LREC maintained contact with Course-directors, dissertation students to ensure compliance	LREC; Course Directors	Continuing (completed at UG, continuing at PG)
3. Formal internal guideline for compliance with UG dissertation ethics (from 2018)	LREC to discuss with SLT – completed, there has been considerable discussion with Course-directors and dissertation tutors; I also delivered a session to our MA Social History students in February	LREC	Completed 28.02.18

Conclusions and recommendations

LREC needs to ensure that colleagues in English and Media have spoken to their PG students about ethics compliance for their dissertations (due late Summer).

**Research Ethics Audit Outcomes / Action Plan:
School of Clinical & Applied Sciences**

Executive Summary

Audit monitoring summary – School of Clinical and Applied Sciences.

Action Requested

For information.

Appendices

None

Author

Name: Dr Rob Brooks

Job title: School of Clinical and Applied Sciences Research Ethics Lead/Course Director

Date: Occupational Therapy

1st May 2018

Approval Route

None

Research Ethics Audit outcomes – action plan monitoring

Introduction

Review of actions to date

Action Plan Monitoring

	Issue	Proposed Action	Responsibility	Deadline	Outcome to date
1.	Use of online system by research supervisor's in SCA.	Coordinator to work with LRECs to provide training and support for those staff still using paper based applications.	RB + LRECs	January 2018	<ul style="list-style-type: none"> LREC's report that all staff within their subject group are now using the online system
2.	Training and support for new LRECs	Coordinator to develop an induction and training process for new LRECs	RB	July 2018	<ul style="list-style-type: none"> LRECs met in Dec 17 and agreed that this would be done on an informal basis as turnover of LRECs is low
3.	Training and support to new and existing research supervisors	LRECs and coordinator to consider and address school specific training needs in the SREG meeting. LRECs to provide support to staff within their group.	LRECs	March 2018	<ul style="list-style-type: none"> Guide for staff – this has been completed Coordinator to offer subject group support/training Coordinator and LRECs to offer a programme of teaching/training throughout the year.
4.	Accurate recording of Online data.	Coordinator and Ethics admin to explore reporting data for 2017/18	RB + Admin	August 2018	<ul style="list-style-type: none"> Angela Hill has been appointed School Research Ethics Administrator. RB in discussions around data for annual report.
5.	LREC peer support and case review	Case (application) review in SREG meetings.	LRECs	November 2017	<ul style="list-style-type: none"> On-going

Conclusions and recommendations

The action plan for the School of Clinical and Applied Sciences continues to be achieved, with some items on-going.

2016/17 Research Ethics Audit outcomes – action plan monitoring: School of Health & Community Studies

Executive Summary

The purpose of this report is to feedback on the action plan identified as part of the audit for School of Health & Community Studies.

3 actions were identified:

1. Ongoing monitoring of staff workload from level of detailed feedback given to applicants.
Action: DF to continue to monitor at quarterly School Research Ethics meetings. LRECS are maintaining ongoing records of concerns.
2. Ensure ethical approval is gained for all studies, using either a tick box or additional criterion in turnitin for all submissions, prior to commencing marking.
Action: LRECS have briefed all dissertation module leaders at UG and PG level. This will be audited at end of year. LRECS and staff have been reminded that failure to evidence ethical approval on submission will be referred to Academic Integrity Board.

We have had a second example of a student who undertook research without any ethical approval. This case was referred to the Academic Integrity Board and an appropriate penalty applied.

3. The reports for the School need to be accessible to research module leaders and LRECS during the year in order that outstanding decisions can be chased.
Action: Ongoing action supported by Sheila Casey.

Action Requested

This update report is for information only.

Author

Dr Deborah J Fox

School Research Ethics Co-ordinator, Health & Community Studies.

9 May 2018

Research Ethics Audit – action plan monitoring: School of Social Sciences

Executive Summary

An update on progress of the Action Plan agreed at School Academic Committee is presented

Action Requested

The report is for information.

Appendices

None

Author

Name: John Willott
Job title: Principal Lecturer
Date: 24 April 2018

Approval Route

April 2018 School of Social Sciences - School Academic Committee

School of Social Sciences Research Ethics Audit – action plan monitoring

Introduction

Since the previous meeting, progress of the Action Plan agreed at School Academic Committee is presented.

Key activities have been:

SREC, LRECs, Chair of URESC and School Admin Support met to discuss issues on Thursday 1st & Friday 2nd March. Items discussed included:

- **Deployment:** It was felt that for some groups with large cohorts, the deployed hours were insufficient, particularly as the applications tended to come in waves, rather than spread throughout the year. The solution was not just to increase hours for LRECs, but to have more of them so that the workload could be managed and students have the responses within a reasonable time.
- **Data protection & security:** The current norm is for confidentiality to be assured via keeping files in locked filing cabinets or password protected computers. However, with storage increasingly in the cloud, and synching across multiple devices, the files are not on a single computer or USB. So best practice would be to have individually protected (and so encrypted) files which contain any sensitive information.
- **Security sensitive research:** There is some confusion about what constitutes research which comes under this, including PREVENT duty (currently Q.23 of the risk analysis). A draft Guidance document with examples has been prepared (see Appendix) and will be discussed at URESC on 16 May 2018.
- **Data quality:** While the School Action Plan is to increase staff and student applications for ethics approval, a report generated on 28th February 2018 for staff applications showed there were considerable problems with data quality. School Administrator has met with staff responsible for the on-line system to discuss issues. This aside, the report suggest 42 staff are engaged in 84 projects (see attached report). Given that there are approximately 130 academic staff in the school it suggests not all research is being captured and undergoing ethical scrutiny, even allowing for the fact that some staff will be new, or be a co-investigator on a project.

SREC met with Head of School to discuss ongoing ethics issues and Action Plan monitoring on 24th April. Key items discussed were:

- **Staff approvals:** HoS would discuss with Subject Heads to ensure full compliance.
- **LRECs:** Plans would need to be developed to ensure there was sufficient capacity for LRECs, and experience was shared. There needed to be an internal checking process to ensure consistency in decision-making. This was in part ensured by the end of year School Ethics Audit, where LRECs would sample a number of applications/approvals made by other LRECs as part of the quality assurance programme.

Action plan summary

	Issue	Action	Responsibility	Deadline	Progress
1.	As most staff in the School are research active there seem relatively few staff notifications/ethical approvals (except for Psychology)	SREC to liaise with Heads of Subject and research leaders to ensure compliance.	SREC	Oct 2017	Head of School discussing with Subject Heads to ensure all staff are compliant.
2.	Significant numbers of new staff so development sessions on ethics procedures required	SREC to liaise with Heads of Subject to ascertain staffing numbers and requirements so sessions can be timetabled	SREC	Oct 2017	HoS and LRECs contacted to ensure new staff are inducted and to identify further support needs
3.	Administrative support switching from old Faculty structure	SREC to liaise with Dean of School to ensure administrative support	SREC	Oct 2017	Staff member has received training on online system & generating reports
4.	Understanding of security sensitive projects and consequent requirements	SREC to communicate to Heads of Subject, Course Directors and Dissertation Module Leaders to ensure clarity, and to incorporate into staff development sessions	SREC	Oct 2017	Meetings held 1 st & 2 nd March 2018 and draft guidelines produced
5.	Clarity around research ethics requirements for international (DL) students	SREC to work with Psychology Group and URESC to ensure compliance and best practice	SREC	Jan 2018	SREC working with Prof. Eddie Halpin & Martin Watson. Draft report completed for discussion.

Conclusions and recommendations

The Committee is invited to receive the report.

Appendix

Guidance on Question 23

Question 23 of the Research Ethics application requires notification of security sensitive research, which includes terrorist or extreme groups. There is a lack of definitional clarity in these terms which is causing confusion among staff and students. The driver is the University's obligations under the Terrorism Act (2006) and Counter-Terrorism and Security Act (2015) – also known as the PREVENT duty. This broadly applies to current terrorist activity which is considered to be of relevance to UK security, UK nationals or the global war on terror. The intention is not to stop research but to ensure that security-sensitive material which could be construed as supporting or promulgating terrorism is not distributed. Ethical scrutiny will also protect researchers from suspicion and potential criminal investigation.

So projects which would need reporting under these requirements would include:

- Studies on any of the groups currently proscribed by the Home Office – see https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/670599/20171222_Proscription.pdf
- These would include for example
 - Studies of the activities of current far-right groups, e.g. infiltration of the far right into music scenes
 - Studies of current international terrorist networks

The following types of project would not normally need reporting:

- Historical studies of terrorism, e.g. French reign of terror; colonial (e.g. Boer War) studies; history of the IRA
- Mainstream media analysis of reporting of terrorism, e.g. using the Lexis Nexis database or British Newspaper Archive to analyse discourse and text
- Research on general public perceptions of terrorism, e.g. via interviews or surveys

If in doubt, supervisors should discuss with their LREC and the Chair of the University Research Ethics Sub-Committee

Prevent Update 2017-2018

Executive Summary

This report provides an overview of applications made on the on-line system for approval to undertake research that falls under the Prevent Duty so far in 2017-2018.

Action Requested

The sub-committee is required to note the report.

Appendices

None.

Author

Name: Professor Karl Spracklen

Title: Chair, URESC

Date: 21 April 2018

Approval Route

21 April 2018

Professor Karl Spracklen / Chair, URESC

Introduction

- 1 The Counter-Terrorism and Security Act 2015 contains a duty on specified authorities to have due regard to the need to prevent people from being drawn into terrorism. This is also known as the Prevent duty. Universities are one of the key specified authorities that have to show they comply with the remit of the Prevent Duty, and research is clearly one aspect of higher education's work where the Government requires information that we are doing all we can to assess and monitor anything considered to fall under the remit of Prevent. Our university revised the risk assessment on the research ethics system to enable 'Prevent Duty' research to be checked and approved through this sub-committee and its Chair. This has allowed us to ensure monitoring is effective while balancing academic freedom.
- 2 This report provides an overview of applications made on the on-line system for approval to undertake research that falls under the Prevent Duty so far in the academic year 2017-2018.

Monitoring so far 2017-2018

- 3 In the period 01 September 2017-21 November 2017 there were seven student applications for approval to undertake research that falls under the Prevent Duty. Four were rejected as they were sent by mistake. Two gained approval, and that approval was given by the Chair of URESC as all were low-risk. One has been sent back as it needs supporting material, but again it is very low risk. The students are all L6 project/dissertation students from across the University. There were no staff applications to approve.
- 4 In the period 22 November 2017-20 February 2018 there were twelve student applications (all UG, from a range of courses with Criminology the most commonly cited) that fell into this process. Ten were genuine, and all these were low-risk applications that received approval. Two were submitted by mistake and were rejected on those grounds. One staff project was submitted under this process, and was approved light-touch as it had already received approval from Huddersfield University.
- 5 In the period 21 February-21 April 2018 no applications were submitted.

Conclusions and recommendations

- 6 The sub-committee is required to note the report.

Research Ethics Procedures

Executive Summary

This report provides an overview of progress made on the new Research Ethics Procedures, and the new version of the on-line application and approval system.

Action Requested

The report is **for decision**. The Sub-committee is required to approve the new arrangements.

Appendices

None.

Author

Name: Professor Karl Spracklen

Title: Chair, URESC

Date: 07 March 2018

Approval Route

25 April 2018

Professor Karl Spracklen / Chair, URESC

RESEARCH ETHICS PROCEDURES

Introduction

- 1 In the last academic year UREC recommended a number of changes to be made to the Research Ethics Procedures and the on-line system, following the formal review of the Policy. The new version of the Policy has been approved and adopted by the University.
- 2 This report provides an overview of progress made on the new Research Ethics Procedures, and the new version of the on-line application and approval system provides.

Progress report

- 3 IT have been working on a new system that includes the changes to the Procedures and some of the changes to the system we requested. The new system has been built and has been tested by members of URESC and Penny Wymer from LBS. The Chair and Stuart Morris met with IT and agreed to sign-off on the system at the end of January, and people who attended the Away Day provided feedback on new system. At the Away Day it was agreed that the changes to the existing system were only a temporary measure, and a brand-new system needed to be built.
- 4 Now the new system is ready to be launched, we will need to find someone to lead the drafting of the Procedures, and someone to be the named contact on the system page. The Chair and Stuart Morris met with Cathy Barnes (Research and Enterprise Director) and she has agreed her office will take ownership of the system and the Procedures. She has appointed a senior member of her team (Head of Research) who will take named ownership of these, and who will then lead the design and delivery of a new system from June onwards.
- 5 There still remains the problem of who will re-draft the Procedures in time for their publication at the beginning of June. We agreed with Cathy Barnes that Sheila Casey would be asked to be brought in to do this work, subject to her getting agreement from Sheila's Dean. A verbal report will be provided on this.
- 6 I believe that moving the Procedures and the System to the URO will ensure that research ethics is more visible in the management and operation of research at the university. It makes sense to connect research ethics more closely to other research system. And it gives research ethics additional resources. However, I believe the Policy needs to continue to be owned by Governance, and this sub-committee.

Conclusions and recommendations

- 7 The sub-committee is required to approve the new arrangements outlined in the report.

Research Ethics Audit Process – 2017/18

Executive Summary

The report proposes the process of research ethics audit to be followed by each School in 2017/18.

The report provides an overview of why an audit process is required and provides the timescales to be adhered to and the report template to be used.

Members of the sub-committee are invited to comment specifically on the following points:

- (a) Whether the proposed process is fit for purpose?
- (b) Whether there are any further areas that could be addressed in the audit process?

Action Requested

This report is **for decision**. The Sub-Committee is invited to discuss and approve the proposed research ethics audit process for 2017/18.

Appendices

Appendix 1 – School Research Ethics Report Template

Author

Name: Stuart Morris
Job title: Governance Officer (Academic)
Date: 03 May 2018

Approval Route

08 May 2018 Professor Karl Spracklen – Chair of the Research Ethics Sub-Committee

Research Ethics Audit Process – Covering 2017/18

Introduction

- 1 The terms of reference for the University Research Ethics Sub-Committee ('URESC') expect the sub-committee to oversee the implementation of the University Policy & Procedures for Research Ethics and monitor ethical approval within the Schools. The Schools are required to submit an annual audit report to the URESC outlining and reviewing how the Policy is being implemented whilst also recommending where improvements should be made.

Audit Process

- 2 The proposed template (Appendix 1) covers all the elements required by the Policy and the terms of reference of the University Research Ethics Sub-Committees and the responsibilities of the Schools.
- 3 The Schools are asked to:
 - (a) Provide details about how the recommendations made in the outcomes of the previous audit at the older, relevant, faculty level have been addressed through the action plan;
 - (b) Provide a summary of all ethical authorisations and approvals during 2017/18 as set out in the Policy and Procedures for Research Ethics (using the attached template);
 - (c) Provide statistical details of *all* research ethics staff development training undertaken within the School during 2017/18 (including details of the number of staff that have attended training sessions);
 - (d) Provide a review of what Schools have in place to assure themselves that international students are complying with the University's Research Ethics Policy and procedures.
 - (e) Provide a review of the guidance provided by each School in the module handbooks concerning the consequences of failing to adhere to the University policy & procedures for research ethics.
 - (f) Provide an action plan to be implemented during 2018/19 which will be reviewed as an element of any audit of research ethics covering the 2018/19 academic term.

Timescales

- 4 The following timescales and deadlines are proposed to ensure the relevant reports can be fully considered at School and University Level

<u>Task</u>	<u>Deadline</u>
Agreed Audit process released	Following consideration by and agreement of Research Ethics Sub-Committee 16 May 2018
Collation of data / statistics	July & August 2018
Production of School Research Ethics Report and consideration / discussion by School Academic Committee (or School Research Ethics Forum if one is in place)	First School Academic Committee of 2018/19 and before end of September 2018 deadline for submission to University Research Ethics Sub-Committee)
Deadline for submission of final School Research Ethics Report to University Research Ethics Sub-Committee	End of September 2018
Consideration of School Research Ethics Audit Reports by University Research Ethics Sub-Committee.	October 2018

Conclusions and recommendations

- 5 The Sub-Committee is invited to approve the proposed research ethics audit process for 2017/18.

DELETE ALL SECTIONS HIGHLIGHTED IN YELLOW

Research Ethics Audit Report Covering 2017/18 – Name of School

Name of School:	
Author of School Report:	
Outcomes / Actions carried over from the last audit undertaken via the old faculty structure :	
<p>(Outline / explain the outcomes of the previous audit, any actions which arose which were relevant to the School and the relevant action taken)</p>	
<p>What is the impact of the changes implemented as a result of the action plan?</p>	

2017/18 Applications and Statistics:

Discuss the number of ethical applications made and the categories in which they were submitted. Tables 1,2 and 3.

Do these figures demonstrate anything which the sub-committee may need to be aware of?

How might this inform the action plan for 18/19?

Overview of Staff Development and Attendance at Staff Development:

Provide details of the Staff development relevant to research ethics offered during 2017/18 and the attendance statistics in this box.

Do the figures demonstrate anything the sub-committee needs to be aware of?

How might this inform the action plan for 18/19?

Outcomes of the Sampling Exercise and School Academic Committee scrutiny:

Provide details of precisely what was sampled...

What outcomes / comments / conclusions can be drawn from this exercise?

How might this inform the action plan for 18/19?

Research ethics and student projects undertaken outside of the UK:

Provide a review of what Schools have in place to assure themselves that international students are complying with the University's Research Ethics Policy and procedures.

Information provided to students regarding non-compliance with the Research Ethics Policy:

Provide a review of the guidance provided by each School in the module handbooks concerning the consequences of failing to adhere to the University policy & procedures for research ethics.

Name of School Research Ethics - Action Plan 2018/19

Issue	Action	Responsibility	Deadline
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Table 2 Postgraduate Taught course Research Ethical Authorisation and Approval for the Academic Year 2017/18

Subject Group/School	Courses / Modules	Number of ethical authorisations	Number of local level ethical approvals	Number of School level ethical approvals	Number of University Level ethical approvals	Number of students expected to apply for Ethical authorisation or approval	Difference in number of students enrolled and decisions made	Comments on figures by course.
						<i>(how many students in a L7 cohort expected to undertake a Major Independent Study project or similar)</i>		

Table 3 – Postgraduate Research Ethical Authorisation and Approval for the Academic Year 2017/18

Subject Group/School	Number of ethical authorisations	Number of local level ethical approvals	Number of School level ethical approvals	Number of university level ethical approvals	Total number of ethical authorisations / approvals required for new students	Difference in number of students enrolled and decisions made	Comments

Table 4 – Staff Ethical Authorisation and Approval for the Academic Year 2017/18

Subject Group/School	Number of local level ethical approvals	Number of School level ethical approvals	Number of university level ethical approvals	Total number of ethical approvals required for staff projects.	Difference in number of students enrolled and decisions made	Comments

Ethical Data Sharing

Executive Summary

The report presents a paper written by Michelle N Meyer (Geisinger Health System, Danville, Pennsylvania) concerning a tutorial that provides practical tips for sharing research data in ways that are effective and ethical.

Action Requested

The report is **for discussion**. The Sub-Committee is invited to discuss report.

Appendices

None.

Author

Name: Dr Andrew Wilson
Job title: Senior Lecturer, School of Social Sciences
Date: March 2018

Approval Route

n/a

Practical Tips for Ethical Data Sharing

Michelle N. Meyer

Geisinger Health System, Danville, Pennsylvania

Advances in Methods and
Practices in Psychological Science
1–14
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www.psychologicalscience.org/AMPPS


Abstract

This Tutorial provides practical dos and don'ts for sharing research data in ways that are effective, ethical, and compliant with the federal Common Rule. I first consider best practices for prospectively incorporating data-sharing plans into research, discussing what to say—and what not to say—in consent forms and institutional review board applications, tools for data de-identification and how to think about the risks of re-identification, and what to consider when selecting a data repository. Turning to data that have already been collected, I discuss the ethical and regulatory issues raised by sharing data when the consent form either was silent about data sharing or explicitly promised participants that the data would not be shared. Finally, I discuss ethical issues in sharing “public” data.

Keywords

morality, data sharing, IRB, research ethics, responsible conduct of research

Received 9/16/17; Revision accepted 11/21/17

In 2011, I attended the annual Social, Behavioral, and Educational Research Conference of Public Responsibility in Medicine and Research (PRIM&R). PRIM&R is essentially the guild for institutional review board (IRB) administrators and other research-oversight personnel and offers a Certified IRB Professional (CIP) credential along with best practices for IRB review of research involving human participants. That year, the conference organizers, during some introductory remarks, showed a slide with a quotation from an actual IRB submission: “After the study is completed,” the slide read, “videotapes will be destroyed personally by the investigator with a sledgehammer.” The exact purpose of that slide has been lost to memory, but presumably it was meant to rouse the early-morning audience with an amusing illustration of the lengths to which some exasperated researchers will go to assure their IRBs that participants’ data will be protected.

Over the years, as I have watched the open-science movement blossom, that slide has come to illustrate, for me, something else: how far the IRB and research-ethics communities have to go in embracing data sharing. At the risk of stating the obvious, it is rather difficult to share data that have been sledgehammered to smithereens.

Why should researchers share their data? There are several legal, ethical, and practical reasons. Journals (e.g., Cozzarelli, 2004; *Nature*, 2017; *Science*, 2017),

funders (e.g., National Institutes of Health, or NIH, Office of Extramural Research, 2007; National Science Foundation, or NSF, 2014, Article 44; PCORI, 2016), and professional societies (e.g., American Psychological Association, or APA, 2017, § 8.14) are increasingly requiring some form of data sharing. Even if a data-sharing clause is not explicitly included in a grant, researchers conducting publicly funded research arguably have an obligation to return the data they were paid to collect to the public realm. And even if research is not publicly funded, when a scientist publishes a claim about the world, he or she invites that claim to be tested by others through reanalysis and replication (Meyer & Chabris, 2014), activities that require access to the original data and methods, respectively. This obligation is even more critical in the wake of the “replication crisis,” when the public’s and funders’ confidence in science appears to be fragile. Moreover, some scientific questions can be answered only with very large samples that require a consortium approach in which many researchers pool their data. Also, data sharing can be in researchers’

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self-interest, as there is some evidence that it leads to increased citation of the original research, at least in the case of clinical trials with cancer patients (Piwowar, Day, & Fridsma, 2007), gene-expression microarray studies (Piwowar & Vision, 2013), astronomy research (Henneken & Accomazzi, 2011), and astrophysics research (Drachen, Ellegaard, Larsen, & Dorch, 2016). And a demonstrable history of data sharing may be attractive to funders. Last—but not least—research participants are often motivated by their ability to contribute to science and want their data to be widely shared.

None of this is to say that, once one has decided to share data, the path forward is entirely straightforward. Any researcher who publishes should be prepared to immediately share data for the limited purpose of allowing other researchers to reproduce those published analyses. (Data should be shared publicly if at all possible, but may be shared only upon request if absolutely necessary to protect or keep promises to participants.) But reasonable people can disagree about when to share data for broader purposes, such as enabling other researchers to conduct new analyses or to combine the data with other data sets.¹ Data can be extraordinarily expensive and time-consuming to collect. And not every researcher is equally positioned to exploit a data set quickly before sharing; some have teams of graduate students and postdocs, whereas others work nearly entirely by themselves. Depending on the circumstances, it may be entirely acceptable for data collectors to embargo their data for a significant period of time, until they are able to produce one or more publications. (A probable exception is when the data are, say, medically actionable and withholding the data would directly harm people.) Reasonable people can also disagree about how secondary researchers should credit original data collectors.

In this Tutorial, I first offer several dos and don'ts for enabling newly collected data to be shared. I conclude with thoughts about what to do when one wants to share data that were previously collected without participants' explicit consent to data sharing.

Preparing to Share Data Effectively and Responsibly

DON'T promise to destroy your data

The strong default rule in science should be that research data will not be destroyed. Ordinarily, researchers should not volunteer to take a sledgehammer, or any other tool of destruction, to their data. And ordinarily, IRBs should not require the inclusion of data-destruction clauses in IRB applications, protocols, or consent forms. Neither the NIH nor NSF requires destruction of data, nor does the Common Rule (Federal Policy for the Protection of

Human Subjects, 2017), the federal regulations that govern most federally funded research with human participants and strongly inform IRB review of even non-federally funded research.

There will, of course, be exceptions when data destruction is reasonable, but these should be rare, and any act or IRB requirement of data destruction should be explicitly justified. For instance, when participants' identities are no longer important for purposes of reproducing or replicating the research and the continued existence of the research data poses a very significant privacy risk to participants, then destroying identifiers (or the code linking identities to data) may be reasonable. Sometimes, raw data themselves are nearly inextricably linked to identity, as may be the case with the kind of video data that the nameless researcher mentioned in the opening paragraph pledged to smash. If participants were recorded, say, discussing illegal behavior, then destroying the video footage would likely be justified.

However, as I discuss later, there is a wide range of options for data sharing, from depositing data into a public repository open to all, to allowing access only by qualified researchers who have signed a strict data-use agreement. Even if researchers, for privacy reasons, never share their data with anyone else, retention can be important in allowing them to double-check the integrity of their original research and to defend their work if it is questioned (Neyfakh, 2015). In a world where safe-deposit boxes exist, raw data should be both highly identifiable and highly sensitive before the last resort of data destruction is contemplated.

DON'T promise not to share data

Too often, consent forms promise participants that their data “will be kept private and confidential to the extent permitted by law,” or that “only the research team will have access” to the data. Such routine promises are often thoughtlessly included in modern consent forms that are adapted from earlier studies. Sometimes researchers may intentionally submit consent forms that promise the data will not be shared (or that are silent about data sharing) in an effort to obtain quicker IRB approval. This shortsighted strategy will cause considerable difficulties (which I discuss later) if the researcher later wishes to or (pursuant to evolving journal and funder requirements) must share data.

DON'T promise that research analyses of the collected data will be limited to certain topics

After promises to destroy data and promises not to share them, the next most problematic language found in many consent forms is language that suggests the

data will be used only for particular research purposes. Although the original researcher may never wish to conduct other analyses of the data, secondary researchers may well wish to do so. Original researchers should, to the extent possible, disclose how they themselves plan to use the data. But in asking participants to additionally consent to data sharing, original researchers should make it clear that other researchers may use the data for a variety of other purposes, up to and including any purpose at all, without recontacting participants or obtaining their consent to those new purposes.

DO get consent to retain and share data

Instead of promising to destroy or not to share data, researchers should build data-retention and data-sharing plans into IRB applications, experimental protocols, and consent forms. Researchers need not reinvent the wheel; several examples of data-sharing language (often approved by one or more IRBs) are available online and may be adapted as appropriate for different studies (see Databrary, n.d.-a, n.d.-b; Halchenko & Gorgolewski, 2015b, 2015c; Inter-university Consortium for Political and Social Research, 2017c; Murphy, 2016). Participants should be told what types of individuals will have access to their data: other researchers at the same institution, researchers at other institutions, commercial entities (and if so, whether participants will share in any resulting profits), governments, or the general public. They should also be told the purposes for which their data may be reused: for reanalysis and replication only or for new analyses (and if the latter, whether there will be any limits on the kinds of secondary analyses that may be conducted).

In making these disclosures, researchers should err on the side of obtaining participants' consent to broader and more public data sharing. If the data turn out to be more sensitive than anticipated, researchers retain flexibility to choose a more limited form of data sharing than the obtained consent permits. The converse, of course, is not true.

Tiered consent options can be used to provide participants with some control over how broadly their data are shared for secondary research purposes. The level of consent can vary along two different axes: That is, participants can be given a choice over whether to share some but not all of their data, and they can also be given a choice over whether to share their data with some groups but not all others. (Participants should generally *not* be given the option of withholding their data from other researchers who aim only to reproduce the original analysis, but should be told that their data may be shared for those purposes.) However, it will generally also be ethically acceptable if participants'

only choice is to consent to their data being shared as described in the protocol (which may indicate very broad sharing) or not to participate in the study at all.

DO incorporate data-retention and -sharing clauses into IRB templates

Many IRBs have developed protocol and consent templates to help ensure that researchers address all critical aspects of their studies, as required by the Common Rule and institutional policy. Researchers may not be thinking about the eventuality of data sharing when their focus is on simply gaining approval to collect the data in the first place, but including data-sharing clauses in IRB templates would nudge researchers (and IRBs) toward data sharing and help reorient all parties from a culture of data secrecy to a culture of data sharing.

Templates are only defaults, and a data-sharing clause could be overridden when the IRB (or the researcher) believes that circumstances dictate doing so. But researchers and IRBs should not assume that data cannot ethically be retained and shared. Neither should they assume that individual participants or participant populations necessarily view their data as sensitive or—even if they do—believe that their data should be destroyed or kept secret by the primary research team. In general, it will be much more reasonable to ask questions about how and with whom data may be shared than to ask questions about whether it may be shared at all. Even highly sensitive, highly re-identifiable data, such as those collected through the Personal Genome Project, can be shared publicly if participants' comprehension of the risks is confirmed through brief quizzes administered during the consent process (Lunshof, Chadwick, Vorhaus, & Church, 2008). Consent comprehension quizzes can be used in other studies to ensure that participants understand the risks of a variety of levels of data sharing. With such safeguards in place, there should be no excuse for an IRB to prevent participants from making a knowing, voluntary decision to share their data.

DO be thoughtful when considering risks of re-identification

Two contrary impulses must both be avoided when data sharing is contemplated. First, it is natural for researchers to be enthusiastic about their research and—at least in the case of those who are laudably buoyed by the current open-science momentum—about sharing their data. But that eagerness, and the fact that re-identification is itself a specific domain of expertise, can prevent researchers from exercising necessary caution and reflection before sharing.

An “anonymous” data set, for instance, may easily cease to be anonymous if it includes variables that allow relatively unique individuals to be identified. A recent string of high-profile re-identification “attacks” by researchers has shown that it is possible to re-identify some data on the basis of, for example, full ZIP code, full birth date, and sex (Sweeney, 2002); Web search queries (Barbaro & Zeller, 2006); online movie reviews (Narayanan & Shmatikov, 2008); genomic data (Gymrek, McGuire, Golan, Halperin, & Erlich, 2013); cell-phone data (de Montjoye, Hidalgo, Verleysen, & Blondel, 2013); taxi-passenger data (Tockar, 2014); and credit-card meta-data (de Montjoye, Radaelli, Singh, & Pentland, 2015).

Some data, although not easily re-identifiable by the public, are easily re-identifiable by people who know the participant. In some cases, that may be acceptable; in others, it may cause considerable harm. For instance, a hospital paid a \$2.2 million fine for allowing a television crew to film and broadcast the treatment and subsequent death of an “unidentified” patient whose family recognized him during the broadcast (Ornstein, 2016). Similarly, some psychology research involves studying family members. If anonymized data are reported for pairs or other small groups, or via couple indicators, then one participant need only identify his or her own responses in order to identify those of another family member.²

On the other hand, it is important to avoid a second impulse, to overestimate the risk of re-identification. Re-identification attacks by researchers have received a great deal of media attention (some people would say media hype; Barth-Jones, 2012a, 2012b). Risk is the magnitude of harm discounted by the probability of that harm occurring, and a great deal of data collected under the auspices of psychological science could be re-identified without any significant harm being done to participants. The harm from re-identification of some kinds of data, such as health data, can be difficult to estimate to the extent that laws regarding discrimination and preexisting conditions are uncertain.

Estimating the probability of re-identification is difficult because it, too, is a moving target: As the amount of available data about an individual increases, any one data set about that individual becomes increasingly re-identifiable. More data about most of us is becoming available over time. Yet it is important to consider not only the technical feasibility of re-identification, which is where the bulk of attention has been placed, but also the incentives, or lack thereof, for people to seek to re-identify research data sets, as well as the costs to them of attempting to do so (Wan et al., 2015). To date, as far as we know, research data sets have been re-identified only by privacy researchers seeking to demonstrate the technical feasibility of doing so.

Notwithstanding this admonition not to overreact to re-identification risk, all reasonable measures should

be taken to de-identify data except when the data are incontestably innocuous or participants have knowingly given clear consent to share identified or readily identifiable data. In the wake of the string of re-identification attacks I mentioned earlier, some critics have all but dismissed as worthless the de-identification tools outlined in the regulations implementing the Health Insurance Portability and Accountability Act (HIPAA; Standards for Privacy of Individually Identifiable Health Information, 2002, § 164.514(b)(2)), as well as other de-identification tools. Such criticism sweeps far too broadly. For instance, Sweeney’s (2002) re-identification of Massachusetts Governor Bill Weld on the basis of his five-digit ZIP code, full date of birth, and sex occurred prior to, and indeed prompted revisions to, the safe-harbor provision of the HIPAA Privacy Rule (Standards for Privacy of Individually Identifiable Health Information, 2002). Prior to that revision, Sweeney offered a theoretical estimate that 87% of U.S. individuals could be re-identified on the basis of these three variables. She later testified, however, that if the same data set met HIPAA’s safe-harbor provision—under which ZIP codes are limited to the first three digits and birth dates are limited to year of birth—only 0.04% of individuals could be re-identified (Barth-Jones, 2012a, 2012b). Similarly, a systematic review of known re-identification attacks on health data found that most “re-identified” data sets had not been properly de-identified according to current standards in the first place, weakening claims about the efficacy of re-identification techniques (El Emam, Jonker, Arbuckle, & Malin, 2011).

Researchers can also use a variety of anonymizing tools instead of or in addition to HIPAA’s safe-harbor de-identification, which involves removing 18 identifiers. Other techniques include “masking” original data by replacing them with random data and “blurring” variables by sharing them at a reduced “resolution” (e.g., reporting age ranges instead of specific ages in years or larger geographic regions instead of ZIP codes). HIPAA’s Privacy Rule itself permits a second approach to de-identification: expert determination, in which an appropriate expert uses “generally accepted statistical and scientific principles and methods” to render data not individually identifiable, so that the risk of re-identification is “very small” (Standards for Privacy of Individually Identifiable Health Information, 2002, §164.514(b)). However, most researchers—and most IRBs—lack the expertise to properly de-identify or obfuscate data by going beyond rote application of HIPAA’s safe-harbor rules. As both the identifiability of data sets and the imperative to share data grow, the long-term solution may be to embed de-identification experts into research institutions, much as experts in statistics and survey methods now form standing “cores” that serve the research enterprise in many institutions.

In the short term, institutional privacy offices will tend to have more expertise in recognizing re-identification risks and in recommending solutions than will most IRBs. Helpful open-source de-identification tools also exist (Halchenko & Gorgolewski, 2015a; OpenfMRI, n.d.), and some data repositories review deposits for disclosure risks and offer de-identification and similar curation services (Inter-university Consortium for Political and Social Research, 2017a, 2017b).

DO consider working with a data repository

Researchers should strongly consider depositing their data in a repository rather than waiting to be asked for their data. In an effort to obtain data for reanalysis, Wicherts, Borsboom, Kats, and Molenaar (2006) e-mailed the corresponding authors of 141 articles published in APA journals. All authors who publish in these journals must sign the APA Certification of Compliance With APA Ethical Principles (APA, 2003), Principle 8.14 of which requires that psychologists share data with other “competent professionals who seek to verify the substantive claims through reanalysis.” Wicherts et al. sent more than 400 e-mails, often including detailed descriptions of their study’s aims, IRB approvals, signed assurances not to share the data further, and their curricula vitae. Yet after 6 months, 73% of the authors had still failed to share their data. Most of those authors explicitly refused or said they were unable to share, whereas others promised to share but did not or simply never responded to the requests. Only 11% of the authors shared their data after the first request.

Even if both data requestors and original data collectors are well intentioned, inertia by both parties may present an avoidable obstacle to efficient data sharing. Data repositories allow the original data collectors to provide maximum access by sharing once. Many repositories also enable preregistration, data analysis, posting of preprints, and sharing with lab members. They often provide other useful services as well, so that they offer one-stop shopping for the modern researcher.

DO be thoughtful when selecting a data repository

Researchers should consider the governance options available at different data repositories when selecting one, as a given repository may be more suitable for some data sets than for others (see Table 1). For instance, some repositories are entirely open, whereas others make data available only to “qualified researchers” (usually those who have registered an affiliation with a research institution, which may be asked to

vouch for their research-ethics training and document that they have permission to conduct independent research). Limiting data access to qualified researchers excludes citizen scientists (and, at some institutions, trainees) and is controversial for that reason (The White House, 2016, p. 2). However, institutions can usually deter their affiliates from violating data-use agreements, whereas citizen scientists answer to no one, so restricted data sharing may be more appropriate for sensitive data; in those cases, less detailed versions of the same data sets may be made publicly available. Some repositories permit depositors to control the level of access to their data, and this control may include an option to make the data available to specific researchers via a private link. Also, some repositories have established data-use agreements or other terms of service that preclude, for instance, attempts to re-identify or recontact participants. Publications with sensitive data that are shared in a repository with documented processes for accessing such data are eligible for a special version of Open Science Framework’s Open Data badge (Center for Open Science, n.d.).

Sharing Data That Were Previously Collected Without Explicit Consent to Share

So far, I have focused on best practices that, going forward, will bake data-sharing plans into IRB applications, protocols, and consent forms. But many researchers laudably wish (or are required) to share data that have already been collected via a consent form that either was silent about data sharing or promised that data would not be shared. What should researchers do in such cases?

Ethical considerations

Data sharing poses two risks to participants. One risk is that their data will be associated with their identity by someone they did not choose to share that identified data with; this can lead to harms, such as stigmatization and discrimination, in addition to basic loss of privacy. The other risk is that participants’ data—even if not associated with their identity—will be used for research purposes to which they would not have consented, which would render them complicit in what they deem to be inappropriate research. The ethical and regulatory question is whether it is appropriate to impose these risks on participants, either without their explicit consent (when the consent form was silent about data sharing) or in contradiction to what they were promised when they gave their consent.

Whether data sharing in these circumstances is ethically appropriate or not must be determined on a

Table 1. Governance Attributes of Some Social-Science and General Data Repositories

Repository	Data type	Access tiers and licensing	Data-privacy constraints specified on the Web site	Data citation and other incentives
Databrary, https://nyu.databrary.org (New York University, with support from Pennsylvania State University)	Video, audio, and related metadata in the developmental and learning sciences	Five tiers are available: public, authorized users (data are available to users who are registered and have signed an access agreement cosigned by their home institution), excerpts (data are available to authorized users, who may show clips during presentations; see Gilmore, Kennedy, & Adolph, 2018, this issue), private (data are available only to collaborators), and unreleased (data are accessible only by the depositor). Use is limited to noncommercial research and educational purposes.	Sharing requires that participants signed the Databrary release template or an IRB has determined that the obtained consent contains equivalent language. In text documents, participants may not be identified by names or initials. IRB approval is required to upload personally identifiable data for sharing or to conduct research with personally identifiable data available on Databrary.	A Databrary-specific citation is generated for each volume when it is shared, and users agree to properly cite all Databrary resources used in their scholarly work.
Dryad, http://datadryad.org ^a	Content associated with scholarly research documents that are published, in press, or under review	Many journals integrate their submission process with Dryad. By default, data and other content associated with a scholarly research document are made public under a Creative Commons CC0 waiver upon online publication of that document. The availability of a postpublication embargo of data depends on journal policy. Some journals routinely allow postpublication embargoes of up to 1 year, in which case depositors may select this option at the time of submission. Dryad will facilitate longer embargoes, or embargoes of data associated with publications in other journals, with written permission from the journal editor or publisher.	Dryad specifies that “human subjects data must be properly anonymized and prepared under applicable legal and ethical guidelines.” ^b Dryad permits no direct identifiers and no more than three indirect identifiers per data set. Although depositors are responsible for ensuring that these policies are met, every data package is reviewed by a curator for (among other things) the presence of personally identifiable or otherwise sensitive or inappropriate information.	Dryad assigns a DOI to each “data package” (all data files associated with a publication plus the metadata describing the set) and to individual data files.
figshare, http://figshare.com	Research data and other outputs (figures, theses, etc.) from any science field, in any file format, up to 5 GB; data deposited by an individual user should not be uploaded for commercial purposes, cannot have been previously published with a DOI, cannot have been copyrighted, and cannot contain broadly defined sensitive information	Data may be marked as private (accessible only to the uploader while logged in or to other people via a privately shared link) or public (under various Creative Commons licenses, some of which restrict use to noncommercial purposes or preclude alteration of the data file, figure, or other content). Additional Creative Commons and customizable licenses (including a restrictive-license template for sensitive data) are available through institutional figshare accounts.	Data uploaded by individual users may not contain “sensitive personal data,” as defined by Section 2 of the U.K. Data Protection Act of 1998. Researchers depositing ethically sensitive data may choose to share only metadata.	figshare provides DOIs, including DOI reservations prior to publication. For each research output, figshare displays the number of views, downloads, and citations it has received, as well as its Altmetrics, and also enables in-browser visualization.

(continued)

Table 1. (continued)

Repository	Data type	Access tiers and licensing	Data-privacy constraints specified on the Web site	Data citation and other incentives
Harvard Dataverse, http://dataverse.harvard.edu (Institute for Quantitative Social Science, Harvard University) ^c	Quantitative and qualitative data in any format, from any discipline	The default license for all data sets is the Creative Commons waiver (CC0) that allows reuse of data without conditions. However, Dataverse offers other legally binding data-use and licensing agreements that depositors may require downloaders of their data to sign and also permits upload of customized agreements. Depositors may use a “Guestbook” feature to collect data about downloaders of open-access data. Although metadata are always open access, files themselves may be restricted use, in which case downloaders must be registered users.	Data may be uploaded only after the depositor has received all relevant approvals, including approval from an IRB, if required. Data uploaded by any one user must not contain information that would enable re-identification of any participants using the information available across that user’s uploaded data sets and dataverses. Specifically, uploads cannot contain individuals’ account numbers (e.g., Social Security numbers, credit-card numbers, medical-record numbers, health-plan numbers) or biometric identifiers (e.g., fingerprints, retina prints, voiceprints, DNA). Exceptions are allowed when identifiable information has already been made public, when the data are identifiable but reflect the public roles or other nonsensitive aspects of public figures, when a “sufficient length of time” ^d has passed since data collection, when participants have given explicit informed consent to public release of the data, and when the data pertain to deceased individuals (in the case of data created by a U.S. federal government agency or under a federal contract).	A citation that includes data-set version and a DOI is generated and automatically presented when a data set is created. In addition, tabular data uploaded in any of several standard formats are assigned a Universal Numerical Fingerprint and are automatically converted into files that can be downloaded in multiple formats. Tabular data can be analyzed within the Dataverse platform using the TwoRavens application, and data that include geospatial coordinates can be mapped using WorldMap.

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Table 1. (*continued*)

Repository	Data type	Access tiers and licensing	Data-privacy constraints specified on the Web site	Data citation and other incentives
ICPSR (Inter-university Consortium for Political and Social Research, University of Michigan), https://www.icpsr.umich.edu/icpsrweb ^a	Social and behavioral research data of all file types	The vast majority of ICPSR data holdings are public-use files with no restrictions on access beyond ICPSR's standard terms of use. However, in some cases, ICPSR provides vetted researchers and sponsored-supervised students access to restricted-use data versions that retain confidential or sensitive data. To request access to restricted-use data, an investigator must submit an application that describes the proposed research and includes a confidential data-security plan; a signed pledge of confidentiality; a restricted-data-use agreement signed by the user and a legal representative from his or her institution; and, in some cases, IRB approval or an exemption. Data may be provided in encrypted format, via a virtual data enclave, or (in the case of highly sensitive data) via a physical data enclave in Ann Arbor, MI.	Data containing identifying information may be deposited under conditions that are consistent with the consent form and IRB approval. Trained data curators review all deposited data to assess disclosure risk and, when necessary, either modify the data or restrict access to protect participants' confidentiality. Consultation on disclosure risk is available. Review of informed consent to ensure that data sharing is appropriate is also available.	To make data easier to use, ICPSR cleans and enhances data files and creates descriptive metadata. All data collections receive a data citation including a persistent DOI. When users cite the data (especially if they include the DOI), ICPSR is able to track the citations in a bibliography that allows other researchers to assess the impact and reuse of data collections.
OpenfMRI, http://openfmri.org (Stanford Center for Reproducible Neuroscience)	All forms of neuroimaging data that include MRI images and associated data	Unless otherwise noted, data are available under the Creative Commons CC0 1.0 license.	Data must be de-identified prior to sharing. Depositors are advised to receive either IRB approval to share the de-identified data or a determination from their IRB that sharing is allowed.	OpenfMRI provides a unique, permanent accession number for each data set. Users are encouraged to follow the Open Data Commons (n.d.) Attribution-Sharealike Community Norms and, in particular, to cite OpenfMRI in reports using data downloaded from OpenfMRI.

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Table 1. (continued)

Repository	Data type	Access tiers and licensing	Data-privacy constraints specified on the Web site	Data citation and other incentives
openICPSR (a self-publishing service operated by ICPSR), ^c https://www.openicpsr.org	Social and behavioral research data of all file types	Data at openICPSR are made available under an Attribution 4.0 Creative Commons license. Self-publishers choose to either make the data available for immediate public download or to restrict access. If access is restricted, users must apply for access and pay an administrative fee.	Self-publishers must attest that no individuals can be identified from information in the data collection. ICPSR does not conduct disclosure analysis on openICPSR collections.	Data collections are not curated by ICPSR and remain in their original format, although self-publishers may pay to have the data curated by ICPSR (i.e., cleaned and enhanced so they are easier to find and use). All openICPSR collections do receive a data citation including a persistent DOI.
OpenNeuro, https://openneuro.org (Stanford Center for Reproducible Neuroscience)	Neuroimaging data in Brain Imaging Data Structure (BIDS) format	Uploaded data are private (i.e., only collaborators can view and edit the data) for a limited time and then become public. Data and related analytic results are made publicly available under a Creative Commons CC0 or CC-BY license no later than 36 months following the first successful analysis of data from more than 1 participant; users may apply for up to two 6-month extensions.	Uploaded data must be owned by the depositor, who must have obtained necessary ethics permissions to share the data publicly. The data must not contain any HIPAA identifiers (e.g., names, ZIP codes, dates of birth, acquisition dates, facial features on structural scans).	OpenNeuro provides a unique, permanent accession number for each data set. It plans to add DOI functionality in the future. Data authors have free access to supercomputer analysis of their data via OpenNeuro's Web interface.
Open Science Framework, https://osf.io (Center for Open Science, Charlottesville, VA)	General science content, including data, materials, and code	Access may be public (depositors select from common licenses or upload their own) or private (accessible only to the depositor, contributors to the project or component, and users with a view-only link generated by the depositor).	Depositors should consult their institutions about HIPAA compliance concerns.	DOIs (no versioning) and Archival Resource Keys (ARKs) are available for public projects and registrations. Every project, component file, and user is assigned a unique, persistent URL that enables preformatted citations to be displayed on every Project Overview and Component Overview page. Each project can connect to preregistrations or preprints.

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Table 1. *(continued)*

Repository	Data type	Access tiers and licensing	Data-privacy constraints specified on the Web site	Data citation and other incentives
Zenodo, https://zenodo.org	Any research output (including multimedia) from any field; up to 50 GB per data set	Data may be marked as open, embargoed (data will become public at the end of a specified time), restricted (access is available only with the permission of the depositor), or closed. Depositors must specify a license for all publicly available files. Data are available for nonmilitary purposes only.	Data depositors are responsible for ensuring compliance with copyright, data-privacy, and other laws and for ensuring that the data are suitable for sharing.	Zenodo assigns DOIs to all publicly available uploads and also enables DOI versioning (i.e., a file can be modified after publication and users can cite different versions of a file or the entire set of files).

Note: This table summarizes information obtained through personal communication with representatives of the repositories in January 2018. For a comparative review of other aspects of data repositories, see Dataverse (2017). HIPAA = Health Insurance Portability and Accountability Act of 1996 (see Standards for Privacy of Individually Identifiable Health Information, 2002); IRB = institutional review board.

^aUsers pay a fee for this service, unless a journal or institution pays the fee. ^bSee <https://datadryad.org/pages/humanSubjectsData>. ^cDataverse, which was developed by Harvard University, is an open-source Web application for creating data repositories. Harvard Dataverse is a data repository that was made using that software and is open to data depositors and researchers worldwide. In the future, Harvard Dataverse plans to integrate with DataTags (<https://datatags.org>), which provides different transit, storage, and access options to support the sharing of data of varying degrees of sensitivity. The access and data-privacy policies described in this table reflect current options. ^dSee Restriction 6 at <https://dataverse.org/best-practices/harvard-dataverse-general-terms-use>. ^eCuration services are not provided.

case-by-case basis. But in general, the argument for sharing will be stronger the more of the following conditions are met:

- The original consent form was merely silent about data sharing, and did not include a promise not to share data
- The data are not especially sensitive (i.e., re-identification would be unlikely to cause significant harm to participants)
- The data are not individually identified and are not especially likely to be re-identified (i.e., there are low incentives for anyone to re-identify the data or the data are unlikely to be re-identifiable alone or in combination with other available data sets)
- The shared data will be accessible only under restricted conditions, protected by agreements prohibiting re-identification
- Sharing will be limited to secondary research purposes that fall within the scope of the research described in the original consent form
- Sharing will be limited to secondary research purposes participants are not known to object to

Even when some of these considerations are not met, it is important to balance concerns about data privacy and data repurposing with the recognition that many participants prefer greater, rather than less, sharing of the data they contributed to science. Participants typically volunteer for research with the expectation that all reasonable efforts will be made to ensure that the results are correct, and data sharing for reanalysis and replication purposes helps to meet that objective. Also, participants who are members of groups that traditionally have been underrepresented in research may have a particular interest in having their data used widely (although their data may, for similar reasons, be more vulnerable to re-identification than other participants' data are). An especially strong case exists for nonconsensual data sharing for the limited purpose of reanalysis. In approving original research, IRBs must determine that the risks to participants are reasonable relative to the expected benefits of the research (Federal Policy for the Protection of Human Subjects, 2017, § 46.111(a) (2)). Those expected benefits may include direct benefits to participants, but given the IRB system's view of what constitutes a research-related benefit (e.g., incentives such as gift cards do not count; Meyer, 2013, pp. 276–279), the benefits of psychological research are likely to take the form of knowledge that is reasonably expected to result. Research analyses that cannot be reproduced because data cannot be shared arguably fail to qualify as knowledge at all, much less valuable

knowledge. Similarly, it is a tenet of research ethics that research that is not well designed to rigorously answer an important question is unethical, because it means that any research-related risk (even, some people would say, the modest burden of time spent by participants) is necessarily wasted (Emanuel, Wendler, & Grady, 2000). Today, it is clear that scientific rigor and integrity require routine reanalysis and replication, which in turn require data sharing for at least those purposes.

Regulatory considerations

Except for data that are subject to HIPAA, data sharing exists in a sort of regulatory twilight zone. The Common Rule does not prohibit data sharing and is—or should be—no obstacle to consensual data sharing. Moreover, under the Common Rule, secondary research using shared data that are neither identified nor “identifiable”—that is, data from individuals whose identity cannot be “readily ascertained” (Federal Policy for the Protection of Human Subjects, 2017, § 46.102(e)), either directly or indirectly, through coding systems (Office for Human Research Protections, 2008)—does not constitute human-participants research. (Note that this narrow regulatory definition of “identifiable” ignores other methods of re-identification.) As a result, one prominent advisory body has concluded that it is not a Common Rule violation for an investigator to conduct secondary research on nonidentifiable data when that research falls outside the scope of the original obtained consent (Secretary's Advisory Committee on Human Research Protections, 2011, III, FAQ #3).

But what about the act of data sharing itself? Data sharing alone does not constitute human-participants research, and most retrospective data sharing will occur after a research protocol is closed out by an IRB, assuming that the original research was not exempt from IRB review in the first place (Federal Policy for the Protection of Human Subjects, 2017, § 46.104). But there is something artificial about separating the act of data sharing from the rest of a research study's trajectory, even if data sharing is contemplated only after the fact. IRBs review preresearch recruitment plans, so there is no particular reason why they could not review postresearch data-sharing plans (leaving aside the important fact that most IRBs are far less qualified to review data-sharing plans than they are to review recruitment plans). Certainly, institutions can implement policies that empower their IRBs to review data-sharing plans, even if data sharing is not covered by the Common Rule. Moreover, sharing data that were collected using a consent form that promised the data would not be shared likely constitutes a protocol violation. Researchers should therefore always consult their IRBs

before sharing data when participants were promised otherwise. If the incremental risk of data sharing above and beyond the risks to which participants already consented is minimal, and if certain protections are in place, an IRB may approve an amendment to the protocol to allow data sharing without recontacting participants and obtaining their consent for the new purpose (which is often infeasible).

Sharing “Public” Data

One final comment regarding sharing data with repositories is in order. The Common Rule does not consider nonintervention research to involve human participants unless the data obtained are not only identifiable but also “private”—that is, data “about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place” or data that have “been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record)” (Federal Policy for the Protection of Human Subjects, 2017, § 46.102(e)(4)).

Expectations of privacy for tweets and public Facebook posts are evolving as media routinely republish or broadcast this content (sometimes with identities intact, sometimes with identities blurred). But existing data found on unlocked Twitter accounts and on Facebook posts set to “public” surely fail to meet the Common Rule’s definition of “private.” As a result, neither analyzing those data nor resharing them by depositing them in a public repository constitutes human-participants research subject to IRB review under the Common Rule. Nevertheless, aggregating otherwise disparate bits of public data in one analyzable data set amplifies attention to the information that users disclosed and enables inferences about individuals that they may not have predicted or intended. It also creates a permanent record that will persist even if those individuals delete their original posts. Researchers collecting sensitive public data should therefore consider whether it is appropriate to de-identify those data, especially if identities are not critical to them.

More troubling is the possibility that some researchers consider to be public data that they are able to access only by using false pretenses to join a closed community in which the data are shared for specific purposes. In 2016, for instance, researchers scraped data from more than 68,000 user profiles on the dating site OkCupid.com. The data set included username, age, sex, gender, sexual orientation, and location. It also included users’ answers to 2,543 questions probing their political, religious, and moral beliefs; masturbatory

habits; risk-taking (including illegal) behaviors; and sexual preferences. The researchers used responses to 14 of these questions to infer users’ general cognitive ability and uploaded the data to a repository where it was available to anyone. When asked, the lead researcher responded that they had made no attempt to de-identify the data set, citing the fact that it was “already public” (Hackett, 2016, comment by E. Kirkegaard). (After ethical questions were raised about the data set, the repository first password-protected the files and then, following OkCupid’s notice of copyright violation, removed them entirely.)

At the time, portions of OkCupid user profiles, including information on age, gender, and sexual orientation, were indeed publicly accessible through standard search-engine queries (that no longer appears to be the case). But answers to the survey questions were accessible only to people who had created an OkCupid account and answered the same questions. Users admittedly could set certain survey answers to “private,” in which case they were accessible only to the company for use in its matching algorithm. But the fact that users were willing to disclose personal information to fellow members of a particular community, for a particular purpose (finding appropriate matches and being transparent with potential dates about their preferences), does not mean that they would have agreed to share the same information with researchers, much less with the public, and much less in a permanent data repository. The researchers appear to have been able to access those sensitive, re-identifiable data only by signing up for an OkCupid account under the pretense that they shared the purpose that brought that community together.

Conclusion

Psychological science has borne the brunt of negative publicity concerning the replication crisis. But it is also leading the way toward more rigorous, reproducible science. One important tool in the reproducibility tool kit is data sharing, which enables reanalysis, replication, and well-powered consortium science. Historically, IRBs and many researchers have prioritized data secrecy over data sharing. Participants do often have privacy interests that are important to consider. Consequently, they should be asked for their permission to share their data, and care should be taken in deciding how and with whom their data are shared. But it is past time for the research community to realize that participants typically also expect that the data they contribute will be used to advance scientific truth, not merely to make scientific claims that cannot be verified.

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M. N. Meyer is the sole author of this article and is responsible for its content.

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The author(s) declared that there were no conflicts of interest with respect to the authorship or the publication of this article.

Notes

1. For instance, the Open Science Framework (OSF) awards its Open Data badge to researchers who make their data “publicly available on an open-access repository,” but only those data that are “needed to reproduce the reported results” must be included (OSF, 2016, Criteria 1 and 2).
2. I thank reviewer Paul W. Eastwick for this example.

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Schedule of meetings and business 2017/18

Executive Summary

The report presents the Sub-Committees schedule of meetings and business for 2017/18.

Action Requested

The report is for information. The Sub-Committee is invited to note its schedule of meetings and business for 2017/18.

Appendices

None.

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Date: 30 April 2018

Approval Route

n/a

Research Ethics Sub-Committee: Schedule of meetings and business for 2017/18

04 October 2017	06 December 2017	07 March 2018	16 May 2018
School Research Ethics Audits 2016/17	2016/17 Research Ethics Audit outcomes – action plan monitoring	2016/17 Research Ethics Audit outcomes – action plan monitoring	2016/17 Research Ethics Audit outcomes – action plan monitoring
Insurance cover for research and potential clinical trials	Proposal for away-day for research ethics in the University	Feedback from away-day for the management of ethics in the University	Research Ethics Audit process 2017/18
List of institutions/ethics committees that have been agreed for light touch approval process	School Research Ethics Audits 2016/17	Update on the development of a Protocol for Research being undertaken abroad	Ethical Data Sharing
Authorised IRAS sponsor signatory change - information for schools	Research Ethics Procedures		Research Ethics Procedures
Research Ethics Procedures	Risk protocol for research undertaken abroad		Research Data Management
Overview of the management of Research Ethics at School level	Code of research integrity		Research Ethics Audit outcomes: Film, Music & Performing Arts
	Proposal for away-day for research ethics in the University		
Standing items			
Membership & terms of reference (first meeting only)		PREVENT update	
Declarations of interest			
Minutes of the last meeting			
Matters arising			
Schedule of business			

* European Code of Conduct for Research Integrity – mapping – October 2018

