

Ethics Policy (Human Participants) – Category Guidelines

March 2012

Introduction

In order to effectively manage ethical review and to ensure appropriate levels of scrutiny to ensure the University is compliant with its obligations under law and to its insurers the UEC has set different levels of review appropriate to the risk and seriousness of certain categories of studies. The aim is to enable responsible ethical review of studies yet not to unnecessarily delay commencement of good research.

There are 3 levels of review and approval dependent on the category of the study:

- ▯ Category A studies will require review and approval of the Research Governance and Insurance Offices before they can start in addition to that of the FEC.
- ▯ Category B studies require approval from the FEC before they can start.
- ▯ Category C studies still require registering on ERGO and the oversight of an FEC (by monitoring) but can be approved by a single member of their FEC or such other suitably qualified individual designated by them to do so (but not the researcher or supervisor for their own study).

UEC shall keep these Categories under review and may change the criteria as it considers appropriate subject to giving adequate notice to FECs and the research community.

What types of studies fall in which review category?

Category A

These are the type of studies that are required by our insurers to have this additional approval level and/or that the University Ethics Committee considers are of a nature that this additional review is necessary before the research can start.

The studies that will fit in this category are those that involve any or more of the following:

- administration of medicinal products (including placebos)
- investigations of medical devices ¹and studies that use a device on the participant that is not yet CE marked or licensed for its intended use
- ingesting food or drink or other products (including vitamin supplements, nutritional studies etc) which exceed normal recommended consumption levels, are outside any market

¹ A medical may be an instrument, machine, apparatus, implement, machine contrivance, implant or other item of a similar nature intended for the diagnosis, cure, mitigation, treatment or otherwise used towards the prevention of disease in man.

authorisation, or where there is product warning and the participants are likely to be covered by that product warning²

- that involve treating, preventing or diagnosing disease, assisting or altering the process of conception or investigating methods of contraception
- collection of and/or research using human tissues
- invasive techniques of any kind (including taking blood samples, ultrasound scans, medical resonance imaging or similar)
- that require ethics approval from an independent external ethics committee (e.g. NRES)³

In addition where the study involves the type of research/study which the UEC considers has a serious factor below combined with the participant being of the type that UEC considers special care needs to be taken to ensure their true informed consent is being given and/or the research/study is otherwise responsibly being undertaken.

² An example is many over the counter drugs and vitamins contain warnings to consult your doctor if you are pregnant or breast-feeding before consumption

³ Studies that will receive funding from the US National Institutes of Health or another US federal funding agency will require this

<p>Type of activity/procedure that has a serious factor</p>
<p>Studies or procedures that are reasonably expected to / involve</p> <ul style="list-style-type: none"> • induce anxiety, stress or other harmful psychological states on a momentary basis • induce physical discomfort and/or pain beyond which that they may routinely encounter in their everyday life • expose the participants to visual, auditory or other stimuli beyond that which would normally be experienced in everyday life • ingesting food or drink or other products (including vitamin supplements, nutritional studies, inhalation of gases etc) • eliciting information from participants that could render them liable to criminal proceedings (e.g. drug abuse or child abuse) • alter the participants normal patterns of sleeping, eating or drinking • collect sensitive personal data • involve coercion, deception, inducement or covert surveillance • involve questions about sensitive topics (including sexual behaviour, political views, gender, ethnic status etc)
<p>AND</p>
<p>Type of participant where special care is required</p>
<p>Individuals who are:</p> <ul style="list-style-type: none"> • under 18 years old⁴ • pregnant or breastfeeding mother • detained in lawful custody (in a prison, remand centre, young offender institution, secure training centre or attendance centre, or under the powers of the Immigration and Asylum Act 1999) • is under the supervision of the probation services • homeless or living in sheltered accommodation • otherwise vulnerable adults⁵

⁴ Under 16's would require parental consent and those 16-17 may require parental consent depending on the nature of the study undertaken.

⁵For the purpose of this Table A an "otherwise vulnerable adult" includes someone who has and/or is:

a) a learning or physical disability;

Individuals who do NOT:

- have the capacity to give consent in accordance with the Mental Capacity Act 2005⁶
- have the capacity, or appear not to, to give free and informed consent for any reason (including under the influence of drugs or alcohol, being coerced, confused etc)

Notwithstanding that the individual participant is not list above (i.e. is an adult that is otherwise healthy and not-vulnerable) but where the type of activity/procedure is one listed above as having serious factor and it is reasonably likely that the discomfort, pain or negative reaction induced or felt will last beyond the duration of the test/procedure or more than for a very short period thereafter then special care is also required

Where the FEC has set strict guidelines within which safety of participants can be assured for any particular type of research or testing and the use of which are approved in principle by the Research Governance Office and Insurance Offices this may mean review can be undertaken by Category B review.

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- b) a physical or mental illness, chronic or otherwise, including an addiction to alcohol or drugs;
 - c) reduction in physical or mental capacity;
 - d) a dependency on others in the performance of, or a requirement for assistance in the performance of basic physical functions;
 - e) a severe impairment in the ability to communicate with others,
 - f) receiving domiciliary care in their own home;
 - g) an impairment in his/her ability to protect themselves from assault, abuse or neglect.

⁶ Section 2 of the Mental Capacity Act 2005 "a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain." And the inability to make a decision is where they are unable to:

- (a) to understand the information relevant to the decision (including the consequences of deciding one way or another as well as not making a decision)
- (b) to retain that information,.
- (c) to use or weigh that information as part of the process of making the decision, or.
- (d) to communicate his/her decision (whether by talking, using sign language or any other means)..

Category B

All research/studies which do not fall within Category A review criteria will be considered as requiring a Category B review unless it is agreed the Category C criteria is met. The FEC may at its sole discretion escalate a matter to a higher level of review.

Any research/study involving human participants identified in Table A above as needing special care or any type of research/study which involves any of the activities or procedures as having a serious factor should as a minimum have Category B review. FECs should pay particular attention to ensuring the quality of information sheets and consent forms used by researchers.

Opt out consent should only be used in exceptional circumstances where the FEC considers the risks are adequately mitigated and clear instructions given to participants on their right and how to withdraw consent.

Category C

It is recognised that there are a significant number of studies undertaken at the University which involve human participants but which have minimal risks attached. In cases of low risk studies and in order to assist in the management of approvals in a timely fashion UEC has agreed the use of a "light touch" review.

UEC believes that the criteria for the level Category C review are best set on a discipline specific basis. The FEC wishing to use the Category C review option should set criteria and develop checklists to ensure adequate self-evaluation by the researcher (or the supervisor in case of a student) prior to the review by the individual designated by the FEC (who shall be someone other than the researcher/supervisor of that study).

Without being prescriptive the types of research anticipated as possibly falling within this category are the following:

- Anonymous questionnaires provided these do not touch on sensitive topics
- Market or opinion research
- Customer satisfaction surveys
- Studies using previously collected anonymous data which cannot be traced back to the individuals who provided them by any of the study team
- Performance of verbal / paper & pencil / computer based tasks provided it is not involving any of the activities or types of participants outlined in Table A
- Service evaluation / audit / needs assessments commissioned by an external service provider. (Where this involves participants outlined in Table A above approval from RGO on the criteria and checklists set by the FEC should be obtained.)

Studies which use Opt-Out consent would normally fall to Category B review as would any studies which involve NHS Staff or facilities and/or which may use anonymised patient/NHS data.