University of Chester

RESEARCH GOVERNANCE HANDBOOK

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PART I – INTRODUCTION, APPLICATION AND DEFINITION OF RESEARCH

1. In the context of this policy, research is defined in line with the Frascati manual, namely "creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications".

2. This Handbook sets out procedures for the governance of research and related activities undertaken under the auspices of the University of Chester ('the University') and seeks to ensure a consistent research framework. The principles and requirements set out in the Handbook and the associated procedures and policies therefore apply:

   2.1. to all such research undertaken by staff (including staff who hold visiting posts if the research is undertaken on behalf of, or is held out as being research of, the University) and students (undergraduate or post-graduate) of the University; and
   2.2. (where the context permits and with any necessary modifications) to scholarship, advanced scholarship and knowledge transfer undertaken as specified in paragraph 2.1.

3. The public is entitled, and the University is committed, to high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements in the governance and conduct of research. 'Governance' of research means setting standards and defining mechanisms to deliver them; monitoring and assessing arrangements; improving research quality and safeguarding the public (by enhancing ethical scientific quality, promoting good practice, reducing adverse incidents, ensuring that lessons are learned and preventing poor performance and misconduct). Proper governance of research is therefore necessary to ensure that the public and funding bodies can have confidence in and benefit from research, by seeking to:

   - protect the safety, dignity, rights and well-being of research participants;
   - promote useful, ethical, valid, safe and affordable research;
   - prevent futile, unethical, invalid, dangerous and extravagant research.

4 Faculties and Departments may supplement the guidelines in this Handbook with more detailed guidance in order more closely to reflect the specific needs of a particular academic discipline or mode of research or to meet the requirements of external organisations, such as research councils and funding or professional bodies. However, any supplementary

guidance should not derogate from the principles set out in this Handbook and should be approved by the Faculty research ethics committee.

5 All staff who are engaged or participate in or who manage the conduct of research are required to familiarise themselves with the content of this Handbook and relevant University policies on areas such as health and safety, supervision of research students, complaints procedures etc. Furthermore, professional accountability extends to ensuring a sound ethical basis for all research projects and responsibility for raising ethical concerns rests with all project staff, not just the PI or lead investigator. This includes circumstances where staff are commissioned to undertake research or consultancy work on behalf of an external body.

6 Faculty research ethics committees are responsible for ensuring informed decisions are taken on the approval of any project which involves consideration of ethical issues. A Faculty which has not established a research ethics committee should give consideration to doing so and in the meantime should submit any research project which involves consideration of ethical issues for approval by the research ethics committee of another appropriate Faculty. To avoid duplication of effort, projects must not be considered by more than one internal research ethics committee even when more than one Faculty has an interest in the project. The Chairs of the relevant committees must agree which one committee will be responsible for consideration of the project. In the event that the Chairs are unable to reach an agreement, the Pro Vice-Chancellor (Research & Knowledge Transfer) will decide which committee should consider the project.

PART II – GUIDING PRINCIPLES

7 The University is committed to upholding the principles, expectations and responsibilities set out in the Universities UK *Concordat to support research integrity*. The concordat defines the core elements of research integrity to be:

- **Honesty** in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.
- **Rigour,** in line with prevailing disciplinary norms and standards: in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.
- **Transparency and open communication** in declaring conflicts of interest; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes sharing negative results as appropriate; and in presenting the work to other researchers and to the general public.

- **Care and respect** for all participants in and subjects of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the stewardship of research and scholarship for future generations.

Responsibility within the University for oversight of research integrity rests with the Pro Vice-Chancellor (Research & Knowledge Transfer), who is the first point of contact for individuals seeking further information on matters of research integrity.

8 Research staff and students must be honest and objective 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 work, including experimental design, generating and analysing data, recognising the true cost of research, applying for funding, publishing results, recognising any real or potential conflicts of interest and acknowledging the direct or indirect contribution of colleagues, collaborators and others. Research must conform to all applicable legal and ethical requirements. These will include obtaining informed consent where necessary, appropriate screening of researchers working with vulnerable groups, protection of participant data and confidentiality and strict adherence to licensing requirements for any animal or biomedical research.

9 Research should be undertaken in accordance with commonly agreed standards of good practice, such as those laid down in the Declaration of Helsinki for the conduct of clinical research. These fundamental and widely accepted principles may broadly be categorised as:

- Beneficence – 'do positive good'
- Non-malfeasance – 'do no harm'
- Informed Consent
- Confidentiality/Anonymity

10 In assessing beneficence and non-malfeasance, relevant considerations will be risk, harm and hazards, including emotional and mental distress, and possible damage to financial and social standing, as well as physical harm. Other considerations are:

10.1 The research should be scientifically sound and the purpose should be to contribute to knowledge.

10.2 The research should be undertaken and supervised by those who are appropriately qualified and experienced. Appropriate qualifications include independence, impartiality and absence of inappropriate conflict of interest.

10.3 The importance of the objective should be in proportion to the inherent risk to the participant. Concern for the interests of the participant prevails over the interests of science and society.

10.4 The research should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the participants or to others.

10.5 Research should not be undertaken where the hazards involved are not believed to be predictable.
10.6 Adequate facilities and procedures should be in place to deal with any potential hazards.

11 Research, and those pursuing it, should respect the diverse and multicultural nature of society. Whenever relevant, research should take due account of age, disability, gender, sexual orientation, race, culture and religion in its design, undertaking and reporting. The body of research evidence available to policy makers should reflect the diversity of the population. Inclusion or exclusion of particular groups should be capable of reasoned justification. Other parties and organisations involved with the University in research projects should be committed to the promotion of equality and the avoidance of unlawful discrimination.

PART III – ETHICS, OVERSIGHT AND AUTHORISATION OF RESEARCH

Existing Research

12 All existing sources of evidence, especially systematic reviews, must be considered carefully before undertaking research. Research which duplicates other work unnecessarily, or which is not of sufficient quality to contribute something useful to existing knowledge, is unethical.

Authorisations and Regulatory Codes

13 No research requiring internal or external authorisation, consent or licence shall commence until such authorisation etc. has been granted.

14 Applicable University, Faculty and/or Departmental procedures and guidance notes for the authorisation of research must be followed before any commitment is entered into for the research to be carried out and before any of the research, or any of the steps leading to the undertaking of the research, are commenced. As indicated in paragraph 6, the research ethics committee of the relevant Faculty, where established, or of another appropriate Faculty, is responsible for ensuring informed decisions are taken on the approval of any projects involving consideration of ethical issues. Responsible members of research staff should ensure that there are satisfactory documented responses on all or any of the matters set out in paragraphs 9 and 10 above and the following:

14.1 demonstration that a project is well formulated in terms of drawing on the relevant literature;
14.2 demonstration that a project is ethically, methodologically, analytically and scientifically sound;
14.3 an outline of the nature of the research subjects and participants (including animals) and how they are to be selected;
14.4 details of the remuneration, if any, to be offered to participants;

14.5 details of any treatment, observation or other research process to be followed in respect of participants or subjects and an explanation of the hazards, dangers, discomforts or other forms of disturbance to which subjects may be directly or indirectly exposed as a result;

14.6 identification and assessment of risks in relation to the health and safety of participants or subjects, staff and other persons (these may include matters dealt with in the policies on health and safety, lone workers and field trips) and risks to property and demonstration of the steps which have been taken to minimise these risks and to deal with the possibility of untoward events;

14.7 a schedule of the main stages of the project and the timescale for their completion;

14.8 an explanation of how confidentiality will be maintained;

14.9 a copy of the proposed participant information sheet;

14.10 details of the full economic costing of the project and how this is to be funded;

14.11 confirmation of the terms and conditions of any funding and that these are not unusual or unethical, undermining of academic integrity or restrictive of the University;

14.12 details of the staff required to work on the project and whether any of these are proposed to be new appointments for which Senior Management Team approval has been obtained;

14.13 details of any specific agreements or arrangements relating to intellectual property.

Further information on many of these matters appears below. If researchers are in doubt as to what is appropriate they should seek advice from the University Research and Knowledge Transfer Office.

15 Researchers should make themselves familiar with the regulatory codes and codes of conduct and ethics relevant to their areas of research, including those of relevant professional organisations, and ensure that research which they propose is designed to comply with such codes.

Planning and Risk/Benefit Analysis

16 All potential risks of undertaking a particular research project to both participants and researchers must be identified, assessed and managed and any human participants monitored so as to keep adverse effects to a minimum. Risks must be fully explained to human potential participants before consent to participate is given. ‘Risk’ in this context includes pain, discomfort, distress, inconvenience, abstinence, changes to lifestyle and unexpected disclosure of information. The possibility of potential benefits to be derived from participation in research should be both assessed and communicated prudently and realistically to participants.

Research Involving Human Participants

17 All research involving human participants to be undertaken by staff or students of the University must be submitted to the appropriate research ethics committee or other appropriate ethical scrutiny mechanism. The term 'research involving human participants' should be taken in its broadest sense and would include the following: questionnaires, interviews, medical or clinical research, student practicals and the use of bodily materials or fluids.

18 Where a woman is to be involved as a research subject, the possibility that she is, or is about to become, pregnant should be considered.

19 Researchers should ensure the confidentiality of personal information relating to research subjects and participants and that the research fulfils the requirements of the Data Protection Act 2018 (see further the section on Data Protection in Part IX below).

20 Research participants have the right to choose whether or not to participate in research and obtaining informed consent is central to the ethical conduct of research involving human subjects (see further Part V below).

Human Tissue Act 2004

21 Research should comply with the Human Tissue Act 2004 and with any applicable guidance and codes of practice issued by the Human Tissue Authority. A licence to store human tissue for research or other purposes under the Act is likely to be required for each separate storage facility. A licence fee is payable for each licence. For the use of tissue from patients, the consent of the patient is required except in the circumstances specified in the Act, such as when a research ethics committee has agreed to the study and the samples are anonymised. For the use of tissue taken post mortem, the consent of the person concerned given before they died, or of the relatives of the deceased, must always be obtained. Agreeing to such research involves relatives in difficult choices. Arrangements must be described for the respectful and lawful disposal of material once the research is completed, and for the reporting of the findings of the research to relatives, if they wish it. The new Human Tissue Authority is responsible for regulating and giving guidance on the storage and use of human tissue and organs. See flowchart at appendix 5.

Research Involving the National Health Service

22 All research falling within paragraphs 22.1-22.7 below must be submitted to the relevant NHS Trust Research Ethics Committee before the research can begin. For information regarding access to patient records, reference should be made to paragraphs 139-142 below.

22.1 Patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It also includes NHS patients treated under contracts with private sector institutions.
22.2 Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above.
22.3 Access to data, organs or other bodily material of past and present NHS patients.
22.4 Foetal material and IVF involving NHS patients.
22.5 The recently deceased in NHS premises.

Research falling within paragraphs 22.6-22.7 below no longer requires review by an NHS Research Ethics Committee. However, approval from an appropriate University research ethics committee and the NHS R&D Office at all research sites must be obtained before the research can begin.

22.6 The use of, or potential access to, NHS premises or facilities.
22.7 NHS staff recruited as research participants by virtue of their professional role.

Details of how to apply can be found on the Health Research Authority (HRA) website (http://www.hra.nhs.uk). Researchers must follow any applicable NHS Trust consent policy before involving patients in research and the consent process must be documented in the patient records. The HRA took over responsibility from the Department of Health for the Research Governance Framework on the 1st January 2015. The Framework applies to all research in health and social care relating to the responsibilities of the Secretary of State for Health. New guidance can be found here http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/

23 From September 2013, the registration of clinical trials on a public database became a formal condition of NHS ethical approval for such projects. Please see paragraphs 91-95 for further information on registration of trials.

24 Research projects that have been approved by an NHS Research Ethics Committee are required to provide progress and end of study reports to the Committee. End of study reports will seek confirmation that declared intentions to publish have been fulfilled. It is important, therefore, that applications are realistic and do not promise forms of dissemination or publication that cannot be delivered.

Sponsorship of health-related research

25 All research projects falling under the Research Governance Framework for Health and Social Care must have a formal Sponsor. A Sponsor is an organisation or group that takes on responsibility for confirming there are proper arrangements to initiate, manage and finance a study (though need not be the funder of the study).

26 University policy is that, it will take on the role of Sponsor **only** as a last resort and so every effort should be undertaken to find suitable alternative sponsors. Further details can be found in the University's *Policy on Sponsorship of Research Projects under the Department of Health Research Governance Framework*.

Specific Approval Procedures (including research on human embryos, genetically modified organisms and food or food processes)

27 Certain types of research require specific assessment and approval procedures as set down in national guidelines. These include research involving human embryos, genetically modified organisms (including gene therapy) and xenotransplantation. Researchers intending to undertake research falling into these categories must be aware of, and follow, applicable national procedures.

Research Involving Animals

28 The use of animals in scientific procedures is regulated by the Animals (Scientific Procedures) Act 1986 and its accompanying codes of practice and processes. Animals protected under the Act are any living vertebrate other than man from the stage of its development when it becomes capable of independent feeding. Certain immature forms are also protected, together with any invertebrate of the species *Octopus vulgaris*. Procedures which the Act regulates include experimental or other scientific procedures applied to a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm.

29 Regulated procedures cannot be carried out without the grant of a licence of each person who undertakes work under the Act, of the programme of work and of the place(s) where scientific procedures are carried out. The University's premises are not licensed; regulated procedures on protected animals may not therefore be lawfully undertaken on those premises. University staff may, however, be able to apply for and obtain personal and project licences for procedures to be undertaken under the auspices and supervision of another organisation on licensed premises not owned by the University, subject in all cases to compliance with the provisions of contracts of employment governing exclusivity of service (see Appendix 1).

30 The controls in the Animals (Scientific Procedures) Act 1986 do not extend to any of the following:-

30.1 procedures applied to animals in the course of recognised veterinary, agricultural or animal husbandry practice;

30.2 ringing, tagging or marking of an animal, or application of any other humane procedure for the sole purpose of identification of protected animals, if this causes no more than momentary pain or distress and no lasting harm;

30.3 administration of materials to animals as part of a medicinal test in accordance with the provisions of Section 32 of the Medicines Act 1968;
30.4 humane killing of an animal by a method appropriate to the animal.

31 However, even in situations where the Animals (Scientific Procedures) Act 1986 does not extend specific protections, the provisions of general legislation protecting animals against unnecessary cruelty still apply (Protection of Animals Act 1911 and Animal Welfare Act 2006). Accordingly, when undertaking research which could involve the use of animals, the following principles should be followed:

31.1 replacement of animals by non-animal methods wherever possible;
31.2 reduction of numbers to the minimum necessary to obtain valid results where replacement is not possible;
31.3 refinement of all procedures to minimise adverse effects;
31.4 any animal kept for research is entitled to the best care and attention possible.

32 Research involving animals which does not fall under the Animals (Scientific Procedures) Act 1986 and its accompanying codes of practice and processes (such as behavioural or observational studies) must be submitted to the relevant University research ethics committee before the research can begin.

33 The University requires that all research involving pets or other similarly privately-owned animals should meet with legislative and regulatory requirements and be subject to ethical review (Staff/Postgraduate Faculty review; Undergraduate Departmental review). If research requires consent from pet owners (or other similarly privately-owned animals) its processes should follow standard practices of research involving human participants, i.e. to uphold the principle of informed consent, to maintain participant confidentiality and ensure appropriate data protection.

34 The University has a number of members of staff with expertise and experience in the field of animal research ethics (see Appendix 6), whom researchers may consult or co-opt during the design and review of projects involving animals. All research projects involving animal participants should be directed to specific Faculty Research Ethics Committees with the expertise necessary to review the project.

35 All students and members of staff have a duty to report all alleged research misconduct, including any breaches of the law. Any potential breaches of animal welfare laws or issues of non-compliance will be rapidly responded to. Any breaches of law or incident of non-compliance should be reported immediately to the Pro-Vice-Chancellor Research and Knowledge Transfer. See also the University's 'Public Interest Disclosure Policy'

36 Any student or member of staff of the University who has concern that such standards are not being observed in the conduct of any research project may report such concern under the provisions of the University's policies and procedure on the reporting of serious malpractice and abuse ('whistleblowing').

The Environment

37 Studies of rare animals or plants protected by law may require approval or licence by Natural England or the Marine Management Organisation (or equivalent authorities in other countries).

38 Collection of non-pest species which are not protected by law should only occur if it can be established that collection poses no threat to the population. It is an offence under the Wildlife and Countryside Act 1981 to dig up wild plants without permission of the landowner and it is an offence to collect eggs of the majority of wild birds.

39 No programme of field work should be carried out that could result in any significant deterioration in the environment of the area studied and sampled. It should be noted that any alteration to the environment is likely to result in deterioration unless it is specifically designed to improve it, for example, a conservation management programme.

Research outside England

40 Research carried out in more than one country is subject to the local ethical review regulations of each country. Research conducted outside England may also require additional approvals via an appropriate review procedure in each country where the research will take place. One of the following will apply and must be complied with in these circumstances (see Appendix 4 for a flow chart of these processes).

40.1 Where a country has independent ethical review regulations that do not recognise approval given by a research ethics committee based in England, researchers must:

- 40.1.1. obtain confirmation in writing from an appropriately experienced collaborator based in that country of the requirements of local ethical review procedures which apply to their research;
- 40.1.2. obtain ethical approval of their research via the local review procedures, as required;
- 40.1.3. obtain from the appropriate agency any relevant additional permission(s) required to undertake their research;
- 40.1.4. submit a copy of the review requirements, application(s) and approval/permission letter(s) to the relevant University research ethics committee (for information, where approval is not also being sought via the University process).

40.2 Where a country has ethical review regulations that recognise approval via specific English research ethical review processes, researchers must:

40.2.1. obtain confirmation in writing from an appropriately experienced collaborator based in that country of the English ethical review process recognised within local regulations which apply to their research;

40.2.2. obtain ethical approval for their research via the recognised English review process (e.g. University research ethics committee, NHS research ethics committee);

40.2.3. obtain from the appropriate agency any relevant additional permission(s) required to undertake their research;

40.2.4. submit a copy of the review requirements, application(s) and approval/permission letter(s) to the relevant University research ethics committee (for information, where approval is not also being sought via the University process).

40.3 Where a country has no clear research ethical review processes, researchers must:

40.3.1. obtain confirmation in writing from an appropriately experienced collaborator based in that country that no ethical review requirements exist which apply to their research;

40.3.2. obtain from the appropriate agency any relevant permission(s) required to undertake their research;

40.3.3. obtain ethical approval via the English review process that would apply to the research if it were to be undertaken in England (e.g. University research ethics committee, NHS research ethics committee);

40.3.4. submit a copy of the confirmation that no local review requirements exist, application(s) and approval/permission letter(s) to the relevant University research ethics committee (for information, where approval is not also being sought via the University process).

41 Ethical approvals provided by the University are given in accordance with the requirements of English law only. For the avoidance of doubt, although many ethical review processes within the United Kingdom (such as those for research involving the NHS) are harmonised at present, researchers have a responsibility to ensure that, where data is to be collected within the United Kingdom but in a non-English jurisdiction, they comply with any different or additional requirements in force at that time in Wales, Scotland or Northern Ireland. Further advice may be sought from the Research and Knowledge Transfer Office.

42 In the case of clinical trials, as defined by the University's insurers (see paragraph 84.3), insurance cover is available only for investigations conducted entirely within the United Kingdom and involving participants who are residents of the United Kingdom. The University, therefore, will not under any circumstances approve its staff or students to undertake a clinical trial which would involve non-UK resident persons as participants or be conducted wholly or partly overseas.

43 Where research is to be conducted overseas, researchers and research ethics committees must ensure that all data protection principles of the Data Protection Act 2018 continue to be followed (see paragraphs 132-138). For example, personal data may be transferred to a country outside the European Economic Area only if that country has a level of protection for the rights and freedoms of data subjects in relation to the processing of personal data equivalent to that in the United Kingdom.

Umbrella research programmes

44 Where a member of staff wishes to propose a broad umbrella research programme under which a number of students (undergraduate or postgraduate) would conduct individual dissertation projects that contribute to the overall programme, the following guidance should be followed by faculties and departments:

44.1 Prior to the involvement of any student, the member of staff must first obtain approval from the relevant research ethics committee for the umbrella research programme. This application for approval should make clear that the programme would be divided into independent sub-projects.
44.2 Each student should separately seek approval for the sub-project relating to his or her dissertation.
44.3 Each sub-project must be distinct and self-contained; the failure of an individual sub-project must not jeopardise the success of any other sub-project.
44.4 Where data collected for the purposes of a sub-project is also to be used within the umbrella research programme, this must be specified explicitly in participant information sheets.

University staff research projects

45 Staff research projects not requiring ethical approval should be approved via an agreed system. Records of the approvals should be kept within the Department or Faculty and reported to Research and Knowledge Transfer Office periodically.

Procedure for approval of recruitment of University staff and students to external research projects

46 The University is approached periodically by external researchers seeking to recruit University staff and/or students as participants in research projects. Regardless of the department of the University to which requests to recruit staff or students are sent initially, to ensure consistency across the institution all such requests must be forwarded to Research and Knowledge Transfer Office and are required to include the following information:

46.1 Evidence that the project has received ethical approval and a copy of the approved application for ethical review.

46.2 A rationale for the involvement specifically of University of Chester staff and/or students in the project. The rationale must demonstrate how the project will generate new data that goes beyond existing publicly available data.

46.3 A brief description of the project, including:

46.3.1. The research questions the project aims to address;

46.3.2. Who the intended participants are;

46.3.3. When recruitment would take place;

46.3.4. What participation in the project would entail;

46.3.5. The anticipated time commitment associated with participation, and the period over which this would take place;

46.3.6. The nature of the data to be collected and how this will be stored, both during the project and after it has ended;

46.3.7. How the anonymity and confidentiality of participants will be maintained in dissemination of the research.

46.4 Copies of Chester-specific project documents, including:

46.4.1. participant information sheets;

46.4.2. consent forms.

In advance of applying for ethical approval from their home institution, external researchers are encouraged to seek advice from a relevant research ethics committee of the University to ensure that participant information sheets and consent forms are tailored appropriately to be specific to the University of Chester.

46.5 Details of the intended participant recruitment methods (including copies of any advertisements) and the requested role of the University, if any, in this process. Please note that it is **not** permitted to use all staff or all student email lists to recruit participants to research projects.

46.6 Evidence that the home institution of the researcher has appropriate insurance in place to cover liability for the research.

47 Requests will be assessed by a senior officer of Research and Knowledge Transfer Office in consultation, where necessary, with the Pro Vice-Chancellor (Research & Knowledge Transfer) or other members of the University's Research Ethics Advisory Board. As part of the approval process, Research and Knowledge Transfer Office will confirm permission from the appropriate Dean or Director of the faculty or department from which the researcher intends to recruit. In the case of intended recruitment from two or more faculties or departments, permission will be sought from an appropriate member of the University senior management.

48 The approval process does not constitute ethical review of the project. Instead, it is intended to assess, inter alia, the following:

48.1 How members of the University might be affected by participation in the project and the attendant potential benefits and risks;

48.2 Resource implications for the University arising from participation by its staff or students;
48.3 Reputational benefits or risks of the University's association with the project;
48.4 Whether the University's involvement would extend beyond a gatekeeper role and, if so, the potential associated benefits and risks.

49 Once the University approves such a request the normal process would be to add a notice on the main news section of the Portal with a link to the details of the research project on the R&KT Portal pages.

Procedure for approval of recruitment of University staff and students to internal research projects

50 Where a member of the University's staff or student body wishes to recruit participants from within the University, points 42-45 above will be taken into consideration. It is acceptable for a department or faculty to approve details of the research project to be circulated internally if they are satisfied that the project meets all of the necessary ethical requirements.

Use of social media and publicly available data

51 It is increasingly likely that research participants may be recruited via social media. In such cases there needs to be clarity about who and where the participants are, how they are screened and recruited and the questions that they will be asked. Ethics Committees must ensure that these issues are given due consideration.

52 Information to be distributed via platforms such as Facebook, Instagram, Twitter or other social media should meet the same standards as that expected in traditional media. The text of posts or tweets should be submitted to the relevant ethics committee for approval.

53 Careful consideration should be given to the ethics of research conducted on materials posted on public online spaces. Care should be taken in both consent and data management processes to respect individuals and their privacy. Please refer to the RKTO Portal pages for further information on publicly available data.

External projects with University of Chester Co-Investigators

54 Where a research project led by another institution seeks to recruit University staff and/or students but involves a member of the University as Co-Investigator, the relevant research ethics committees within the University and at the institution of the Principal Investigator must agree in advance what form the ethical review of the project will take. In many cases, one ethics committee will take responsibility for undertaking the

review on behalf of all collaborating institutions, with such review to include consideration of the arrangements at each site. However, there are circumstances in which separate reviews by more than one institution may be appropriate, such as projects where participants may be subject to moderate to high risk, or where interventions vary significantly between sites.

55 In addition, the relevant University of Chester research ethics committee shall be responsible for deciding whether the project will also be required to follow the above procedure for approval of recruitment of University staff and students to external research projects.

PART IV – CONTINUING REVIEW AND FINAL REPORTING

56 If the duration of a research project is longer than one academic year, its progress should be reviewed by the Faculty research ethics committee not less frequently than annually in order to ensure that the project remains on schedule and that the University remains in compliance with any contractual or other terms and conditions to which the project is subject and is likely to continue to do so.

57 A final written report must be submitted at the end of each research project to the Research and Knowledge Transfer Office, inter alia:

57.1 indicating whether the project was completed satisfactorily or was terminated prematurely and, if the latter, the reasons for such termination;
57.2 providing a summary of the results;
57.3 giving details of any complaints received and how they were addressed;
57.4 detailing any lessons learnt which may be of general applicability.

PART V – PARTICIPANT CONSENT

Principles of Informed Consent

58 Informed consent is at the heart of ethical research. Most studies involving individuals must have appropriate arrangements for obtaining consent based on the provision of sufficient relevant information. Researchers are responsible for selecting means of communication that are most appropriate to potential participants and which ensures that they are fully informed before deciding whether or not to join a study.

59 For consent to be valid in law the person giving consent must have capacity to do so. Capacity requires the ability to comprehend and retain information relating to the decision to take part in the research. Adults are presumed to have capacity. To be valid, consent must be given voluntarily

and based on adequate information. Silence or acquiescence in taking part in a research project, where the person does not know what the research involves, is not valid consent. Researchers should avoid making assumptions about the extent of participants' knowledge.

60 The following principles apply:

60.1 Each potential participant must be adequately informed prior to commencement of the research of the aims, methods, anticipated benefits and potential hazards of the research and any discomfort it may entail.

60.2 Consent should be required in writing and records of consent should be maintained for not less than ten years from the date of the final report.

60.3 All participants should be volunteers. Considerable care should be taken where consent is sought from those in a dependent position.

60.4 It should be made clear that refusal to participate or withdrawal of consent will not lead to any adverse consequences. For example, students must be assured that any decision not to participate will not prejudice their academic progress in any way.

60.5 Where researchers wish to offer payments to participants, this must be declared to (and approved by) the reviewing research ethics committee. Exceptionally, and where justified, participants may be paid reasonable expenses and compensation for their time and trouble, but these must not be of a form, taking into account the nature and background of the participant, that they amount to an undue incentive to take a risk or could introduce bias into the sample. The details of any payments to be made to participants must be stated clearly in participant information sheets.

60.6 Consent must be obtained from a legal guardian in the case of minors or any others who do not have the legal competence to give informed consent (see further paragraphs 68-69 below).

60.7 Participants should be made aware of the procedure for making complaints.

60.8 Researchers must follow any applicable NHS Trust consent policy before involving patients in research and the consent process must be documented in the patient records.

61 Effective written consent requires as a minimum documented confirmation, signed and dated by the participant, that s/he has read and understood the participant information sheet (see paragraph 65 below) and has had the opportunity to ask questions; that s/he understands that participation is voluntary and that s/he is free to withdraw at any time, without giving any reason; and that s/he agrees to participate in the research.

62 Researchers should give consideration to how they would manage the consequences of participants exercising their right to withdraw their participation from the research.

63 Where projects undertaken by students on research methods modules draw their participants from the cohort of students on that module, the relevant faculty or department may exercise its discretion in deciding what level of ethical review and consent is required. Seeking informed consent in such cases is considered good practice and due regard must always be given to relevant professional standards and the provision for students on the module to opt-out of the group of participants without prejudice to their ability to undertake the module. The collection of a large dataset on participants that can be interrogated by students on the module in a number of different ways to form distinct projects may be deemed acceptable, provided ethical approval is given by the relevant faculty on this basis.

64 Large group or crowd observations in ethnographical, anthropological or similar settings (for example observation of football crowds) do not require participant consent. Where there is doubt as to whether participant consent should be sought in these circumstances, advice should be obtained from the Research and Knowledge Transfer Office.

Participant Information Sheets

65 Participant information sheets communicating the details above should be given to each potential participant. The information sheet is crucial. It must:

- 65.1 be written in plain language, avoiding jargon and technical concepts;
- 65.2 tell volunteers who the researcher is, why the research is being done, and what the objectives are;
- 65.3 be clear about the procedures the volunteer will undergo, or the nature of the questions to be asked;
- 65.4 be clear about the risks and what measures are being taken to minimise these; and provide advice and back-up should the volunteer feel disturbed or unwell;
- 65.5 state the remuneration or compensation to be made, if any;
- 65.6 state categorically that the volunteer may withdraw at any time without having to give a reason and without detriment to future treatment or services;
- 65.7 explain that if a participant is harmed by taking part in the research, there are no special compensation arrangements. Accordingly, the University does not accept liability for harm which does not result from its negligence and while there may be grounds for legal action if the harm results from negligence, the participant may have to incur legal costs to bring such an action.
- 65.8 include the following statement within the Participant Information Sheets and any other relevant material:

Data Management and Storage: Participants should note that data collected from this project may be retained and published in an anonymised form. By agreeing to participate in this project, you are consenting to the retention and publication of data.

66 Participants should be given time and the opportunity to discuss the information with relatives and friends and to ask questions of the researcher(s).

67 Participant Information Sheets should include details of an independent point of contact within the relevant Faculty to whom initial complaints, queries or concerns about any aspect of the research should be addressed in writing. It is recommended that the point of contact be specified by role (rather than by the name of an individual member of staff) and include a postal address and, if relevant, a generic or departmental email address.

Participants Lacking Capacity to Consent

68 Those who are unable to give consent on their own behalf are entitled to special protection. The Mental Capacity Act 2005 comes into force in 2007 and will require researchers to respect an incapacitated person's previous wishes and to consult someone, such a carer, who is able to take an independent view of that person's interests, wishes and feelings. Care is needed when seeking consent from children and from vulnerable adults, such as those with mental health problems or learning difficulties. Arrangements must be made to ensure that relevant information is provided in appropriate written or pictorial form and that the role and responsibilities of parents, carers or supporters are clearly explained and understood.

69 Further advice on the involvement of children in research and how consent should be obtained is available in the Medical Research Council Ethics Guide 'Medical Research Involving Children' (2004) available at http://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/ and the Royal College of Paediatrics and Child Health website at http://www.rcpch.ac.uk. In particular, the MREC guidelines stress that children should only be research participants when it is absolutely essential and the information cannot be gained from adults.

PART VI – ADMINISTRATIVE AND FINANCIAL MATTERS

Record of Researchers

70 The University will maintain records of all students and staff authorised to conduct research under its auspices.

Third Party Funding

71 The decision as to whether to accept funds from a particular source is one which, in most normal circumstances, should be taken at Faculty level, with individual researchers exercising their own judgement, having consulted the Dean of Faculty. Nevertheless, Faculties have a responsibility to endeavour to ensure that applications are not submitted to, or funds received from, dubious or questionable sources by ensuring that they have in place appropriate mechanisms for the scrutiny of applications for external research funding prior to submission.

72 Faculties, Departments and individual researchers should not accept research funding from a sponsor where the nature of the research and/or the association with the sponsor are likely to bring the name of the University into disrepute or (notwithstanding paragraph 73 below) the terms to which funding is subject are unusual, might undermine the academic integrity of the research or may require researchers to act unethically.

73 Accordingly, whilst Faculties and individual researchers should be sensitive to the views of other major sponsors on whom the University depends for research funds, there must be no restriction on the freedom to interpret or publish findings, unless agreed between the researcher and the sponsor at the commencement of the research.

74 All funding of research must conform to the University's financial policies and procedures including, but without limitation, the adequacy of such funding to support the research and authorisation of grant applications, award letters and contracts.

Documentation and Contractual Compliance

75 It is essential that clear documentation is kept in respect of each research project. This will apply particularly where researchers are employed by more than one organisation, work takes place on sites not owned by the University and/or there is more than one funder. Key submissions, approvals and decisions in respect of research, and any amendments thereof, must be systematically documented and securely stored. External funders will have their own unique terms and conditions, application forms and procedures and project proposals should take full account of these and supply complete and accurate information.

76 The provision by other parties of services, resources or other support in respect of a research project should be documented in an enforceable agreement which clearly defines each party's rights and obligations and is signed by or on behalf of all parties before the University undertakes any commitment in respect of the project. Research grants and contracts shall be accepted on behalf of the University by the Vice-Chancellor.

77 Any key obligations applicable to funding or to contracts with third parties – for example, conclusion of the research and delivery of a final report by a specified date – should be carefully noted and systems put in place to

ensure compliance in order to avoid the University becoming liable for damages for breach of contract or other penalties and/or being unable to recover research grant funds.

Contract languages

78 The University has limited resources to process contracts not written in English. Therefore, it is a requirement that all contracts (or similar legal documents) relating to the procurement or supply of goods or services must normally by written in English. Exceptionally, contracts in one of the following languages may be acceptable: Welsh, French, German, Spanish.

Full Economic Costing

79 The University has a responsibility to ensure that all research to which it allocates resources in any way is a proper use of those resources and of charitable funds and that it provides value for money. This should be confirmed by the supervisor of a project.

80 Each proposed research project must be costed according to the full economic costing model, which requires the assessment of all direct and indirect costs, including space/estates charges, the cost of all academic and support staff working on the project and adequate recurring investment for infrastructure. Resources are also required for dissemination and publication of results and should be built into costings. All costings must be submitted for approval to the Research and Knowledge Transfer Office using the pro forma designed for this purpose prior to their submission to funding bodies or other partners for consideration.

Budgetary Arrangements

81 Each grant or contract will have a named supervisor or grant holder and will be assigned to a specific budget centre. Control of pay and non-pay expenditure will be contained within the budget centre. All orders for goods and services must be on official University documentation with the appropriate signatories. The head of the budget centre may delegate day-to-day control of the account to a supervisor or grant holder, but any overspend or under-recovery of overheads is to be the clear responsibility of the budget centre with any loss being a charge on departmental funds.

82 Funders' regulations may vary, but in general the allocation of funding for an externally funded research project cannot be varied from the budget headings included in the grant application unless prior permission is obtained from the funder. Funds supplied for a specific research project may only be used for items required for that specific project.

83 Research should be undertaken with financial probity and in compliance with rules set out by HM Treasury and the University's own financial regulations. Any student or member of staff of the University who has

concern that such standards are not being observed in the conduct of any research project may report such concern under the provisions of the University's policies and procedure on the reporting of serious malpractice and abuse ('whistleblowing').

Legal Liability and Insurance

84 The University must be able to compensate anyone harmed as a result of its negligence or other breach of duty and for this purpose it maintains, inter alia, the insurances listed in paragraphs 84.1-84.3 below. The insurance cover provided is subject to the detailed terms, conditions and exclusions in the relevant policy and its inclusion in this Handbook is for information only. In cases of doubt, the advice of the Director of Legal Services (SPVC) should be obtained.

84.1 Public liability insurance: insurers may indemnify the University and specified others, including students and employees, against legal liability for damages in respect of accidental bodily injury, death, disease or illness of any person (excluding persons participating in clinical trials, as to which see paragraph 84.3).

84.2 Professional indemnity insurance: insurers may indemnify the University against legal liability for damages in respect of claims arising from the University's acts, neglects, errors or omissions occurring or committed in good faith (excluding liability arising from participation in clinical trials).

84.3 Clinical trials insurance: insurers may indemnify the University and specified others, including students and employees, against legal liability for damages in respect of accidental injury to any research subject arising out the undertaking of any investigation or series of investigations conducted by the University in the United Kingdom on any person for a medicinal purpose (as defined in the policy). This insurance specifically excludes liability which the University has agreed to accept unless the University would have been liable in the absence of agreement.

85 University staff 'contracted' to work on others' research, for example a clinical trial for the NHS, rather than the University, must ensure that the NHS will indemnify them for liability they may incur whilst working on such trials.

Non-Negligent Harm

86 The University will not under any circumstances agree to accept liability to compensate any person for harm which does not result from the negligence of, or other legal cause of action attributable to, the University (often referred to as 'non-negligent harm' or 'no-fault liability'). Accordingly, the University must not engage in any research project which requires it

to agree either to accept such liability or to indemnify other persons or organisations against such claims.

Risk Assessments

87 An appropriate assessment of risk should form part of the planning for all research projects. All ethical review or other approval processes should include an assessment of risk, both to the researcher themselves and to any participants or other third parties. Risk assessments for individual projects may range from reference to standard departmental or laboratory risk assessments for desk or laboratory based research, to specific risk assessments carried out using the standard procedures for projects involving travel abroad or field trips, for example. Further advice is available from the Research and Knowledge Transfer Office or the Director of Legal Services' Office (SPVC) (see also paragraphs 100-103).

Open access publishing

88 The University expects that academic merit should normally drive decisions on how and where to publish. Where the chosen publisher offers an open access option (whether Gold or Green route), the University encourages researchers to take advantage of this, where appropriate.

89 Many research funders, including the UK research councils, the Wellcome Trust and the European Commission, require grant holders to make the articles arising from the work they fund available free of charge to all readers. Where funders have requirements of this kind, researchers may comply either by publishing their articles in open access journals (where articles are made available free of charge to readers upon publication, usually in return for the payment of a fee by the author – so called 'Gold' route to open access) or by depositing copies of the full text of articles in the University's institutional repository, ChesterRep ('Green' route). Guidance on depositing articles in ChesterRep, and complying with publishers' restrictions, is available from the Institutional Repository Manager, Learning and Information Systems.

90 When considering publication in an open access journal, researchers should note the following:

90.1 At present, the University does not normally contribute from its own funds towards the cost of open access publishing. Where a member of staff considers there may be a special case which merits an exception to this policy, they should seek prior approval from the Research and Knowledge Transfer Office.

90.2 If a specific external grant application foresees the need to publish in an open access medium, and if the funder is willing to pay the extra costs of the publication within the grant awarded, then the University is prepared to process the payment of the open access charge.

90.3 Where funders are willing to fund open access publication costs, this is often restricted to costs incurred during the period of the grant. Costs that will be incurred after the project and grant have ended – as would often be the case with publication costs – may not be eligible for funding. Further advice on cost eligibility is available from the Research and Knowledge Transfer Office.

Registration of health-related research studies

91 Any study registered in the University's name on a publicly-available database must be included on a single 'preferred' register. This is intended to provide data consistency but not to preclude additional registration on alternative registers where this is required (or funded) by an external agency. ClinicalTrials.gov is currently designated as the University's preferred register.

92 ClinicalTrials.gov is free to use, and the University holds an institutional account on its Protocol Registration System (PRS). Studies for which the University is acting as Sponsor can be registered on the site either by the Research and Knowledge Transfer Office or, after having requested an individual user account from the Research and Knowledge Transfer Office, by the study's Chief Investigator.

93 All studies meeting the Health Research Authority or International Committee of Medical Journal Editors definition of a clinical trial must be registered on ClinicalTrials.gov prior to recruitment of the first participant.

94 All studies required by an external agency to be conducted in accordance with the Declaration of Helsinki must be registered on ClinicalTrials.gov prior to recruitment of the first participant.

95 Other observational (or non-interventional) studies may be registered on ClinicalTrials.gov upon the request of the Chief Investigator.

PART VII – RIGHTS AND DUTIES IN EMPLOYMENT AND RESEARCH MISCONDUCT

Appointing Staff

96 The University's human resource management services procedures for the appointment of staff must be followed, including, when vacancies arise, the preparation of detailed job descriptions and person specifications and use of open and non-discriminatory appointment procedures, so as to define the ideal candidate fairly and objectively, to help ensure that the University discharges its duty to promote equality between different equality target groups and that it operates within the law. Sponsors or funders of research should not have control over University appointments.

Duties, Supervision and Staff Development

97 The supervisor of a research project shall ensure that the specific duties of the members of the research team are documented and communicated to each member and that academic staff who supervise research projects and the training of students undertaking them are competent to do so.

98 The University and its Faculties will ensure that research and academic staff are adequately trained and that appropriate procedures and mechanisms are in place for the mentoring of research staff. This will include ensuring that researchers are aware of their responsibilities not only for the conduct of their research, but also to their colleagues and the wider community.

Criminal Records Checks

99 The advice of the University's Institutional Compliance Officer should be sought in good time in advance of the commencement of a research project as to whether the involvement in the project of any individual researcher requires an appropriate Disclosure and Barring Service check.

Health and Safety

100 Researchers should consider health and safety issues during the research planning stages. Research may involve the use of potentially dangerous or harmful equipment, processes, substances or organisms. The safety of participants and of research and other staff must be given priority at all times and health and safety regulations must be strictly observed – including the provision of information, containment, shielding and monitoring and the safety of those working alone on or off University premises. Prior to the commencement of fieldwork, risks to the personal safety of employees and others must be assessed and recorded and measures identified to reduce such risks to safe levels. Individual members of staff, as well as the University itself, have a statutory duty under the Health and Safety at Work etc Act 1974 to take reasonable care for their own health and safety and that of fellow workers and students.

101 Regulations of general application which may be relevant include:

Management of Health and Safety at Work Regulations 1999 (SI No 3242)
Workplace (Health, Safety & Welfare) Regulations 1992 (SI No 3004)
Manual Handling Operations Regulations 1992 (SI No 2793)
Personal Protective Equipment at Work Regulations 1992 (SI No 2966)
Provision and Use of Work Equipment Regulations 1998 (SI No 2306)
Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995 (SI No 3163)
Control of Substances Hazardous to Health Regulations 2002 (SI No 2677)

102 Where equipment or facilities are accessible to staff of both the University and a partner (for example an NHS Trust), common rules governing safe working practices will be adopted. Where the regulations applicable to Trust and University employees, equipment or facilities differ, the regulations of the party employing the persons concerned or owning that equipment or facility will apply.

103 Further advice may be obtained from the University's Director of Human Resource Management Services and the Health and Safety Adviser.

National Health Service Honorary Contracts

104 Anyone who is not employed by an NHS Trust but who requires access to patients of the Trust or their relatives, or organs, tissues or information relating to such patients or relatives, must hold an honorary contract with the Trust. This applies to all categories of staff including doctors, nurses, allied health professionals, scientists, managers, technical and administrative or clerical staff. Trusts endeavour to ensure that applications for honorary contracts will normally be processed within four weeks of receiving the complete necessary documentation but University staff should be aware that the issue of an honorary contract is not a formality.

Research Misconduct

105 Those involved in undertaking research must abide by the policies regarding research misconduct of both the University and, if different, any sponsor or other third party (such as an NHS Trust) for whom the research is being carried out.

106 All employees have a duty to report examples and suspicions of misconduct. For the avoidance of doubt, research misconduct does not include honest error or honest differences in the design, execution or interpretation or judgement in evaluating research methods or results. Examples of research misconduct include (without limitation) the following:

106.1 Failure to comply with policies of the University (including this Handbook) and, if applicable, those of third parties according to which the research is to be conducted.
106.2 Failure to obtain appropriate authorisation to conduct research.
106.3 Abuse of research subjects or materials.
106.4 Senior staff unreasonably pressurising junior staff, for example to 'cut corners' to meet deadlines or to analyse or interpret data in a particular way.
106.5 Fabrication, falsification, plagiarism or deception in applying for funding, proposing, carrying out or reporting results of research.
106.6 Forgery of whatever nature.
106.7 Deliberate, dangerous or negligent deviations from accepted practice in carrying out research (such as lack of informed

consent), including failure to follow established protocols if this failure results in the risk of unacceptable harm.

106.8 Misuse of personal data.

106.9 Distortion, misrepresentation or suppression of research data.

106.10 Inappropriate attribution of authorship.

106.11 Misquotation or misrepresentation of other authors.

106.12 Use or disclosure of information in breach of an obligation of confidentiality or of the Data Protection Act 2018.

106.13 Use of information sources, including the Internet, in a way which breaches relevant rules, policies or codes of conduct.

106.14 Fraud or other misuse of research funds, resources, facilities or equipment.

106.15 Failure to recognise and declare competing interests or misrepresentation of interests.

106.16 Exaggeration or falsification of expense claims, claims for costs or expenses not incurred or any form of false accounting.

106.17 Facilitation of misconduct in research by, for example, collusion or concealment of such action by others.

107 Where research misconduct is alleged against a member of staff or research student of the University, such allegations will be investigated in accordance with the *Procedure for the Investigation of Misconduct in Research* published by the UK Research Integrity Office and, where necessary, dealt with in accordance with the University's staff or student disciplinary rules and procedure. The *Procedure for the Investigation of Misconduct in Research* is available on the Research and Knowledge Transfer Office Portal pages. Allegations of research misconduct against a member of staff or research student should be submitted to the Dean of Academic Quality and Enhancement (or, in their absence or where there may be a conflict of interest, to the Dean of Students).

108 Allegations of research misconduct against students on taught programmes fall under the University's academic malpractice procedures and should be submitted to the chair of the relevant Subject (or Programme) Assessment Board.

109 If an allegation of research misconduct involves NHS patients, it will also be investigated by the relevant Trust under the terms of its own policies. Employees of the University must co-operate with any properly constituted investigation of allegations of misconduct.

110 The University is required to report scientific misconduct concerning an academic or researcher to Research Councils UK and may also be required to report research misconduct to statutory bodies or other agencies whose role includes oversight of the proper conduct of research, sponsors and/or other third parties in accordance with the terms governing the funding of a research project.

111 Where an allegation of research misconduct is upheld, the University reserves the right to refuse to endorse any future funding applications by the individual, or individuals, involved.

PART VIII – INTELLECTUAL PROPERTY

General

112 Intellectual property (IP) includes patents, copyright (including computer programs), designs, trademarks, semi-conductor topography, plant variety rights and confidential information and know-how. Wherever possible the University wishes to see its IP protected so that it may be developed and exploited for the general benefit of the community and for the financial benefit of the University and its research sponsors. It is the responsibility of researchers to identify any IP issues relating to their particular research project. It should not be assumed that IP issues will arise in relation to every piece of research.

Arrangements between the University and Its Staff and Students

113 Under English law, inventions and other IP made in the course of a person's normal employment belong to the employing organisation. The contract of employment between the University and academic staff accordingly contains terms providing for the ownership by the University of IP created by researchers in the course of their research which will apply in the absence of specific agreement to the contrary. These are set out in Appendix 1.

114 Except in the case of students supported by outside bodies where specific provisions relating to IP are embodied in the conditions of the support, all postgraduate students are required to agree to assign to the University all their rights to IP arising from their studies or research at the University, to be managed by the University in accordance with its normal custom and practice.

Arrangements between the University and Partner Organisations

115 When IP is generated by joint research between the University and other bodies (for example the NHS), then in order to ensure an outcome which will be fair for both organisations and lead to greatest return, the organisations together should decide:

115.1 who owns the IP;
115.2 who is to manage the IP and how costs are to be met;
115.3 how any derived benefit is to be shared.

116 Such arrangements should operate even if the originator of the IP (the inventor) is solely employed by one organisation. It is often the case that the other makes an indirect contribution to the employment costs as well as a direct contribution to the research costs and so contributes to the development of the IP.

117 Both parties should endeavour to agree ownership and details of revenue-sharing well before any financial benefit is derived, preferably at the initial contract or research proposal stage. Considerations to be taken into account leading to a decision on ownership should include:

117.1 employment status and sources of funding of the inventor;
117.2 contribution to funding of the research activity by each party;
117.3 contribution to and ownership of background and foreground IP.

118 In making the decision the organisations should recognise that if they agree joint ownership of IP with commercial value then one organisation should be given exclusive rights to exploit. The party owning the IP should enter into an agreement with the other party which should include:

118.1 a royalty-free licence to the other party allowing use of the IP for further research;
118.2 a commitment to use best endeavours to exploit the IP;
118.3 a commitment to share benefit on fair terms;
118.4 an agreement to offer assignment of the IP if the party owning the IP fails to exploit.

119 Management of IP, including the responsibilities for meeting the costs of exploiting the IP, should be agreed by both parties.

120 It is by no means certain that IP will exist and, if it does, that it will be successfully exploited, but when it is the parties should agree how the benefit, less the costs of exploitation, will be shared between them. Considerations should include the contribution of each party in its support of the research and the researchers.

PART IX – RESULTS, PUBLICATION AND CONFIDENTIALITY (INCLUDING FREEDOM OF INFORMATION AND DATA PROTECTION)

General Principles

121 The following principles govern the potentially conflicting imperatives of openness and protection of privacy.

121.1 The appropriate use and protection of research participant personal data is paramount. Particular attention must be given to systems for ensuring confidentiality of such personal data and to the security of those systems and to the anonymisation of

research findings. Details that would allow individuals to be identified should not be published, or made available, to anybody not involved in the research unless explicit consent is given by the individuals concerned, or such information is already in the public domain.

121.2 Clear and accurate research records should be kept.

121.3 Those conducting research should open their work to critical review through appropriate professional channels.

121.4 Holders of public office should be as open as possible about all the decisions and actions that they take.

121.5 Research activities are no different in principle from any other public activity and may be subject to Freedom of Information Act requests.

121.6 Commercial confidentiality may affect when and how the above principles will apply to any particular research project.

Openness

122 One of the principles of public life is that holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands. Accordingly, information about non-confidential and non-commercial aspects of research activity should normally be in the public domain. There should be free access to information both on research being conducted and on the findings of the research – positive or negative – once these have been subjected to appropriate scientific review. This information should be presented in a format understandable to the public. Reports should be comprehensible and take language and other needs into account.

Records

123 Researchers should keep clear and accurate records of the procedures and methodologies followed during the research process, any interim results obtained and the results of the final outcomes. This is necessary not only as a means of demonstrating proper practice, but also in case questions are subsequently asked about the conduct of the research, the results obtained or applications for IP protection. Researchers should be aware that the data generated are the property of the University. Data generated in the course of research should be kept securely in paper or electronic format as appropriate for a minimum of ten years from the date of final publication. ‘Data’ in this context includes findings and analysis but excludes samples, arrangements for the disposal of which must be lawful and in accordance with any regulatory requirements or guidance and undertakings given at the start of the research.

124 Researchers should exercise caution when collecting data via the internet and, in particular, in the use of web crawlers to collect data automatically from websites. Although the automatic collection of data for research or

private study for a non-commercial purpose is considered to be permitted within relevant legislation, there is currently no case law in this area. The costs to the University in defending itself against a legal challenge from an organisation opposed to the automatic collection of data from its website could be significant. Therefore, advice must be sought from the Research and Knowledge Transfer Office by any researcher considering the use of web crawlers in data collection.

Publication of Results

125 All those conducting research must open their work to critical review through appropriate professional channels. Once established, findings must be made accessible to those participating (including relatives of any deceased patients who have consented to the use of organs or tissue in the research) and to all those who could benefit from them. This may be through publication and/or other means appropriate to the type of research and in accordance with any contractual terms which govern publication or dissemination of results. Data relevant to findings should also be accessible, subject to any prior necessary anonymisation.

126 Results should be published in an appropriate form and context, usually as papers in refereed journals. Attribution of authorship requires that those identified as authors have either performed the work or made a significant intellectual contribution to it, have read and approved the paper prior to submission and are willing to stand by the results. Mere possession of an institutional position, such as a chair, does not justify authorship credit. Minor contributions to the research or to the writing for publications should be acknowledged appropriately, such as in footnotes or in an introductory statement. Similarly, the contributions of formal collaborators and all others who directly assist or indirectly support the research should be properly acknowledged. If further clarification is required, reference may be made to the guidelines on the attribution of authorship in the Ethical Considerations in the Conduct and Reporting of Research which forms part of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication of the International Committee of Medical Journal Editors (formerly 'the Vancouver Group'), available at http://icmje.org/about-icmje/faqs/icmje-recommendations/. Researchers are referred to the various examples of research misconduct given in Part VII above for practices to be avoided in relation to publication or attribution.

127 In considering and selecting an appropriate context for publication, staff should use their best endeavours to ensure that their research is not published in any forum which would bring the University into disrepute. Such fora may include personal individual or shared external websites (unless there is no reference to the University) and, depending upon the context and research content, non-refereed journals. Where there is doubt as to whether a forum for publication is appropriate, advice should be sought from the Research and Knowledge Transfer Office.

128 Some advances need to be developed commercially if they are to be made widely available. Successful commercial development may depend upon the protection of IP and/or commercial confidentiality at critical points in the innovation process. The timing of the publication of research findings needs to take account of this if the right to IP protection is not to be lost.

129 The following particular factors should be considered where appropriate.

129.1 The possible impact of publication on others, for example the impact of medical research on patients suffering from a condition which is the subject of the research.

129.2 The law of defamation, where a statement is to be published relating to a living individual which tends to lower that person in the estimation of society generally or which may adversely affect their reputation.

129.3 The law relating to diversity and equality, where the University is subject to legal duties to avoid unlawful discrimination and to promote equality of opportunity and good relations between persons of different racial groups, between men and women and between those who are disabled and those who are not.

Google Docs

130 Google Docs is a password protected web-based facility from Google which allows documents to be edited in real time. Staff using Google Docs for collaborative research or knowledge transfer activity should note that the Google Docs Privacy Policy states that “some features (e.g., gadgets) are provided by third parties, who may receive and process your data. When you use one of these features, you may be sharing data with the third party, including allowing the third party to process your data. Access to your data by these third parties is not governed by [the Google Docs] Privacy Policy”. Staff using such features should check the terms of use for the feature carefully to ensure that its use does not grant any licence to the third party to use or distribute data or posted material for any purpose other than enabling the third party to provide the feature. Similar caution must be exercised when posting work on any other web-based service where it is not clear that ownership of data and all intellectual property rights remain with the author. The full Terms and Conditions of Use and Privacy Policy for Google Docs are available at http://www.google.com/google-d-s/intl/en/terms.html.

Freedom of Information Act 2000

131 Research activities are subject to requests under the Freedom of Information Act 2000 and do not differ in principle in this context from any other university activity. Staff must be aware that any written request for information is a legitimate request, even if it does not expressly refer to the Act, as the University is legally obliged to comply with requests within twenty working days. The University receives occasional requests for information from a variety of sources, including private individuals and local

and national media. Those that are clearly marked as requests under the Freedom of Information Act are normally referred directly to the Institutional Compliance Officer. Where a written request is received which appears to exceed normal or everyday requests for information, the Institutional Compliance Officer should be consulted. Information may be exempt, for example, if it is personal data, information intended for future publication, information provided in confidence or information the disclosure of which might affect a person's health and safety or commercial interests. An appropriate response to a request may be no more than to give the title of the project, a brief lay-person's summary of its aims and objectives and the names of the principal investigator and funder(s).

Data Protection

132 University staff and others who process or use any personal data must ensure at all times that they follow the data protection principles specified in the Data Protection Act 2018 relevant to research. If necessary, advice should be taken from the Institutional Compliance Officer.

133 'Personal data' means information which relates to a living individual who can be identified from that information or from that information together with other information in the possession of the data controller (the University). 'Processing' has a wide meaning, which includes obtaining, recording or holding the information or data or sharing it with or disclosing it to others. Data protection should be assumed to apply to all computerised and manual records of personal data, including material in filing cabinets, interview tapes or disks (both audio and audiovisual), schedules and questionnaires.

134 In summary, the data protection principles require personal data to be:

134.1 obtained and processed fairly and lawfully and not to be processed unless certain conditions are met. The most important of these conditions for research purposes is likely to be that the data subject has given consent to the processing of the data. Where data include 'sensitive personal data' – this includes matters such as physical or mental health, racial or ethnic origin, political or religious beliefs, trade union membership, or criminal records – 'explicit' consent from the data subject to the processing of that data is required;

134.2 obtained for a specified and lawful purpose and not to be processed in any manner incompatible with that purpose;

134.3 adequate, relevant and not excessive for those purposes;

134.4 accurate and kept up to date;

134.5 not kept for longer than is necessary for that purpose (personal data which are processed only for research purposes may be kept indefinitely);

134.6 processed in accordance with the data subject's rights;

134.7 kept safe from unauthorised access, accidental loss or destruction;

134.8 permitted to be transferred to a country outside the European Economic Area only if that country has equivalent levels of protection for personal data.

135 All research projects should conform with these principles, which, inter alia, require the following:

135.1 If personal data are stored on a computer or computer network, access to the computer or network must be appropriately protected. Before a computer is disposed of, or passed to another person outside the research project, all personal information stored on the computer must first have been deleted. Paper-based records should be stored in secure, locked cabinets.

135.2 Care must be taken where data collected for one study or purpose are intended to be used for another study or purpose. Such use, without a further consent being obtained for the subsequent use or purpose, may not comply with the data protection principles.

136 The Data Protection Act gives people who are the subject of data the right to access the information about them. Processing of data for research purposes may be exempt from this right of access and from the provisions on further processing of data obtained for another purpose and retention only for so long as may be necessary, provided that the data are not processed to support decisions with respect to particular individuals and are not processed in such a way that substantial damage or distress is likely to be caused to any data subject.

137 Data collected in the course of research must be retained for a minimum period of ten years from the date of final publication in order to allow further analysis by the original or other research teams subject to consent, and to support monitoring by regulatory and other authorities.

138 Under the Data Protection Act, the University, as a data controller, is required to register with the Information Commissioner details of the processing of personal data by the University. The University's registration number on the Data Protection Register is Z6820275.

NHS Patient Information

139 Researchers must follow the relevant NHS Trust's consent policies before involving patients in research (see paragraph 22 above). They must ensure that the consent process is documented in the patient records.

140 'Caldicott Guardian' approval may be required. Every NHS Trust has a Caldicott Guardian, often the Medical Director of the Trust. The Guardian's key responsibilities are to oversee how staff use personal health information and ensure that patients' rights to confidentiality are respected. NHS Trust employees and those with NHS honorary contracts proposing to use patient-identifiable information are required to observe the following six Caldicott Principles for handling such information, compliance with

which will be key indicators governing the Guardian's decision on whether to give approval:

140.1 Justify the purpose(s)
140.2 Do not use patient-identifiable information unless it is absolutely necessary
140.3 Use the minimum necessary patient-identifiable information
140.4 Access to patient-identifiable information should be on a strict need-to-know basis
140.5 Everyone should be aware of their responsibilities
140.6 Understand and comply with the law

141 Information obtained by NHS Trusts for the purpose of providing healthcare is governed by the Access to Health Records Act 1990, the Data Protection Act 2018 and by the common law of confidentiality. Researchers have no right of access to patient-identifiable information unless given explicit consent by the patient or their legal representative where the patient is not competent to give such consent. Anonymised, unlinked data may be used for research without explicit consent from patients provided this has been approved by an NHS ethics committee and by the Trust. Where there is no explicit consent, such access is subject to permission from the NHS Patient Information Advisory Group in addition to ethical and Trust approval.

142 Researchers who are not employed by the relevant Trust must hold an honorary contract and be bound by conditions of confidentiality before they may have access to patient records. Researchers and support workers who do not hold honorary contracts may only be given access to anonymised, unlinked data from which it would be impossible to identify the original patient.

PART X – COMPLAINTS AND INCIDENT REPORTING

143 Informal advice on reporting research misconduct or other concerns about a research project may be sought from the Research and Knowledge Transfer Office.

144 Information seeking the consent of potential participants in a research project should include details of an independent point of contact within the relevant Faculty to whom initial complaints, queries or concerns about any aspect of the research should be addressed in writing. It is recommended that the point of contact be specified by role (rather than by the name of an individual member of staff) and include a postal address and, if relevant, a generic or departmental email address.

145 Formal allegations of research misconduct against a member of staff or research student should be made in writing to the Dean of Academic Quality and Enhancement, or, in their absence, to the Dean of Students.

146 Formal allegations of research misconduct against a student on a taught programme should be made to the Chair of the relevant Subject (or Programme) Assessment Board.

147 Where a complaint about the conduct of a research project is not a formal allegation of research misconduct, students should use the student complaints procedure and members of staff the staff grievance procedure.

148 Research involving an NHS Trust is likely to be covered by the Trust's policy on reporting research-related adverse events to participants. Staff should make themselves aware of and abide by the Trust's Incident Reporting Policy and Procedure (and any similar procedure which may apply to research in which other organisations are involved).

149 The supervisor of any research project must notify any apparent or reported physical harm to a human participant or damage to any property arising from a research project to the Dean of the relevant Faculty, who should in turn notify the Director of Legal Services (SPVC) who is responsible for communication with the University's insurers.

150 The final written report on a research project must contain a section on any complaints received, how they were addressed and any lessons learnt which may be of general applicability.

PART XI – FURTHER DEVELOPMENT OF RESEARCH GOVERNANCE HANDBOOK

151 This Research Governance Handbook will be updated from time to time in the light of matters such as legislative change, developments in best practice and the requirements of Government Departments, Research Councils, funding bodies and other external organisations and in the light of enhanced knowledge and experience of the research community, including staff and research participants and subjects. Any individual or organisation wishing to contribute to that updating process is invited to send their ideas or suggestions to the following address:

The Research and Knowledge Transfer Office
University of Chester
Parkgate Road
Chester CH1 4BJ
United Kingdom
Or by email to: researchoffice@chester.ac.uk

Appendix 1 University Staff and Intellectual Property

EXCLUSIVITY OF SERVICE (extract from contract of employment)

1. External work which is supportive of your professional responsibilities is encouraged by the University Council.

2. Before you enter into an obligation to undertake any external work, including consultancy, you must inform the Vice-Chancellor; however, by way of exception, this requirement does not apply to the following:

    2.1. external examining;
    2.2. acting as an assessor or moderator;
    2.3. the production of scholarly works such as books, articles and papers;
    2.4. any other activity specified in the Policies and Procedures Handbook as not coming within this requirement.

3. The Vice-Chancellor will then decide (within 5 working days or whatever other period may be agreed as being reasonable in all the circumstances) if that work will
    3.1. interfere with the performance of your professional responsibilities, or
    3.2. compete or conflict with the interests of the University of Chester, in which case the University Council may at its sole discretion require you not to undertake the work; such a requirement will not be made unreasonably, will be subject to full consultation with yourself and, if made, will be accompanied by full written reasons for it.

4. Where it is intended to use the facilities of the University of Chester in connection with external work, then prior approval is required in accordance with procedures set out in the Policies and Procedures Handbook.

INTELLECTUAL PROPERTY RIGHTS (POLICIES AND PROCEDURES HANDBOOK)

Definitions

1. 'Teaching Materials' means any materials (including E-Learning Materials) created within the University or created on behalf of the University that are primarily intended (whether by the University or by some third party) to be used by students at any level, for the purposes of any course of study those students are following.

2. 'E-Learning Materials' means Teaching Materials (or any part thereof) in digital form.

3. 'IPR' means patents, trademarks, trade names, design rights, copyright, confidential information, rights in know-how and other intellectual property rights, in each case whether registered or unregistered and including applications for the grant of any of the foregoing and all rights to the same or forms of protection having equivalent or similar effect to any of the foregoing which shall subsist anywhere in the world.

4. 'member of staff' means academic staff, research associates, technicians, or any other members of staff of the University who are employed under a contract of employment (whether fixed term or permanent).

5. 'Scholarly Work' includes items such as books, contributions to books, articles and conference papers and works of a similar nature (other than Teaching Materials) created through the intellectual effort of the member of staff and may include text, images or other media.

Primary obligation

6. The University and the member of staff foresee that the member of staff may make or discover or create intellectual property in the course of his or her duties and the responsibilities arising from them and agree that in this respect the member of staff has a special duty to further the interests of the University.

Ownership of IPR – Teaching Materials, Texts, Scholarly and Other Works, Documents and Other Records and Things

7. Subject to the following provisions, the University and the member of staff acknowledge sections 11 and 215 of the Copyright, Designs and Patents Act 1988.

8. All records, documents and other papers (including copies and summaries thereof) which pertain to the finance and administration of the University and which are made or acquired by the member of staff in the course of his/her employment shall be the property of the University. The IPR in all such original records, documents and papers shall at all times be owned by the University.

9. Subject to paragraph 10, all IPR in any Scholarly Work compiled, edited or otherwise brought into existence by the member of staff in furtherance of his or her professional career shall be owned by the member of staff. The member of staff grants to the University and its authorised users an irrevocable royalty-free non- exclusive licence to use the Scholarly Work for administrative, educational, teaching and research purposes.

10. If Scholarly Work is to be used in Teaching Materials, IPR in the Scholarly Work shall not be assigned or licensed by the member of staff on an exclusive basis to any third party unless provision is made for the University to use such materials on an irrevocable, royalty-free basis for administrative, educational, teaching and research purposes.

11. Subject to paragraph 9, all IPR in any work, design or any other thing, including Teaching Materials, done, created or originated by a member of staff in the course of his/her employment or resulting from simultaneous or sequential contributions over time by one or more staff and/or students shall be owned by the University.

12. Subject to paragraph 9, all IPR in research and scholarly activity, whether undertaken as part of or outside the member of staff's contracted time, and the outcomes thereof, shall be owned by the University.

13. If material from other copyright works is included in Teaching Materials, the member of staff shall identify such material to the University and shall obtain all necessary written permissions from the owners or from any rights organisation authorised by the owner to grant such permissions in respect of such material. Alternatively the member of staff shall, if the University so agrees, provide the University with sufficient information to enable the University to obtain such permissions, but the University shall not thereby be obliged to secure such permissions and may require that the member of staff shall omit any such material from the Teaching Materials.

14. The University hereby agrees and acknowledges that all performers' rights in any video or other recording of the member of staff's own lectures or presentations or similar works are owned by the member of staff. The member of staff grants to the University and its authorised users an irrevocable royalty-free non-exclusive licence to use such material for administrative, educational, teaching and research purposes.

15. Nothing in these provisions shall constitute a waiver by the member of staff of any moral right under the Copyright, Designs and Patents Act 1988, and nothing therein shall constitute an exclusive recording contract within the meaning of Part II of that Act or consent by the member of staff to the exploitation of any qualifying performance for the purposes of that Part.

16. The above paragraphs shall apply except where agreement to the contrary is reached by the member of staff and the University. Where a case arises, or it is thought that a case may arise, where such agreement to the contrary may be necessary, or where it may be expedient to reach a specific agreement as to the application of the above paragraphs to the particular facts of the case, the matter should be taken up between the member of staff and the Vice Chancellor. By way of example, this provision would apply where any question of assignment of copyright or of joint copyright may arise.

Ownership of IPR – Patents and Inventions

17. The provisions of sections 7 and 39–43 of the Patents Act 1977 relating to the ownership of employees' inventions and the compensation of employees for certain inventions are acknowledged by the University and the member of staff.

18. Any matter or thing capable of being patented under the Patents Act 1977, made, developed or discovered by a member of staff either alone or in concert, whilst in the performance of the member of staff's normal duties, duties specifically assigned to him or her or arising out of anything done by him or her to which paragraph 6 applies, shall forthwith be disclosed to the Vice-Chancellor and subject to the provision of the Patents Act shall belong to and be the absolute property of the University.

19.1. In respect of any invention which belongs to University of Chester by virtue of section 39 of the Patents Act, it shall be for the members of the University Council in the first instance to decide whether to apply for patent or other protection.

19.2. In the event that the members of the University Council decide not to apply for patent or other legal protection the member of staff has the right to be notified of that decision so soon as is reasonably practicable thereafter.

19.3. If, following such a decision by the members of the University Council, the member of staff wishes to apply for a patent either him- or herself or with another, s/he must first inform the Vice-Chancellor of their intention to do so. Within a reasonable period of time following such notification the members of the University Council must inform the member of staff whether they would object to the proposed application. The sole ground for such objection is that the patenting of the invention will involve or result in the disclosure to third parties of trade secrets or other confidential information belonging to University of Chester and that such disclosure may damage the interests of University of Chester.

19.4. Where the members of the University Council object under paragraph 19.3 the member of staff undertakes in consideration of the payment of compensation to be determined under paragraph 19.5 below, not to proceed to apply for patent of the invention concerned nor to assist any other person to do so.

19.5. The calculation of compensation referred to above shall have regard to those factors set out in section 41 of the Patents Act. In the event that the members of the University Council cannot agree the amount of compensation, it shall be competent for either the member of staff or the members of the University Council to apply to the president of the Law Society to appoint an arbitrator under the terms of the Arbitration Act, whose decision shall be binding.

Vesting of IPR

20. The member of staff shall (and notwithstanding the termination of his or her employment shall) sign and execute all such documents and do all such acts and things as the University may reasonably require to vest any IPR to which the University may be entitled and to register title in such property in the University, including:

    20.1. to apply for and obtain in the sole name of the University (unless it otherwise directs) any IPR in any country and, when so obtained or vested, to renew and maintain the same;

    20.2. to resist any objection or opposition to obtaining, and any petitions or applications for revocation of, any such IPR;

    20.3. to bring any proceedings for infringement of any such IPR.

21. In the event that the member of staff fails (for whatever reason) within 30 days of a demand by the University to do any thing required by the University under paragraph 20, the member of staff hereby authorises the University in his/her name and on his/her behalf to execute all such deeds or documents and to do any other act or thing as may be necessary or desirable to transfer such IPR to the University and register title therein in the University.

22. The University shall indemnify the member of staff in respect of all costs, claims and damages, howsoever and wheresoever incurred, in connection with the discharge by him or her of any and all such requests under paragraph 20 above.

Exploitation and income

23. The University is free to exploit (whether for financial gain or not) any IPR which is owned by the University, including licensing or assigning the IPR to third parties, or merging the material with other property or things created within the University or elsewhere.

24. Should the IPR prove to be profitable, the University agrees that it shall, in accordance with its normal procedures, enter into good faith negotiations with the member of staff regarding possible rewards. Net income arising from patents/inventions will normally be allocated in the proportions of 60% to the University and 40% to the staff inventor(s). If there is more than one inventor, their share of the net income shall be apportioned equally between them, unless they each agree otherwise. Any inventor may present evidence to support a differential apportionment to the Pro-Vice-Chancellor (Research) and any inventor aggrieved by the Pro-Vice-Chancellor's decision may appeal to the Vice-Chancellor, whose decision shall be final.

25. Subject to the provisions of paragraph 19 above, in the event that the University fails to exploit the IPR or other materials referred to in paragraph 23 above within a period of two years from the creation thereof, a member of staff who is the creator or originator of the IPR or his/her representative may give written notice thereof to the University, and in such event the University shall declare within thirty (30) days in writing whether or not it intends to exploit the same in the foreseeable future. The University agrees it will enter into good faith negotiations with the member of staff with a view to assigning the IPR or other materials to the member of staff, if no prospect of commercial exploitation thereof is to be expected, on terms which shall include an undertaking by the member of staff and any other persons with whom the member of staff has collaborated in the creation of the IPR not to exploit the same in a way that the University reasonably considers to be competitive to the University's own activities. In return, the member of staff shall grant the University and its authorised users an irrevocable royalty-free licence to use such material for administrative, educational, teaching and research purposes.

Credits

26. The University agrees to credit the member of staff for any significant contribution to the IPR provided that to do so does not prejudice in any way the interests of the University. The University shall comply with any request by the member of staff in writing that his/her name be removed from any property or materials where such request is on grounds that the whole or parts thereof are out of date or changed in a manner that might damage his/her reputation.

27. The University may update or in any other way amend the materials or things which give rise to IPR to suit its requirements. The University agrees to consult the member of staff over any significant amendments without any obligation to be bound by the same in deciding on the final form or content of such amendments.

Permitted uses

28. The University grants to the member of staff a royalty-free non-exclusive licence to use Teaching Materials created by the member of staff or jointly with others for non-commercial teaching or research purposes only for as long as the member of staff remains employed by the University. Such licence may continue after the termination of this agreement provided that the use of the Teaching Materials does not damage their exploitation by the University or prejudice in any way the interests of the University.

29. Should the contract of employment of the member of staff terminate, the member of staff shall be entitled to enter into negotiations with the University with a view to permitting the member of staff to make and retain a copy of any Teaching Materials created by the member of staff or jointly with others for his/her use for non-commercial teaching and research purposes. In the case of disagreement over these negotiations, dispute settlement

procedures in accordance with paragraph 33 of these provisions shall be invoked. Neither the member of staff nor his/her new employer is permitted commercially to exploit such Teaching Materials without the express permission of the University.

30. Nothing herein shall grant to the member of staff any right or licence to copy or use any versions of any Teaching Materials updated or in any way amended by the University after termination of the member of staff's employment.

Prohibited uses

31. The member of staff is not permitted to use, assign or enter into any licence for the exploitation of any Teaching Materials or other property in respect of which the University is entitled to the IPR except in accordance with paragraphs 28 and 29 of these provisions. In the event that the member of staff becomes aware of any third party wishing to exploit any such IPR, the third party shall be advised by the member of staff to contact the University as the owner of the IPR.

Termination

32. Save as provided herein, all rights and obligations under these provisions shall continue to be in force after the termination of the employment whose terms and conditions are governed by this agreement in respect of all IPR in Teaching Materials originated by the member of staff during the member of staff's employment, and shall be binding on his/her representatives.

Dispute settlement

33. Any dispute between the University and the member of staff arising out of or in connection with these provisions, except as may be otherwise provided, shall be referred to the arbitration of a single arbitrator appointed by agreement between the University and the member of staff or, failing agreement between them, within thirty (30) days after a request for a reference is made by either party, nominated on the application of either the University or the member of staff by the President for the time being of the Law Society.

Appendix 2 Website addresses

Codes of conduct	
British Educational Research Association	https://www.bera.ac.uk/researchers-resources/publications/ethical-guidelines-for-educational-research-2011
British Psychological Association	http://www.bps.org.uk/what-we-do/ethics-standards/ethics-standards
British Sociological Association	http://www.britsoc.co.uk/media/27107/StatementofEthicalPractice.pdf
Council of Europe	http://www.coe.int/t/dg3/healthbioethic/default_en.asp
Council for International Organisations of Medical Sciences	http://www.cioms.ch/
Declaration of Helsinki	http://www.wma.net/en/30publications/10policies/b3/index.html
Health Research Authority	http://hra.nhs.uk
Ethics Research Information Catalogue	http://www.eric-on-line.co.uk/index.php
General Medical Council	http://www.gmc-uk.org/
National Research Ethics Service	http://www.nres.nhs.uk/
NHS R&D Forum	http://www.rdforum.nhs.uk/content/
Nuffield Council on Bioethics	http://www.nuffieldbioethics.org/
The World Health Organization	http://www.who.int/ethics/en
Information on tissues and organs	
http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/research.cfm	
http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/human-tissue-2/	
http://www.mrc.ac.uk/documents/pdf/medical-research-involving-children/	
Legislation (Acts of Parliament and Statutory Instruments)	
Office of Public Sector Information	http://www.legislation.gov.uk/
Research on Animals	
Home Office	https://www.gov.uk/research-and-testing-using-animals
Natural England	http://www.naturalengland.org.uk/information_for/researchers/default.aspx
Marine Management Organisation	http://www.marinemanagement.org.uk/protecting/wildlife/index.htm

Appendix 3 Sample Honorary Contract

Our ref:

Title of research

Dear [name],

I am pleased to offer you an honorary research contract in [name of organisation]. I would be grateful if you could sign three copies, keep one copy yourselves and return the others to me at the above address.

The contract if accepted will be effective from [date] to [date].

We will not reimburse any expenses you incur unless subject to prior arrangement. Similarly, we accept no responsibility for damage to or loss of personal property, with the exception of small valuables handed to officials for safe custody.

If you are happy with the terms of the contract please sign the enclosed honorary contract and contact myself or the HR Department on XXXXXXX, who will arrange for you to be issued with an ID badge.

Yours etc

Honorary Research Contract for External Researchers conducting research in [name of organisation]

Title of research:
Duration of the study and dates:
Principle Investigator:
Institution:
Contact details:

Name of Local Investigator:
Institution:
Contact details (*including email or telephone number*):

- I , ……of …… have received both ethical and PCT approval to conduct research in [name of organisation] [ethical approval not required]

- I am fully conversant with research good practice as laid down by the Research Governance Framework for Health and Social Care and will abide by the guidelines for good research practice therein.

- In the course of my research I may come across confidential information regarding patients, staff or the business dealings of [name of organisation]. I understand that unauthorised disclosure of such information will result in my appointment with [name of organisation] being terminated and this may lead to legal action (this does not affect your statutory rights under the Public Interest Disclosure Act 1998).

- I acknowledge that this contract expects me to be mindful of the policies and procedures of [name of organisation] and that these may vary between organisations. I accept responsibility of familiarising myself with [name of organisation]'s policies and procedures which I can access at any time via the human resources department.

- I will adhere to the health and safety rules and procedures of [name of organisation] while at work.

- I have provided the research governance lead of [name of organisation] with a copy of the project protocol.

- I will keep the research governance lead informed of the progress of the study or when requested including any deviations from protocol.

- I will report any significant events arising from my research to [name of organisation]'s research governance lead.

- I have read and understood the above information and accept the terms and conditions of this contract which covers the research project named above only. I will return the ID badge to [name of organisation] once the research is finished.

- My research project has a nominated Department of [ ] Sponsor who is willing to indemnify my research.

Signed: Principal Investigator: …… Date: ……

Print name: ……

Local Data Collector: …… Date: ……

Print name: ……

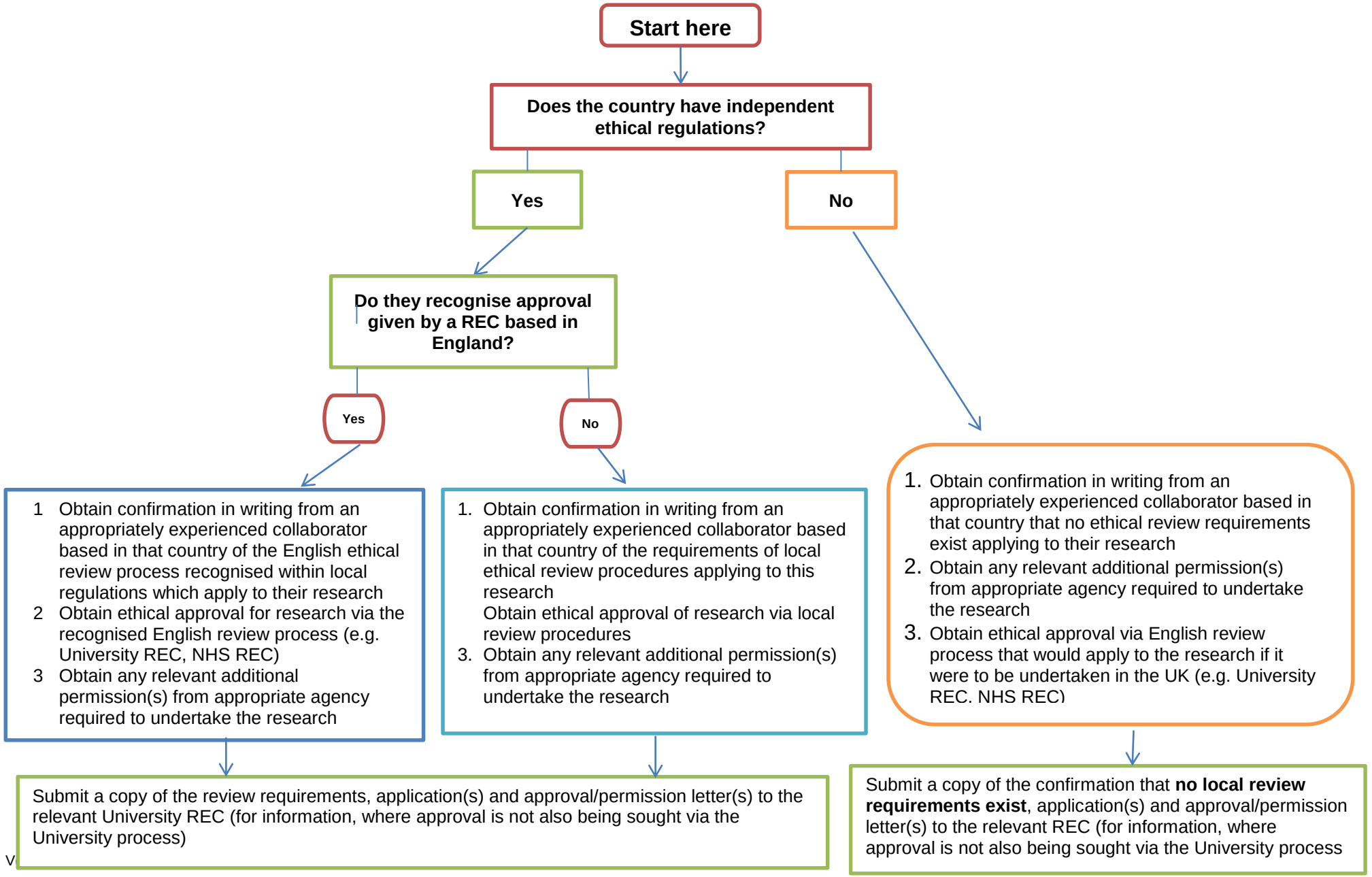
R&D Officer: …….. Date: ……

Print name: ……

FOR OFFICE USE ONLY:

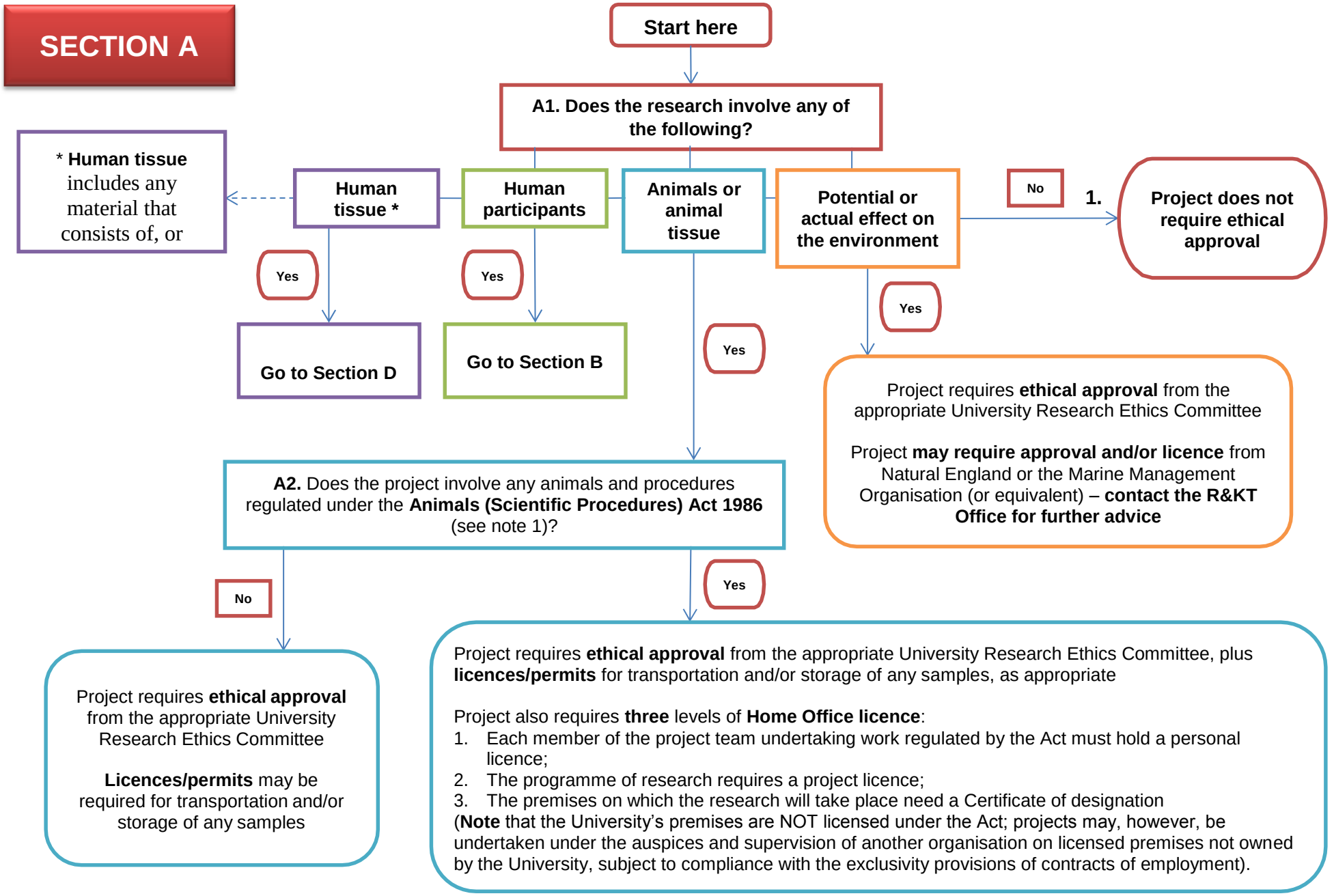
[name of organisation] approval	Yes/No
Ethics Approval	Yes/No/NA
Intellectual Property	Yes/No
Police Screen (children/vulnerable)	Yes/No/N/A
NHS ID Badge	Yes/No/NA

Appendix 4 Ethical Review Processes: Research Outside of England



V

Appendix 5 - UNIVERSITY OF CHESTER: GUIDANCE ON RESEARCH APPROVALS AND PERMISSIONS



SECTION B: Human participants

B1. Is the research a clinical trial?

Does the project involve any of the following?

- treating or preventing disease or diagnosing disease;
- ascertaining the existence, degree of or extent of a physiological condition;
- assisting with or altering in any way the process of conception;
- investigating or participating in methods of contraception;
- inducing (general or local) anaesthesia;

Yes → **Go to Section C**

No ↓

** **Note**: This means any potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions **

B2. Does the research involve the NHS?

Does the research involve any of the following?

- Patients or service users of the NHS (see Note ** above)
- Relatives or carers of patients of the NHS
- Access to data, organs or other bodily materials of past or present NHS patients
- Foetal material or IVF involving NHS patients
- The recently deceased in NHS premises
- Use of, or access to, NHS facilities or premises
- NHS staff recruited by virtue of their professional role

No → Project requires **ethical approval** from the appropriate University Research Ethics Committee

Project may also need **permission from relevant 'gatekeepers'**, e.g. Local Authority if participants are school pupils or staff

Yes ← **B3.** Does the research involve **only** NHS staff, facilities or premises?

Yes ↑ Project requires **ethical approval** from the appropriate University Research Ethics Committee

Project also needs **R&D approval** from the NHS Trust(s) responsible for each research site. This application must be made via the NRES Integrated Research Application System (IRAS)

The project also requires a **Sponsor** (see note 2)

No ↓ Project requires **external ethical approval** from an **NRES Research Ethics Committee**

Project also needs **R&D approval** from the NHS Trust(s) responsible for each research site.
Both the ethics and R&D applications must be made via the NRES Integrated Research Application System (IRAS)

The project also requires a **Sponsor** (see note 2)

Where a project involves both **NHS and non-NHS sites or participants**, ethical approval from the appropriate University Research Ethics Committee is required in

SECTION C: Clinical trials (see also note 3)

C1. Does the research involve a medicinal product?

Medicinal products are substances or combinations of substances which either prevent or treat disease in human beings or are administered to human beings with a view to making a medical diagnosis or to restore, correct or modify physiological functions in humans

Yes → **Contact the R&KT Office for advice**

No ↓

C2. Does the research involve a medical device?

Medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, intended to be used for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

It covers an extremely wide range of products, including, for example:

- first aid bandages
- tongue depressors
- hip prostheses
- X-ray equipment
- ECG
- heart valves
- spectacles
- dental materials

Yes → **Contact the R&KT Office for advice**

No →

C3. Does the research involve <u>solely</u> any one or more of the following?

- questionnaires
- measurement of physiological processes using non-invasive methods
- administration by mouth of foods or nutrients or variation of diet other than the administration of drugs or other food supplements
- psychological activity

Yes ↓

C4. Does the research involve <u>any one or more</u> of the following?

- Non-UK resident participants
- Research sites outside the UK
- Persons under 5 years
- Those known to be pregnant
- Investigating contraception
- Drugs/surgery
- Pharmaceutical products designed/ manufactured by the University
- Genetic engineering

Yes → **Contact the R&KT Office for advice**

No → **Go to question B2 in Section B**

No → **Contact the R&KT Office for advice**

2. # SECTION D: Human tissue

3. ***DEFINITIONS***

'Human tissue' includes any material that consists of, or contains, human cells but not cell lines or hair and nails from living people or human gametes and embryos (these are regulated under the Human Fertilisation and Embryology Act 2008).

However, if conducting DNA analysis, it is an offence to have 'bodily material' with the intent of analysing its DNA without qualifying consent. Bodily material is material that has come from a human body (living or deceased) and consists of, or includes, human cells. This includes hair and nails, and does not specifically exclude gametes. Extracted DNA (where no whole cells remain) is not classed as bodily material.

4. ***LICENCES***

A licence from the **Human Tissue Authority (HTA)** is required to store tissue for use in research, unless the tissue is being stored for use in a specific NRES Research Ethics Committee (REC)-approved project and is not retained after that project for unspecified future use.

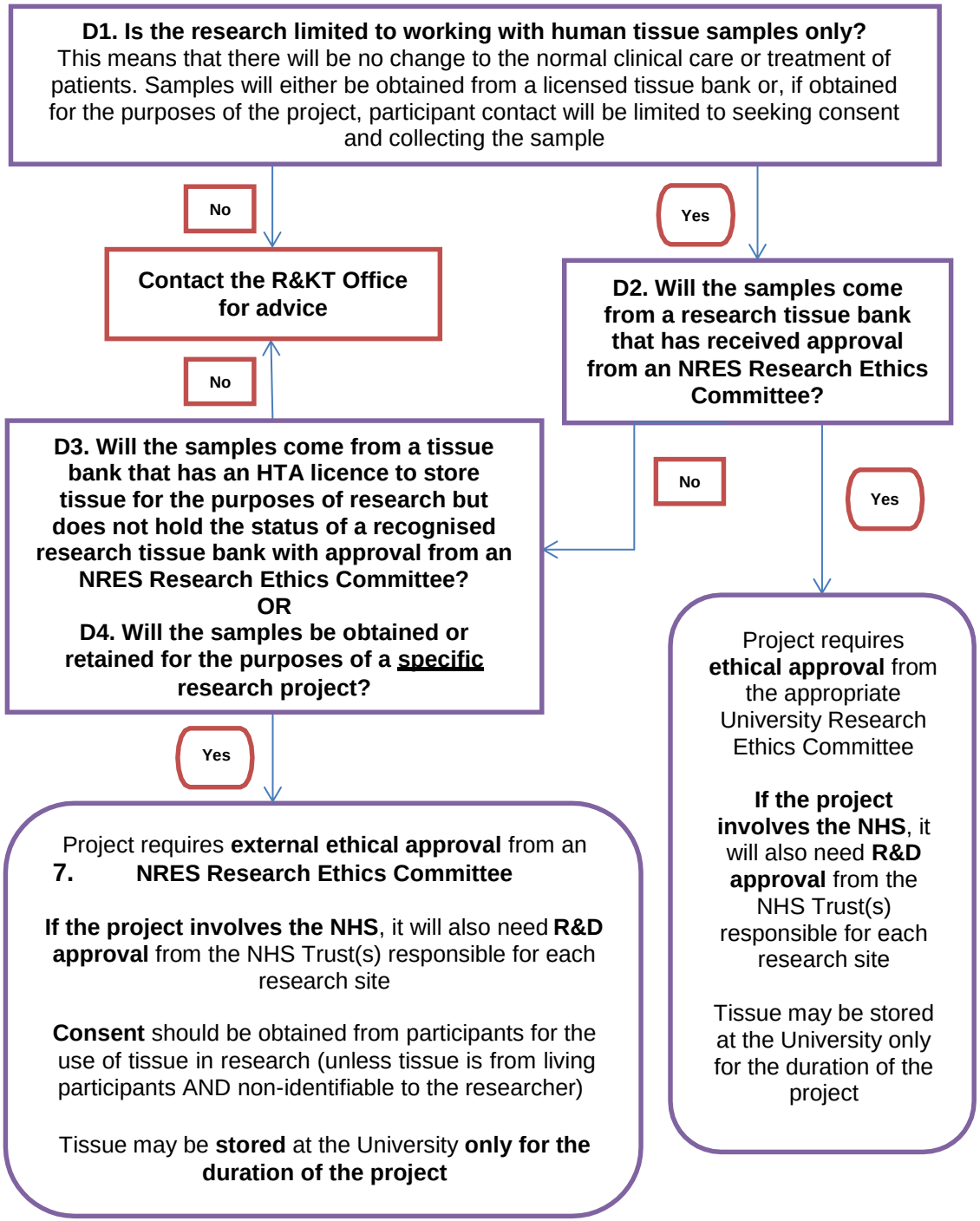
NOTE: The University DOES NOT hold an HTA licence for storing human tissue.

5. ***CONSENT***

Consent is required to use tissue obtained from living patients for research, unless the tissue is anonymous to the researcher and the project has NRES REC approval or it was obtained prior to 1 September 2006. Consent is always required to use tissue obtained from the deceased unless it was obtained prior to 1 September 2006.

6. ***REMOVAL, STORAGE, DISPOSAL***

Tissue must be removed, stored and disposed of in accordance with the HTA Code of Practice (5) on this subject



NOTES

8. Animal (Scientific Procedures) Act 1986

9. DEFINITION OF A PROTECTED ANIMAL

(a) The Act defines a "protected animal" as any living vertebrate, other than man [Section 1(1)]. The invertebrate species Octopus vulgaris has been added by means of the Animals (Scientific Procedures) Act (Amendment) Order 1993.

(b) Protection extends to certain immature forms from the following stages of development:

- mammals, birds and reptiles - from halfway through the gestation or incubation period;
- fish, amphibia and Octopi vulgaris - from the time at which they become capable of independent feeding.

(c) Protection is also provided when regulated procedures are applied at an earlier stage of development if:

- the animal is to be allowed to live beyond the stage of development set out in paragraph (b) above; and
- the procedure may result in pain, suffering, distress or lasting harm after the animal has reached that stage of development.

DEFINITION OF A REGULATED PROCEDURE

(a) A "regulated procedure" is defined by Section 2(1) of the Act as "any experimental or other scientific procedure applied to a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm".

(b) "Pain, suffering, distress and lasting harm" encompass any material disturbance to normal health (defined as the physical, mental and social well-being of the animal). They include disease, injury and physiological or psychological discomfort, whether immediately (such as at the time of an injection) or in the longer term (such as the consequences of the application of a carcinogen).

(c) Regulated procedures may be acts of commission (such as dosing or sampling) or of deliberate omission (such as withholding food or water).

For further information on the Animal (Scientific Procedures) Act, please see: http://www.homeoffice.gov.uk/science-research/animal-research/ or contact the Research and Knowledge Transfer Office.

10. Sponsorship of Health-Related Research

The Department of Health's Research Governance Framework requires that all health and social care research must have a formal Sponsor. A Sponsor is an organisation or group that takes on responsibility for ensuring there are proper arrangements to initiate, manage and finance a study (though need not be the funder of the study).

The University is able to act as Sponsor for research undertaken by its staff and students, but should always be the 'Sponsor of last resort'. The University decides whether to act as Sponsor on a case-by-case basis. Further details on the processes on applying for the University to act as Sponsor are available in the University's Policy on Sponsorship:
http://ganymede.chester.ac.uk/index.php?page_id=1369210&group=3

11. Clinical trials

Please note that not all clinical trials are covered by the University's insurance and there are certain categories of clinical trial for which the University will not act as Sponsor.

Clinical trials involving Medicinal Products or Medical Devices may fall under the remit of the Medicines and Healthcare products Regulatory Agency (MHRA). In particular:

- If a trial meets the legal definition of a **Clinical Trial of an Investigational Medicinal Product (CTIMP)** (that is, falling within the scope of the EU Clinical Trials Directive and the UK Medicines for Human Use (Clinical Trials) Regulations 2004) then it would require a formal **Clinical Trial Authorisation (CTA)** from the MHRA;
- A **Declaration of No Objection** from the MHRA is required for any **Clinical Trial of a Medical Device**.

The University would not agree to act as Sponsor for projects in either of the two above categories. The full definition of a CTIMP is complex (see http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con009394.pdf), but it is important to note that it is fairly straightforward to design a project involving a medicinal product that sounds relatively low risk but which would meet the CTIMP definition.

However, there are some projects which involve medicinal products but which fall outside the remit of the MHRA – such as non-interventional trials (where medicinal products are investigated by observing their use in standard practice) or mechanistic/non investigational (NIMP) trials (where a medicinal product is used but its study is not the purpose of the trial). The University may, in certain circumstances, be able to act as Sponsor for such projects, but advice must be sought from the Research and Knowledge Transfer Office at the outset of the project planning process.

In summary, any member of staff (acting as the supervisor of a student project or as a researcher in their own right) planning a research project which may meet the definition of a clinical trial must contact the Research and Knowledge Transfer Office for advice before beginning to write their proposal.

Appendix 6

University Experts on Animal Research Ethics

Dr Sarah Millsopp – Animal behaviour/ welfare – focussed on pets
Dr Matt Geary – Conservation biology/ animal behaviour – current FREC member
Prof. Tessa Smith – Animal welfare. NC3Rs grant holder
Dr Lottie Hosie – Animal welfare. NC3Rs grant holder
Dr Geraldine O'Connor – Biomedical research/ human studies – previous FREC member
Prof. Eustace Johnson – Biomedical research/human/animal studies. Current FREC Chair. Completed all Home Office modules for research involving animals
Dr Marco Favretto – Biomedical research/genetic modification