**Checklist for FWA compliance and ethical review by the Institutional Review Board**

As part of the approval process, the University’s designated Institutional Review Board (i.e. the ethics committee in Health Sciences) will need to assure that your project meets FWA requirements as laid out in 45 CFR part 46 of the HHS Protection of Human Subjects regulations. To make this process as smooth and speedy as possible, please submit the following:

* Details of the project using the application form(s) agreed with the IRB Chair (for further explanation, see document Institutional Review Board Procedures, Section 2)
* A copy of the table below, to be completed as follows: check the FWA requirements as listed, then indicate in the column provided where the relevant information can be found within the project details. Where necessary, please supply additional information to ensure that the committee can make the necessary checks and decisions easily.
* A copy of the consent documents to be used for the project, ensuring that they reflect FWA requirements below.

**Please note** that if your research involves any of the following:

* pregnant women, human foetuses, neonates
* biomedical and behavioural research involving prisoners
* children

you must inform the Research Integrity Officer and Research Grants and Contracts as soon as possible so that they can check whether the funder also requires compliance with further subparts of the above regulations as part of the conditions for approval under FWA. If so, this must also be demonstrated as part of the application, and an enhanced checklist will be provided by the Research Integrity Officer.

If you have any queries, please contact the Research Strategy and Policy Office in the first instance.

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| **FWA requirements** | **Relevant project information**  |
| Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. |  |
| The IRB needs to be able to weigh up:1. Risks to subjects
2. Anticipated benefits, if any, to subjects
3. The importance of the knowledge that may reasonably be expected to result.

NB the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research), and will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. |  |
| Selection of subjects is equitable. In making this assessment the IRB will take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. |  |
| When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. |  |
| When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. |  |
| When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. |  |

**If the project will be employing standard informed consent procedures:**

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| An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.  |  |
| The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. |  |
| No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. |  |
| The following information shall be provided to each subject: (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (2) A description of any reasonably foreseeable risks or discomforts to the subject; (3) A description of any benefits to the subject or to others which may reasonably be expected from the research; (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. |  |
| When appropriate, one or more of the following elements of information shall also be provided to each subject: (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable; (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent; (3) Any additional costs to the subject that may result from participation in the research; (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and (6) The approximate number of subjects involved in the study. |  |

**If the project proposes to alter or waive any of the above requirements:**

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| An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided if the IRB finds and documents that: (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; AND (2) The research could not practicably be carried out without the waiver or alteration.AND/OR if the IRB finds and documents that: (1) The research involves no more than minimal risk to the subjects; (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation. |  |

**Documenting informed consent:**

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| Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. |  |
| The consent form may be either of the following: (1) A written consent document that embodies the above elements of informed consent. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or (2) A short form written consent document stating that the elements of informed consent required above have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. |  |

**Conditions for exceptions to the above:**

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| An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds EITHER: (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; OR (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. |  |