Guidelines on selection of level 1 or level 2 ethics committee for approval.

There are two levels of Research Ethics Committees (REC) in Trinity College Dublin, denoted Level 1 and Level 2, that approve ethics applications. The criteria for each level is given below. Please review this information to ensure you submit your ethics application to a REC of the appropriate level. If you submit your application to a REC of the incorrect level, your application will be returned without review, which may result in significant delays for you.

Please note

- application to TCD ethics committees does not necessarily preclude staff or students from having to apply to the other relevant local ethics committee
- both staff and students of college **must** apply for Trinity ethics approval even if they have ethics approval from other sources, except if you have ethics approval from the Joint Research Ethics Committee (JREC) Tallaght and are collecting data only from St James or Tallaght hospitals. Please consult your REC to check if they have special procedures for this (*REC to insert here or elsewhere on their site their procedures for this*)
- the principal investigator or student must apply to the REC of the school or faculty to which they belong, unless they put forward a case for approaching a different REC
- it is recommended that studies that have several stages of data collection i.e. particularly those with different data collection methods, different access methods or populations or are dependant on the outcome of the first phase for the development of questionnaire etc. should apply for ethics for each phase separately
- ethics committees are prohibited to grant approval to studies where is country is currently listed on the Department of Foreign Affairs currently advise against travel even if the researcher is familiar with the county or a resident thereof https://www.dfa.ie/travel/travel-advice/
- **The Dental School committee reviews applications at level 1.**

Please tick below all that apply to the current application:

The following categories of research do not require ethics approval	
1. Quality assurance study (e.g. assessment of teaching practice)*	
2. Audits of standard practice (not involving identifiable records) *	
3. Research on publicly available information, documents or data both within and outside Ireland	
4. *In vitro* research on cell lines, microorganisms or non-biological materials ***that does not*** involve primary biological material from humans or animals	

**Please note that 1 &2 only apply for internal publications, i.e. does not apply to theses at masters and above and theses at UG level if published in any way, in these cases ethical permission has to be sought.*

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, involving non vulnerable persons or their data***	
1. Anonymous and other surveys with non-vulnerable adults of a non-intrusive personal nature, including surveys where respondents can be identified and where respondents have given appropriate explicit.	
2. Unrecorded and anonymous observation of individuals in public areas.	
3. Interviews, focus groups or other face to face methods of data collection (consensual) with non-vulnerable adults of a non-intrusive personal nature.	
4. 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).	

5. Analysis of irrevocably anonymised and appropriately collected data, that the researcher has permission from the owner to access.	
6. 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.	
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, these samples cannot be used for genetic testing whether anonymous or otherwise and must be destroyed immediately after the study.	

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 and or the participants are considered vulnerable)***	
1. All study types that the participants are vulnerable participants: - minors - adult participants who are purposively recruited from the following groups: who cannot give consent, have communication difficulties, unconscious or very severely ill, terminal illness, mental illness, dementia, prisoners, those who have a dependant relationship with researcher i.e. line manager, part of the care team.	
2. All study types 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).	
3. Surveys asking questions of a sensitive or private nature.	
4. A project involving a justifiable degree of deception.	
5. A clinical trial of medicines or medical interventions.	
6. Analysis of archival irrevocably anonymised human tissue, or samples i.e. blood for which consent for research was not originally given and was not for a previous research study, must always get new ethical approval.	
7. Research involving collection of invasive biological samples or tissues (excluding saliva, plaque, epithelial cells or small volumes of blood <10 ml from volunteers).	
8. Research on biological samples yielding information that could impact upon treatment (e.g. Human DNA sequencing).	
9. Research where identifiable information obtained may have legal, economic or social consequences for research subjects.	
10. Research that may identify illegal activity.	
11. Projects where each subject is paid (over and above token gestures).	
12. Research that may potentially endanger the subjects, and/or researchers, and/or 3rd parties, and/or the environment.	
14. Research that may have a direct military role.	
15. Research involving humans or their data, that is not publicly available, conducted outside Ireland.	
16. Research involving psychological intervention.	
17. Research where a potentially beneficial or harmful treatment or learning method may be withheld from some participants.	
18. Research involving invasive procedures other than those listed above.	
19. Research not included in this document should be reviewed by an appropriate Level 2 REC.	