RESEARCH WITH PLYMOUTH UNIVERSITY

Research Ethics Policy

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Research ethics: a policy for staff and research students

1. Plymouth University is committed to maintaining and promoting the highest standards of integrity and probity in scientific research. Ethical values are central to our structures and practices of research governance.

2. Attention to the ethical implications of research for research subjects, researchers and research sponsors is an intrinsic part of good research practice. The University has an established set of fundamental principles to ensure Good Scientific Practice, the integrity of research involving human participants, research involving animal subjects, and general principles of data confidentiality and access. Our principles should be taken alongside those of the UK government Chief Scientist[1], the RCUK[2], and relevant professional bodies. The University seeks to ensure that all research for which it has responsibility satisfies these principles. This research governance is undertaken through a University Research Ethics Committee and Faculty Research Ethics Committees. The University will undertake the ethical review of pure and applied research irrespective of funding source, except that research falling under the remit of Department of Health approved ethics committees, shall be referred to the appropriate committee, but must be reported to the Faculty Research Ethics Committee.

Roles and Responsibilities

University Research Ethics Committee

3. Overall responsibility for the development, implementation and monitoring of research ethics policies lies with the University Research Ethics Committee (UREC). The membership of the UREC shall consist of the Dean of Research and Innovation (Chair), the Head of the Graduate School, the Chairs of Faculty Research Ethics Committee and a lay member.

4. The UREC is responsible for approving the terms of reference, membership, procedures and annual reports of Faculty Research Ethics Committees (FRECs) and giving guidance to FRECs as required.

5. The UREC will consider specific ethical matters on an ad hoc basis, for example, if a FREC is unable to reach a decision on a research proposal for whatever reason or if a researcher wishes to appeal against the decision of a FREC. In addition, it will undertake an annual audit of decisions taken by Committees, particularly those decisions taken by expedited review (see below).

6. The UREC will maintain a watching brief on emerging ethical issues relating to research and if necessary will report to Chancellery and/or Academic Board.

7. The UREC will report to the Research and Innovation Committee and will provide an annual report to Academic Board as an addendum to the Research and Innovation Committee's annual report. Minor amendments to this policy can be approved by the Research and Innovation Committee.

8. The reporting relationships of the various committees are summarised in Annex 1.

[1] "Rigour, Respect and Responsibility: A Universal Ethical Code for Scientists" at http://www.bis.gov.uk/assets/goscience/docs/u/universal-ethical-code-scientists.pdf
[2] "Integrity, Clarity, and Good Management: RCUK Policy and Code of Conduct on the Governance of Good Research Conduct" at www.rcuk.ac.uk/documents/reviews/grc/goodresearchconductcode.pdf

Faculty Research Ethics Committees

9. Given the diversity of approaches to research and the specialist nature of some of the issues raised by research projects (e.g. educational research, health research) the University believes the majority of research proposals should be assessed by FRECs.

10. Research that involves National Health Service (NHS) or Social Care Services staff or patients or tissue is subject to NHS and Social Care Governance procedures specified by the Department of Health (DoH). For NHS research, there is now a National Research Ethics Service (NRES) portal, the Integrated Research Application Service (IRAS) which provides a more integrated service for obtaining the necessary approvals. For social care research there is a national Social Care Research Ethics Committee which shares the NHS IRAS system. Both systems require that the scientific quality of research proposals is evaluated **before** external ethical approval is requested. The proposal (external application form and letter of approval) must then be submitted to the FREC Chair.

11. FRECs will operate in various ways appropriate to their constituencies, but all FRECs will provide an annual report to the UREC in the format specified in Annex 2.

Lay member

12. The University shall appoint a lay member of the UREC and provide appropriate training. He/she shall also act as a 'floating member' of all FRECs. He/she will not be required to attend all FREC meetings however he/she will be asked to comment on all proposals which FRECs believe raise significant ethical issues and/or whenever a sponsor requires approval by a lay member.

General policy on the behaviour of Committees

13. All Committees involved in the review of research ethics should be independent of the researcher(s) proposing the research. Whenever a UREC or FREC member has a research proposal considered by their Committee they should normally withdraw from discussion unless required to clarify issues for the other members.

14. Quorum for Committee meetings will be a majority of members. If there are absent members, decisions taken on research proposals can be confirmed by the Secretary obtaining agreement from sufficient absent members after the meeting. When considering research proposals Committees should strive to reach unanimity. If unanimity cannot be achieved, decisions to approve proposals will require the support of at least two thirds of the Committee membership.

15. All Committees will be multidisciplinary and their membership will take due account of equality and diversity issues.

16. Ethical review will normally take place when the research proposal has been confirmed e.g. a grant application has been approved for funding.

17. As well as the University's own policies, Committees must take into account relevant professional ethical codes and the policies of research sponsors. If there is a difference in ethical standards between the University's policy and those of the relevant professional body or research sponsor, Committees shall apply whichever is considered the highest standard of ethical practice.

18. In cases of collaborative research with other institutions, the research participation of Plymouth University members of staff must be considered by the relevant Plymouth

University REC. Ethical approval by another institution is not sufficient to allow the research to proceed.

19. Research which involves human participants will always require ethical approval. However in many cases the risks will be minimal. In such cases FRECs will be able to establish procedures for expedited review e.g. 'virtual' review by e-mail by two members of the FREC or Chair's action. The following research may involve more than minimal risk and should normally be considered by a full Committee:

    - research involving vulnerable groups – for example, children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship
    - research involving sensitive topics – for example participants' sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status
    - research involving groups where permission of a gatekeeper is normally required for initial access to members – for example, ethnic or cultural groups, native peoples or indigenous communities.
    - research involving deception or which is conducted without participants' full and informed consent at the time the study is carried out
    - research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals
    - research which would induce psychological stress, anxiety or humiliation or cause more than minimal pain
    - research involving intrusive interventions – for example, the administration of drugs or other substances, vigorous physical exercise, or techniques such as hypnotherapy.

20. FRECs should consider the potential impact of research on the environment and the questions of environmental sustainability and the sustainability of research.

21. Individual FRECs will have their procedures approved by the UREC.

Monitoring research

22. Committees must identify projects on which ethical issues raised are such that monitoring during the life of the research is required and this will become a condition of approval. Researchers will be given details of the form and frequency of the monitoring which will be proportionate to the nature and degree of risk entailed in the research.

23. FRECs **may** consider conditional approval for an application, requiring annual review and approval (or more frequently as deemed necessary by the FREC) to continue the project. If this is the case a "Continuing Review Approval Form" should be completed and submitted to the FREC.

24. It is the responsibility of the FREC to consider which projects impose a high risk from an ethical standpoint, including any reputational risk to the University and the political sensitivity of the research.

25. Details of identified high risk projects must be reported to UREC in the Annual Report.

Appeals

26. Researchers can appeal against the decisions taken by a FREC either to reject or require significant modifications to research. Initially the appeal should be to the FREC taking the decision. If this is not successful the researcher can request the appeal be considered by the UREC.

27. Appeals referred by a FREC to the UREC will be considered by a sub-committee. This sub-committee will comprise all UREC members with the exception of the FREC Chair referring the appeal for consideration. The sub-committee will receive verbal statements from the relevant FREC Chair and the project researcher. The relevant FREC Chair and project researcher will subsequently be informed in writing of the sub-committee's decision.

Whistleblowing and complaints

28. Anyone suspecting misconduct on the part of a researcher has an obligation to report this in accordance with the procedures described in the following section. Such 'whistleblowers' must not investigate or take action on their own account but must observe appropriate procedures.

29. No one reporting such suspicions shall suffer any disadvantage or action for doing so. The Public Interest Disclosure Act 1998 provides protection for the whistleblower against subsequent victimization by an employer. This protection does not extend to malicious acts of whistleblowing. The University is wholly committed to the protection of all bona fide whistleblowers whatever their status and will regard any subsequent victimization as a disciplinary offence.

30. Where there is a genuine concern about disclosing their own identity, a confidential approach may be made directly to the Dean of Research and Innovation, who will then consider whether to refer the case on through the normal procedures. Where allegations concern or involve the Dean of Research and Innovation, an approach may be made to the Deputy Vice-Chancellor for Research for consideration. Allegations raised anonymously will be considered only at the discretion of the Vice-Chancellor.

Procedure in cases of suspected research misconduct

31. Research misconduct includes the following, whether deliberate, reckless or negligent:

    - failure to obtain appropriate permission to conduct research
    - deception in relation to research proposals
    - unethical behaviour in the conduct of research (the University's policy Ethical Principles for Research Involving Human Participants applies but other ethical issues may also be involved).
    - unauthorised use of information which was acquired confidentially
    - deviation from good research practice, where this results in unreasonable risk of harm to humans, other animals or the environment
    - fabrication, falsification or corruption of research data
    - distortion of research outcomes, by distortion or omission of data that do not fit expected results
    - dishonest misinterpretation of results

- publication of data known or believed to be false or misleading
- plagiarism, or dishonest use of unacknowledged sources
- misquotation or misrepresentation of other authors
- inappropriate attribution of authorship
- fraud or other misuse of research funds or research equipment
- attempting, planning or conspiring to be involved in research misconduct
- inciting others to be involved in research misconduct
- collusion in or concealment of research misconduct by others
- failure to comply with relevant legislation, including that relating to health and safety, data protection, intellectual property and animal experimentation.

The above list is not exhaustive and other misconduct specifically related to research activity may be dealt with under this procedure.

32. The University has a responsibility to investigate allegations of research misconduct fully and expeditiously. It also has a responsibility to protect researchers from malicious, mischievous, or frivolous allegations.

33. Procedures for dealing with alleged misconduct by staff or post-graduate research students are referred to in Section 34 below.

34. Anyone who has good reason to suspect misconduct should report it in confidence as appropriate to their Head of Department/School/Graduate School, Faculty Dean or the Dean for Research and Innovation. Those who raise concerns in good faith will not be penalised in any way for doing so. The safeguards for individuals raising genuine concerns are detailed in the University's Public Interest Disclosure Procedure. Allegations should normally be made in writing, accompanied by any available supporting evidence. All allegations will be dealt with under the appropriate Plymouth University procedure (staff or student).

35. In cases where an allegation implicates someone who is not subject to the University's procedures, the Vice-Chancellor shall bring the matter to the attention of their employer or any other appropriate body.

36. Where the research is funded in whole or part by an outside grant, the Vice-Chancellor shall have regard to the guidance issued by the relevant funding body. The Vice-Chancellor shall ensure that any such body is given appropriate and timely information as to the instigation and progress of an investigation and any referral under disciplinary regulations.

37. In the event of a finding of misconduct, where the person responsible is subject to the regulation of a professional body such as the General Medical Council, the Vice-Chancellor shall consider whether it is appropriate to inform the professional body of any finding.

38. Where the person responsible has published research, especially research to which the misconduct relates, the Vice-Chancellor shall consider whether it is appropriate to inform journal editors or others of any finding.

39. If an allegation has been made publicly, the Vice-Chancellor shall consider whether it is appropriate to make public the outcome of its investigation into the matter.

40. If at any stage an allegation is found to have been malicious or mischievous in nature, the matter may result in disciplinary action being taken against those making the allegation.

Training

41. All members of UREC or FRECs will undertake appropriate training in research ethics. Training in research ethics will also be available to all staff and research students through the Staff Development Programme.

42. An induction meeting will be held for all new members of FRECs. The meeting will introduce them to the Plymouth University Code of Ethics and system of Research Governance.

43. Chairs of FRECs are appointed by the Dean of the Faculty. The Dean and the Associate Dean for Research are to brief the Chair on the responsibilities attached to the role. New Chairs will attend an induction meeting with any new members of the FRECs.

44. Online training will be provided for all new members of FRECs. It is a requirement that all new members undertake this online training during their first year of membership of the Committee.

45. Training workshops will be held at least once each year, when members of FRECs and UREC will have the opportunity to hear about and discuss issues in research ethics.

46. The University is affiliated to the Association of Research Ethics Committees (AREC). All members of FRECs and UREC have access to its journal and publications.

Good Practice in Research

47. All researchers within the University of Plymouth have a duty to society, to their profession, to the University and to those funding their research, to conduct their research in the most conscientious and responsible manner possible. The University seeks to encourage and foster an environment where good research practice is encouraged and where there is adequate mentoring and supervision at all relevant levels. It is a responsibility of Departmental/School heads and Associate Deans Research to convey clearly the standards for research in their departments and relevant areas, and to ensure that adherence to those standards is a matter of course.

48. Many professional associations and research funding bodies have ethical codes and guidelines for the conduct of research. The University would expect that compliance with this Code of Good Research Practice will meet the generic requirements of such bodies, but where additional specialist requirements are incorporated, University personnel are expected to comply as appropriate.

    This Code applies to all employees, research students and visiting researchers of the University, including persons holding honorary University appointments, conducting research within, or on behalf of, the University.

49. Professional Standards - The University expects all staff to observe the principles set down by the Nolan Committee on Standards in Public Life, namely, selflessness, integrity, objectivity, accountability, openness, honesty and leadership.

50. Honesty - At the heart of all research endeavour, regardless of discipline or institution, is the need for researchers to be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research, including experimental design, generating and analysing data, publishing results, and acknowledging the direct and indirect contributions of colleagues, collaborators and others. All University personnel must refrain from plagiarism, piracy or the fabrication of results and any instances of such acts will be taken most seriously and the relevant University disciplinary procedure invoked, if appropriate.

51. Openness - While recognising the need for researchers to protect their own research interests in the process of planning their research and obtaining their results, the University encourages researchers to be as open as possible in discussing their work with other researchers and with the public. Once results have been published, where appropriate, the University expects researchers to make available relevant data and materials to others, on request.

52. In addition, the University expects researchers to observe any appropriate standards of practice set out in guidelines published by funding bodies, scientific societies and other relevant professional bodies.

53. Leadership and co-operation in research groups - The culture of any organisation must be set by individuals in authority. Within the University, it is the responsibility of all senior staff to ensure that a climate which encourages good practice in research is maintained.

54. Within a research group, the group leader is expected to create a research environment of mutual co-operation, in which all members of a research team are encouraged to develop their skills and in which the open exchange of research ideas is fostered. They must also ensure that appropriate direction of research and supervision of researchers and research students are provided.

55. Researchers must state the funding source clearly on their proposal and must consider the ethical implications of the source of funding, including any reputational risks for the university.

56. Documenting results and storing primary data - Throughout their work, researchers are required to keep clear and accurate records of the research procedures followed and of the results obtained, including interim results. This is necessary not only as a means of demonstrating proper research practice, but also in case questions are subsequently asked about either the conduct of the research or the results obtained. For similar reasons, data generated in the course of research must be kept securely in paper or electronic form, as appropriate.

57. Publishing results - It is usually a condition of research funding that the results are published in an appropriate form, usually papers in refereed journals. This has long been widely accepted as the best system for research results to be reviewed and made available to the research community for verification or replication.

58. The issue of authorship is important in the context of good research practice. The University expects anyone listed as an author on a paper to accept personal responsibility for ensuring that they are familiar with the contents of the paper, and that they can identify their contributions to it. The practice of honorary authorship is unacceptable.

59. Acknowledging the role of collaborators and other participants - In all aspects of research, the contributions of formal collaborators and all others who directly assist or indirectly support the research must be properly acknowledged. This applies to any circumstances in which statements about the research are made, including provision of information

about the nature and process of the research, and in publishing the outcome. Failure to acknowledge the contributions of others is regarded as unprofessional conduct. Conversely, collaborators and other contributors carry their share of the responsibility for the research and its outcome.

60. The needs of new researchers - Researchers who are new to the research community may need careful briefing on the University's expectations of good research practice. Responsibility for ensuring new researchers understand good research practice lies with all members of the community, but particularly with departmental heads, group leaders and the supervisors of research students.

61. Integrity in submitting research proposals - Principal Investigators and other named investigators should take all reasonable measures to ensure the accuracy and completeness of information which is contained in applications for funding.

62. Integrity in managing research projects - Principal Investigators and other named investigators should take all reasonable measures to ensure compliance with sponsor, institutional, legal, ethical and moral obligations in managing projects.

63. Conflict of Interest - Anyone involved in any way in the conduct or management of research must identify and declare any conflicts of interest, whether legal, ethical, moral, financial, personal or other nature.

64. Research Misconduct - The University takes seriously any allegation of research misconduct and has established a procedure for dealing with such allegations.

65. Principal Investigators have a responsibility to ensure the safety and well-being of staff working on their projects. They should assess potential risks and harm and should not require any researcher to undertake research that is likely to expose them to physical or psychological harm. All researchers also have a responsibility to consider their own safety and well-being and should raise any concerns with their Principal Investigator or other research manager.

The Integrity of Research involving Human Participants

66. Informed consent - The researcher should, where possible, inform potential participants in advance of any features of the research that might reasonably be expected to influence their willingness to take part in the study.

67. Where the research topic is sensitive, the ethical protocol should include verbatim instructions for the informed consent procedure and consent should be obtained in writing.

68. Where children are concerned, informed consent may be obtained from parents or teachers acting in loco parentis, or from the children themselves if they are of sufficient understanding. However, where the topic of research is sensitive, written informed consent should be obtained from individual parents.

69. Openness and honesty - So far as possible, researchers should be open and honest about the research, its purpose and application.

70. Some types of research appear to require deception in order to achieve their scientific purpose. Deception will be approved in experimental procedures only if the following conditions are met:

- Deception is completely unavoidable if the purpose of the research is to be achieved.
- The research objective has strong scientific merit.
- Any potential harm arising from the proposed deception can be effectively neutralised or reversed by the proposed debriefing procedures (see point 78).

71. Failing to inform participants of the specific purpose of the study at the outset is not normally considered to be deception, provided that adequate informed consent and debriefing procedures are proposed.

72. Covert observation is a legitimate method of research where it is impossible to use other methods to obtain essential data. Covert research must observe current legislation on privacy. In cases of covert research in non-public settings if informed consent has not been obtained prior to the research it should be obtained post hoc wherever possible.

73. Right to withdraw - Where possible, participants should be informed at the outset of the study that they have the right to withdraw at any time without penalty.

74. In the case of children, those acting in loco parentis or the children themselves if of sufficient understanding, shall be informed of the right to withdraw from participation in the study.

75. Protection from Harm - Researchers must endeavour to protect participants from physical and psychological harm at all times during the investigation.

76. Note that where stressful or hazardous procedures are concerned, obtaining informed consent (60) whilst essential, does not absolve the researcher from responsibility for protecting the participant. In such cases, the ethical protocol must specify the means by which the participant will be protected, e.g. by the availability of qualified medical assistance.

77. Where physical or mental harm nevertheless does result from research procedure, investigators are obliged to take action to remedy the problems created.

78. Debriefing - Researchers should, where possible, provide an account of the purpose of the study as well as its procedures. If this is not possible at the outset, then ideally it should be provided on completion of the study.

79. Confidentiality - Except with the consent of the participant, researchers are required to ensure confidentiality of the participant's identity and data throughout the conduct and reporting of the research.

80. Ethical protocols may need to specify procedures for how this will be achieved. For example, transcriptions of the interviews may be encoded by the secretary so that no written record of the participant's name and data exist side by side. Where records are held on computer, the Data Protection Act also applies.

81. Ethical principles of professional bodies - This set of principles is generic and not exhaustive of considerations which apply in all disciplines. Where relevant professional bodies have published their own guidelines and principles, these must be followed and the current principles interpreted and extended as necessary in this context.

Research Involving Animal Subjects

82. Until suitable alternatives become available, use of animals is necessary in some areas of research within the biomedical and biological sciences.

83. Research on living animals is regulated by the Animals (Scientific Procedures) Act 1986 through a stringent licensing system, operated by the Home Office, controlling what can be done, where and by whom. Permission to carry out a specific research project is granted only if the potential benefits to humankind or other animals are judged to outweigh any likely animal suffering. Compliance with legislation is monitored closely through the university Animal Welfare and Ethical Review Board which reports directly to the Office of the Vice-Chancellor. It is also monitored by the Home Office through its Inspectors who make regular visits, some of which are unannounced.

84. All projects involving animal research are underpinned by a commitment to the principles of the 3Rs, and are subject to the University's ethical review process prior to authorisation by the Home Office. The Animal Welfare and Ethical Review Board includes lay representation as well as veterinary and animal care expertise as is required by law. The ethical review process also ensures that high standards of animal care, welfare and accommodation are maintained, and that persons working under the Animals (Scientific Procedures) Act receive appropriate guidance and training.

85. The University uses alternatives to animals wherever possible, such as computer modelling, tissue culture, cell and molecular biology, and research with human subjects.

General Principles of Data Confidentiality and Access

86. Researchers must ensure appropriate open access to primary data resulting from publicly funded research after its current use in research. Data relating to identifiable individuals must be held in accordance with the principles of data confidentiality legislation and any guarantees given to data subjects. Such data must be anonymised before it is made publicly available and researchers may place an embargo on access when anonymity and confidentiality cannot be guaranteed.

87. Researchers must decide what constitutes **'**primary data' in each research project. This will normally be an achievable data set, but may also include laboratory notebooks, completed questionnaires, video and audio files, and interview transcripts. Research notes do not normally constitute primary data for the purposes of this Code.

88. The University expects that primary research data is held securely for a period of ten years after the completion of a research project, or for such longer period as may be required by a research funder. The University has an obligation to ensure that appropriate storage facilities are available. Non-current primary data from research funded at the University must remain in storage at the University when a member of staff changes job to another institution.

89. Research Council requirements for the central archiving of data in electronic form must be observed.

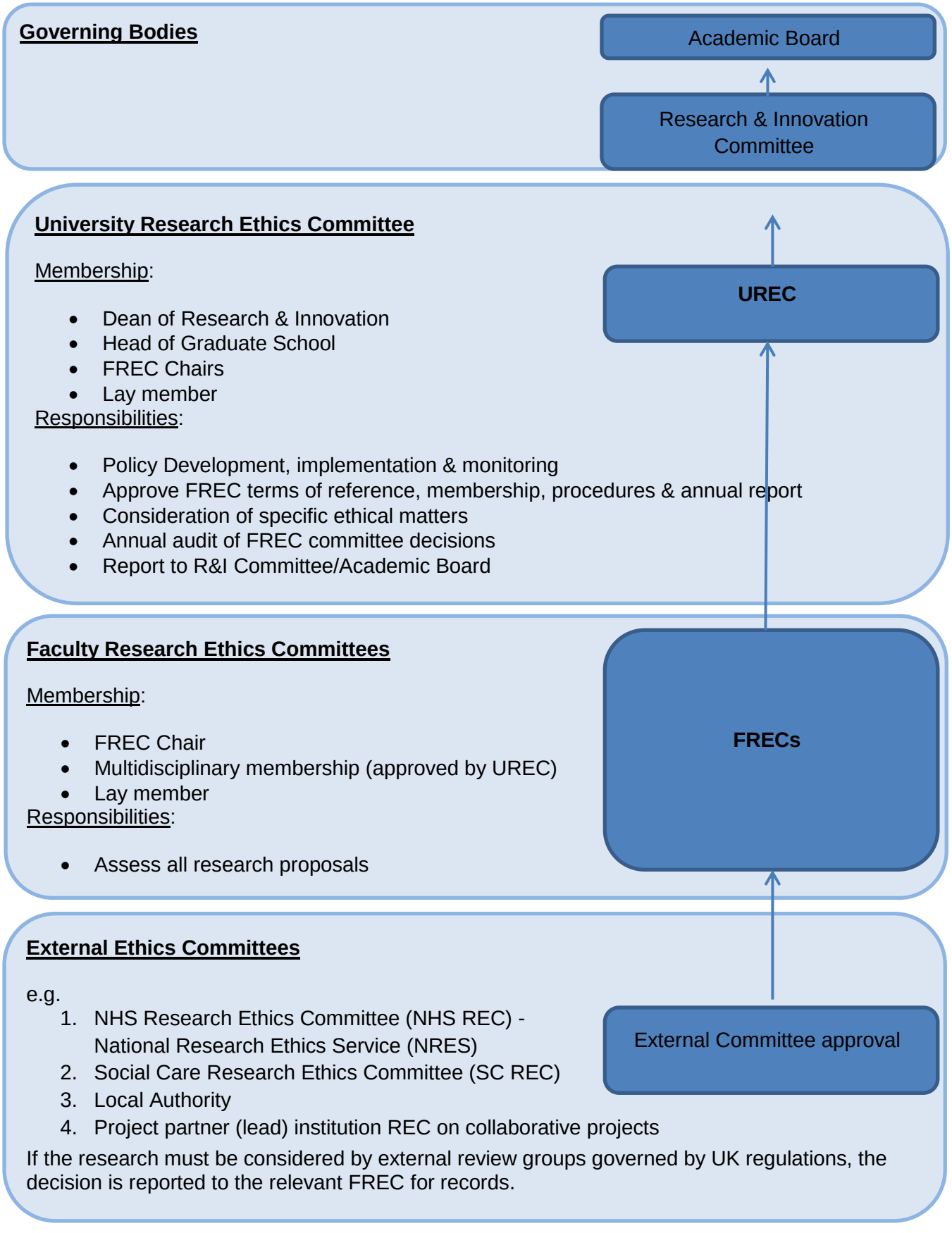
90. Publications arising from publicly funded research should be available through a system of open access wherever possible. Articles should be deposited in the University research repository (PEARL) in accordance with current guidelines and should be available through 'Gold' open access publication wherever possible. Other research reports should be available in open access form unless prevented by commercial or official secrecy requirements. Books and Chapters are not currently required to be

available in open access form, but this will be kept under review in the light of changing requirements.

91. Research activity must comply with any requirements of the Data Protection Act and the Freedom of Information Act. Due consideration must be given to any implications of Intellectual Property legislation.

Annex 1

Reporting Relationships of Committees



Annex 2

Annual reports by FRECs to the University Research Ethics Committee

1. The Chair of each Faculty Research Ethics Committee shall provide an annual report to the University Research Ethics Committee in respect of ethical issues in non-clinical research i.e. research not reviewed by an NHS ethics committee.
2. A template is provided for reports to the University Research Ethics Committee and will include the following:
    - The current Committee membership.
    - Details of any suggested or agreed changes to the approved procedures; Where appropriate, the number of cases referred to external ethics committees;
    - Where appropriate, details of high risk projects identified and under review;
    - Any issues for consideration by the University Research Ethics Committee.
    - Summary of action taken by the Faculty Research Ethics Committee including details of the number and title of applications considered by (a) expedited review and (b) full Committee review, the decisions taken and any particular difficulties encountered or consequent action taken;

3. University Research Ethics Committee will consider the annual reports, offer advice and recommendations as appropriate, and report to Academic Board on any major policy issues or outstanding difficulties.
4. Faculties with nothing to report will be required to submit a statement to that effect.