

Criteria for Research Ethics Committees

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Version	Description	Circulation
1.0	Working draft discussed at REPC 6 th of June and 4 th of July meetings.	REPC
1.1	Working document (REPC minute, September 19 th RE/12-13/20)	Research Committee
1.2	Final version following consultation. Approved Research Committee 21 st January 2014	REPC/Research Committee

Research Ethics in Trinity College Dublin: Criteria for Research Ethics Committees

All research with impact has an ethical dimension and all researchers should reflect on the implications of their work, not just in terms of human (and animal) welfare and dignity, but also the social and cultural impact of their research. Funding agencies are placing increasing importance on ethics approval procedures and the scope of research areas requiring ethical review is growing. In particular, it is expected that research funded by the European Commission, under the aegis of Horizon 2020, will be subject to increased ethical scrutiny. With increased future reliance on such funding, there will potentially be even greater pressure on the College's research ethics review processes.

Clearly, research involving humans and animals will require ethical review, however, other types of research may often have ethical considerations that should be addressed. In order to provide efficient and timely ethical review it has been agreed that all Schools/Units must have a research ethics approval policy in place. Schools/Units may use their own Research Ethics Committee (REC), use another School/Unit's REC or a Faculty REC. There will be two levels of REC; Level 1 RECs will have the power to review and approve "low risk" research, while Level 2 RECs will be concerned with "high risk" research. Membership of each type of committee will be commensurate with the level of risk. Listed below are examples of the types of research associated with each level of REC. Any research project that does not fall under the types listed below must be reviewed by an appropriate Level 2 REC. Research involving hospital patients must always be approved by that hospital's research ethics review procedures.

1. Research not requiring ethical REC approval (but Chairman's Approval should there be an intention to publish)

1. Quality assurance studies (e.g. assessment of teaching practice)
2. Audits of standard practice (not involving identifiable records)
3. Research on publically available information, documents or data

2. All research involving non-human animals must be approved by the Animal Research Ethics Committee

3. Research requiring approval by a Level 1 REC

(no risk to relatively low risk research – i.e. research carrying little or no risks or discomfort greater than usually encountered during normal daily life)

1. Anonymous surveys of a non-intrusive personal nature.
2. Unrecorded and anonymous observation of individuals in public areas.
3. Analysis of irrevocably anonymised and appropriately collected data.

4. Collection of non-invasive biological samples (e.g. hair, nails, saliva, semen, urine, buccal epithelial cells), for research studies that have no prospect of impacting on the healthcare of the participant (controls in particular). An example of an unacceptable protocol is interrogation of BRCA status or any genetic investigation that might have relevance for future treatment.
5. Interviews (consensual) with non-vulnerable adults.
6. Action research (Research initiated to solve an immediate problem or a reflective process of progressive problem solving conducted either by individuals on their own practice or by individuals working with others in teams or as part of a "community of practice" to improve the way they address issues and solve problems [participatory action research]).
7. Collection of specific biological samples using minimally invasive techniques (e.g. blood). Sample collection must be performed by a suitably qualified and competent person and will typically involve the collection of a single vial of <10ml blood.
8. Surveys where respondents can be identified and where respondents have given appropriate explicit consent.

4. Research requiring approval by a Level 2 REC

(moderate to high risk research – i.e. risk or discomfort is greater than that usually encountered during normal daily life)

Moderate risk

1. Surveys asking questions of a sensitive or private nature
2. Questionnaires or observational studies involving children or vulnerable adults.
3. Research where there is a risk of a participant feeling undue pressure to participate by virtue of his/her relationship with the researcher (e.g. student/supervisor; patient/clinician).
4. Projects involving a justifiable degree of deception.
5. Analysis of archival irrevocably anonymised human tissue samples for which consent for research was not originally given, and was not acquired in the course of clinical treatment. (Archived samples taken for a previous research study must always get new ethical approval).

High risk

6. Research involving invasive procedures (other than those listed above).
7. Research involving vulnerable persons.
8. Research where identifiable information obtained may have legal, economic or social consequences for research subjects.
9. Research that may identify illegal activity on the part of the participant.
10. Projects where each subject is paid (over and above token gestures).
11. Research that may potentially endanger the subjects, and/or researchers, and/or 3 rd parties, and/or the environment.

12. Research involving the collection of human tissue.
13. Research that may have a direct military role.
14. Potentially harmful research involving humans conducted outside Ireland ¹ .
15. Research involving psychological intervention.
16. Research where a potentially beneficial or harmful treatment, information or learning method may be withheld from some participants.
17. Research not included in this document should be reviewed by an appropriate Level 2 REC.

Notes:

**Quality assurance and audit studies do not routinely require ethical approval. However, if following the study there is scope to publish the findings of a study an REC may grant a letter of approval if required.*

1. In situations where research ethics approval has been granted by an appropriate research ethics committee elsewhere approval must also be sought from an appropriate Trinity College REC, although at the discretion of the REC chair the submission may qualify for fast-tracked approval.

2. Unless otherwise noted, research involving adults assumes adults with a capacity to consent.

3. Vulnerable groups/persons:

Certain individuals who face excessive risk of being enrolled in research include those with limitations in their ability to provide informed consent to research because of factors such as immaturity or cognitive impairment.

Vulnerability can also stem from individuals' relationships with others, and it is imperative that coercive situations are avoided. Such cases may occur when an employee/student/dependent is asked to participate in research being conducted by a supervisor/mentor.

Additional social factors, such as poverty and lack of access to health care, can also make individuals vulnerable to coercion, exploitation or other risks and need to be considered in reviewing applications.

4. If an REC feels that it is not competent to review an application it may recommend that the application be submitted to a more appropriate Committee. However, it is the REC that chooses the appropriate REC, not the researcher.

5. Membership of RECs

Level 1

At least 3 members with expertise in the relevant research area, one of whom might be external to the School/unit, either from another School/REC in the College or from outside the College. Best practice indicates that each submission should be read by a minimum of 2 people.

¹ Does not apply to material publically available in another jurisdiction.

Level 2

RECs with the authority to review both high- and low-risk research must be comprised of sufficient members of staff to ensure there is expertise relevant to all the disciplines to be served, as well as specialist (e.g. statistics), external, lay and legally qualified members.