

Higher Education within Loughborough College

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Applicable to:	Staff & Learners
Accessible to:	Staff/Learners/Governors/Public

A Guidance for Ethical Approval for Research/Project Procedures in validated HE Programmes

1.0 Introduction:

Ethical considerations are critically important in planning research and teaching, and this guidance is designed to help you in dealing with ethical considerations in these areas.

The guidance sets the context of the processes and principles underpinning any decision by Loughborough College to give consent to a student and/or staff member.

When ethical approval is given, the proposer/researcher and any other researchers involved in the study, remain liable and responsible for adhering to the principles submitted and agreed by the Ethics Committee. Included in this guide is a flow chart and principles included within it should act as guides by which staff and students evaluate proposals and complete the ethics forms. These are included as templates for use in making applications to the 'HE Ethics Committee', as well as seeking consent from participants and/or parents.

This guidance is not intended to hamper the progress of any proposal, but to ensure there is a proper due diligence process that is proportionate to the risk involved in a particular research proposal. In 2015, the committee divided these into 4 areas:

- 1) Non-empirical research, using only secondary or published sources (for example, an extended literature review, meta-analysis or using published data sets)
- 2) Collection and/or analysis of primary, unpublished data from, or about human participants, and or, agencies and organisations, including primary observations of behaviours where people would normally expect privacy i.e. online forums, social media or blogs.
- 3) Laboratory based experimental research in controlled laboratories or related industrial settings.
- 4) Research within NHS and or research on NHS/Social Care Premises or with social care clients or patients. (In this case, additional approval will be needed from NHS and/or Social Care Ethics Panel).¹

¹ Please note that from October 2007 research involving people who are clinically assessed to lack capacity, and therefore cannot give informed consent, must be cleared through the NHS research ethics procedures, not through a University research ethics committee. In all cases, seek advice from the Chair of the relevant Academic Department Ethics Committee, such a referral will require College Ethical Committee agreement before submission to NHS/Social Care.

Equally, the guide offers support in developing both the quality and ethical acceptability of any application. The proforma and any letters of explanation or consent should, in the majority of cases, take very little time to complete. Where they do take time, this should be an indication of problems which need to be dealt with before any research project is undertaken. It should inform both your research proposal and the areas you will need to consider to give the College proper assurance, as well as protecting the rights of participants.

If, during your usage of this procedural document and its suggested processes, you feel that there are things which still need modifying, or issues which need to be raised, please do not hesitate to put your views to the Ethics Committee or any other relevant person.

2.0 Purpose:

The purpose of this document is to establish a system, provide guidance, advice and monitoring on the important issue of Ethics in staff and student research and scholarly projects.

In every case, when research is undertaken by any staff or student, ethical considerations must be given attention.

It is envisaged that a Staff or Student Ethics Application Form will be completed in all cases and further explanatory supplements may be required. How much additional information will depend on the complexity and sensitivity of the proposal:

- For every project by a **student** on a taught module where a major research project is undertaken.
- **For a staff** member who has been authorised by senior staff (SMT level or Executive) at Loughborough College and/or commissioned externally, or as part of an agreed 'scholarly' activity/plan.

As stated, signing and gaining approval for the research from the Ethics Committee does not absolve the researcher(s) for observing general ethical guidelines, for example, abiding by the law, observing copyright, complying with plagiarism conventions, acknowledging authorship etc.

The ultimate responsibility for the ethics in a project and how it evolves remains with the researcher(s) and the academic acting as supervisor

3.0 Policy Statement:

Loughborough College considers the welfare of children and vulnerable adults of paramount importance and aims to safeguard and promote their welfare, safety and health by fostering an honest, open, caring and supportive environment.

3.1: The student / supervisor must protect the participant from physical and psychological discomfort, harm and danger that may arise from the procedures used.

3.2: Where research/lecturing procedures could result in undesirable consequences for the individual participant, the student / supervisor has the responsibility to detect and remove or correct these consequences, including long-term effects.

3.3 The Ethics Policy will be mindful of the overriding principle that Loughborough College is committed to promoting an environment, where every learner is treated with respect and dignity. No learner, member of staff or any related third party should feel disadvantaged on the grounds of ethnicity, sex, age, gender reassignment, pregnancy, marital status, sexual orientation, disability, religious beliefs or any other characteristic.”

4.0 Principles of Good Research Practice:

All those to whom the College regulations apply are expected to:

- Maintain professional standards.
- Be familiar with guidance on best research practice, for example in relation to matters of policy, ethics, finance and safety.
- Observe legal and ethical requirements laid down by the institution or other properly appointed bodies involved in the research field.
- Recognise the importance of good leadership and co-operation in research groups.
- Take special account of the needs of young researchers.
- Document results and keep secure primary data.
- Question findings.
- Attribute honestly the contribution of others.
- Take steps to ensure the safety of all those associated with the research.
- Report any conflict of interest, actual or prospective, to the appropriate person.
- The need for research to ensure that no person experiences disadvantage or unfair treatment as a result of their protected characteristic as defined in the Equality Act 2010.

5.0 Definition of Research Misconduct:

Research misconduct includes the following, whether deliberate, reckless or negligent:

- Failure to obtain appropriate permission to conduct research.
- Deception in relation to research proposals.
- Unethical behaviour in the conduct of research, for example in relation to research subjects.
- Unauthorised use of information which was acquired confidentially.

- Deviation from good research practice, where this results in unreasonable risk of harm to humans, animals or the environment.
- Fabrication, falsification or corruption of research data.
- Distortion of research outcomes, by distortion or omission of data that do not fit expected results.
- Dishonest misinterpretation of results.
- Publication of data known or believed to be false or misleading.
- Plagiarism, or dishonest use of unacknowledged sources.
- Misquotation or misrepresentation of other authors.
- Inappropriate attribution of authorship.
- Fraud or other misuse of research funds or research equipment.
- Attempting, planning or conspiring to be involved in research misconduct.
- Inciting others to be involved in research misconduct.
- Collusion in or concealment of research misconduct by others.

It does not include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results, or misconduct unrelated to the research process. Similarly it does not include poor research, unless this encompasses the intention to deceive. Students who are suspected of research misconduct may be subject to college disciplinary procedures.

6.0 How the System Works- Students:

6.1: When students and project supervisors are contemplating beginning a piece of research, they need to consider the ethical issues which need to be addressed both before it is started and any changes in these as the project progresses. In all cases, students should seek advice at this stage from their supervisor.

6.2: The relevant proforma, a copy of which can be found on HE Learnzone, should therefore be read and completed as appropriate. This document contains proforma's relevant to the ethical assessment of a research project including procedures for obtaining consent and sample consent forms. Electronic copies of forms will be available where appropriate, but a signature must always be produced as proof of compliance or consent.

6.3: The proforma should be read in conjunction with the flow chart prior to the beginning of any research project.

6.4: Any letters to obtain consent must be approved by the relevant Sub or full Ethics Committee. For students your tutor/supervisor will advise you. Their view and advice should be included with the application

for approval. Once cleared, informed consent should be sent by, and returned to the researcher before the research work begins.

6.5: The proforma, a copy of the proposal, and any informed consent letters, and other key documents should be sent to the relevant Sub and/or full College Ethics Committee for 'approval and recommendation'.

6.6: A separate declaration will need to be added to the project, declaring that ethical procedures have been followed.

6.7: Where proposals are not given approval recommendation, they will be returned to the researcher and supervisor for any necessary clarification. The proposal will be considered against 4 recommendations:

- a) Your proposal has been agreed by the Ethics Committee (date), you can commence your research.
- b) Your proposal has been referred back for resubmission with the following recommendations (Insert list of recommendations). Once these have been implemented and approved by your supervisor, you may commence your research. The supervisor will inform the Ethics Committee that the conditions have been met.
- c) Your proposal has been approved following the Ethics Committee on (date) subject to the (list conditions). Once these have been implemented and approved by your supervisor, you may commence your research. The supervisor will inform the Ethics Committee that the conditions have been met.
- d) Your proposal has been rejected following the Ethics Committee on (date) and you are advised to consider a new proposal.

6.8: Where the Ethics Committee makes a recommendation that a proposal be rejected, clear reasons for this decision will be given.

6.9: Normally, a student researcher would take the advice and recommendation of the Ethics Committee and see this as developmental feedback. However, if a proposal is rejected under (d) by the Ethics Committee, and the student or staff member believes they can identify a failure in process, the proposer has right of appeal under College policies and procedures.

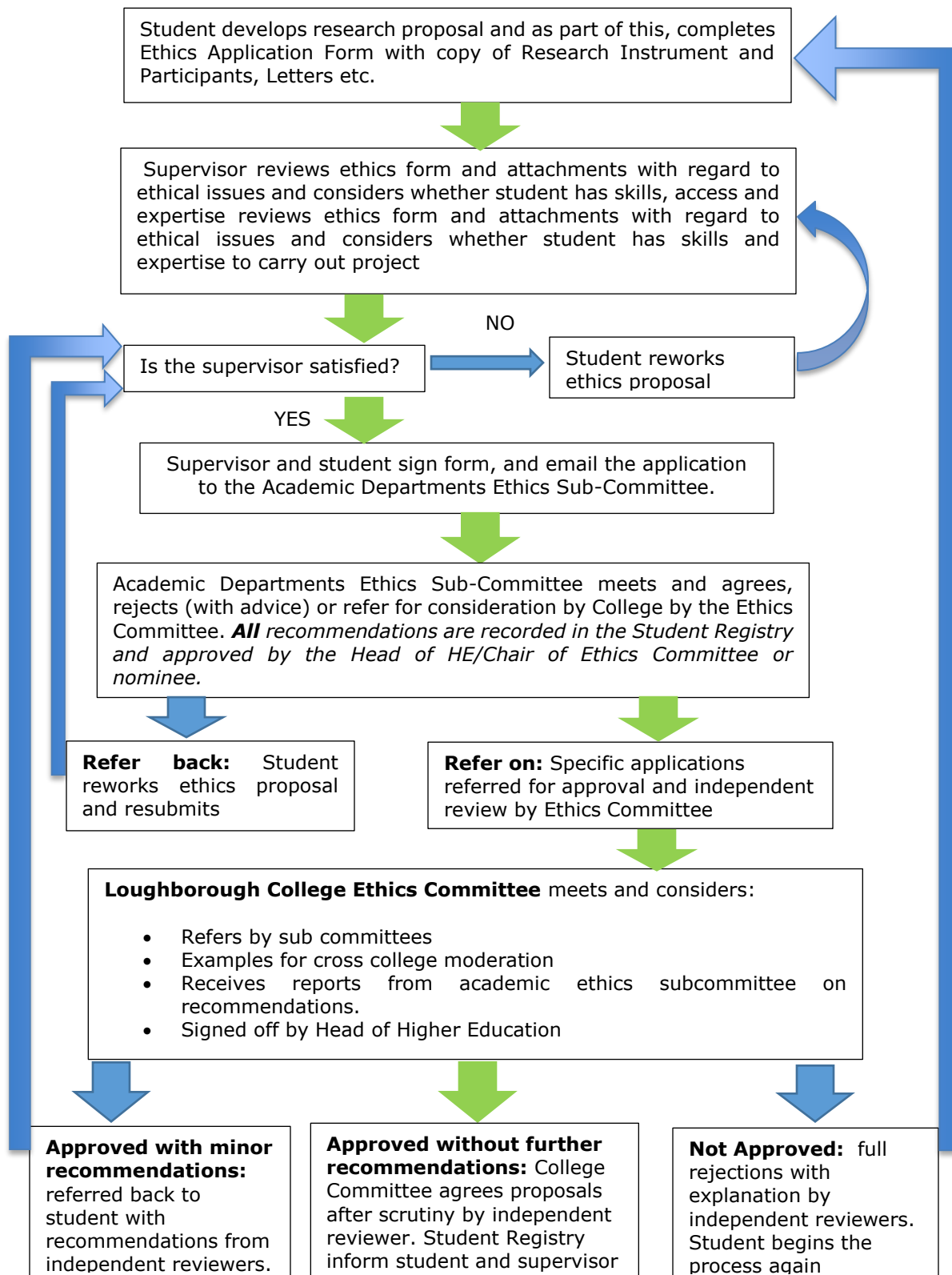
6.10: You are advised to consider in advance any issues with the disclosure of sensitive information during the research process i.e. legal issues, safeguarding concerns etc. Where you are undertaking an organisational study and have safeguarding or other legal or ethical concerns, the said organisation should have policies and procedures which should be used. Your supervisor should be informed (where possible and safe) prior to taking any action.

6.11: Where it is a safeguarding matter, again the organisation may have policies that you are required to follow. In research areas where this is likely in an organisation, this possibility should be clarified before the research begins.

6.12: Where it is with individuals, again, before the research begins, and consent is obtained, the 'limits' of what is meant by 'confidentiality' should be explained and understood by the client and any care workers/family or staff involved.

6.13: All students and staff are bound by statutory and legal requirements. In all cases of doubt or concern, matters should be drawn to the attention of your supervisor, who can seek senior and expert advice.

6.15 Flow Chart Process for Students:



7.0 How the Systems Works- Staff (academic and professional services):

7.1: Before completing any formal processes, a staff member must have agreement from the relevant senior manager to undertake a research based/scholarly/evaluation project.

7.2: Where a staff member is bidding internally or externally for a research based/scholarly/evaluation project. They (again) must seek approval from their senior manager and have sought and gained full or initial agreement (where appropriate) for the project in terms of 'Ethics' clearance from the Chair of the Ethics Committee or nominee or the full committee where a full research proposal is required as part of the bidding submission.

7.3: Staff are advised to utilise the Academic Department's Ethics Sub Committee to advise the development of any bid, before seeking formal approval (including Ethics clearance for any bid/tender.²)

7.4: When a staff member has the agreement of their line manager and has (where required) identified a project supervisor, they must consider the ethical issues to be addressed before any project begins. In all such cases, staff should seek advice at this stage from their supervisor or the Head of Higher Education.

7.5: Where a staff member is undertaking research as part of an externally managed postgraduate research programme, and the subject of the research is directly linked to Loughborough College's business, clients or staff, the College will normally require that the staff member, working as a PG student, to complete the ethical processes within the university they are studying at. In all such cases the staff member will inform the College's Chair of its Ethics Committee and submit: a) a copy of the proposal form b) written confirmation from the University's own Ethics Committee that the project has been approved.³ The Ethics committee will keep a record of such projects and may in some cases, require additional ethical consideration

7.6: The relevant proforma for Ethical Approval, a copy of which can be found on HE Learnzone, should therefore be read and completed as appropriate. This document contains other 'proformas' relevant to the ethical assessment of a research project followed (in appendices) by procedures for obtaining consent and sample consent forms. Electronic copies of forms will be available where appropriate, but a signature must always be produced as proof of compliance or consent.

7.7: The proforma should be read in conjunction with the '**Staff Ethical Approval Flow Chart**' prior to the beginning of any project research.

7.8: Any letters to obtain consent must be approved by the relevant Sub or Full Ethics Committee, where appropriate your supervisor or the Chair of the Ethics Committee (or Academic Department Sub Committee) will advise), as part of the Ethical Approval Process and included with the application for approval. Once cleared, informed consent should be sent by, and returned to the principal researcher before the research work begins.

² The process recognises that for small scale evaluations the bidding process will be tight and often the required information and word limits for bidders is limited. Pre-approval of the Ethical issues will be a step that strengthens the majority of bids.

³ The College through the committee reserves the rights to refer the project back to the university or advise the academic board that it does not support the recommendation for ethical clearance.

7.9: The proforma, a copy of the proposal, and any informed consent letters as well as any research instruments, and other key documents will then be sent to the relevant Sub and/or full College Ethics Committee for 'approval recommendation'.

7.10: A separate declaration will need to be added to the project, declaring that ethical procedures have been followed.

7.11: Where proposals are not given approval recommendation, they will be returned to the researcher and supervisor for any necessary clarification. The proposal will be considered against 4 recommendations.

- a) Your proposal has been agreed by the Ethics Committee (date)
- b) Your proposal has been referred back with the following recommendations and resubmission. (Inserted recommendations). Once these are implemented and approved by your supervisor, you may commence your research. The supervisor will inform the ethics committee that the conditions have been met.
- c) Your proposal has been rejected (date) and required significant re-working to meet Ethical Considerations. (Insert reasons). In this case, resubmission can be considered.
- d) Your proposal has been rejected and you are advised to consider a new proposal.

7.12: Where the Ethics Committee makes a recommendation that a proposal be rejected and in such cases give clear reasons for this decision.

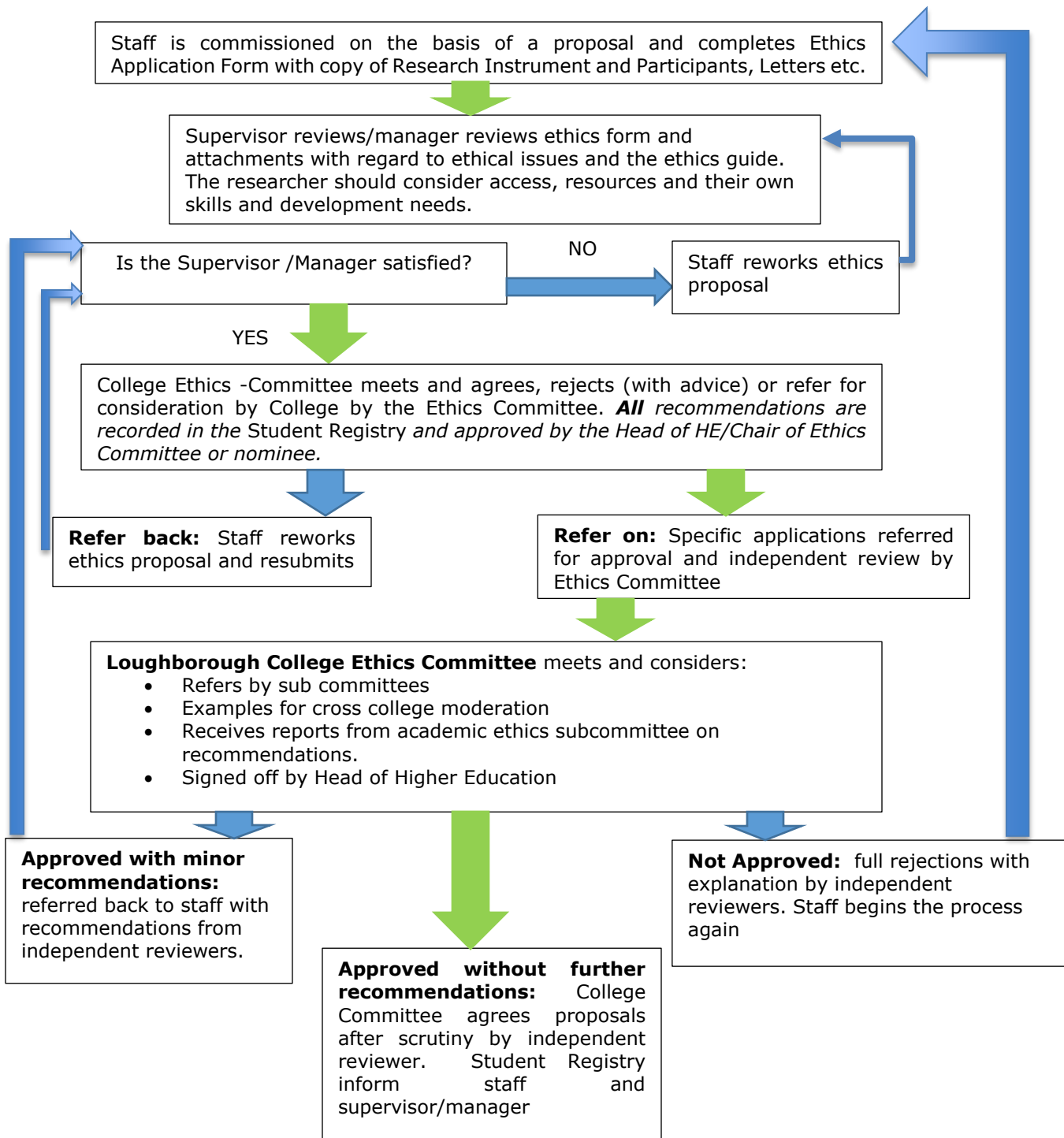
7.13: You are advised to consider in advance any issues of disclosure of sensitive information during the research process i.e. legal issues, safeguarding concerns etc. Where you are undertaking an organizational study, the said organization should have policies and procedures. These should be used and your supervisor should be informed (where possible and safe) prior to taking any action.

7.14: Where it is a safeguarding matter, again the organization may have policies that you are required to follow, in research areas where this is likely in an organization, this possibility should be clarified before the research begins.

7.15: Where it is with individuals, again, before the research begins, and consent is obtained, the 'limits' of what is meant by 'confidentiality should be explained and understood by the client and any care workers/family or staff involved.

7.16: All student and staff are bound by statutory and legal requirements. In all cases of doubt or concern, matters should be drawn to the attention of your supervisor, who can seek senior and expert advice.

7.17 Flow Chart Process for Staff:



8.0 General Principles- Students and Staff

8.1: Where research is carried out by students, it is the joint responsibility of the student and the supervisors to ensure its ethical acceptability prior to the ethics board.

8.2: In planning a study, staff, students, supervisors and managers must carefully evaluate its ethical acceptability. Any aspect which suggests that questions of its ethical acceptability are raised, independent approval from the Ethics Committee must be obtained.

8.3: The primary ethical concern of all students / supervisors lies in considering whether a participant will in any way be a 'subject at risk'.

8.4: The students/staff/supervisor always retain the responsibility for ensuring ethical practice in the research/teaching. They are also the persons responsible for the ethical treatment of participants by collaborators, assistants, other students, and employees.

8.5: Staff/students and their supervisor are both responsible for ensuring that any safeguarding issues are addressed and cleared prior to contact and research taking place.

8.6: These other collaborators, assistants, students, and employees still, however, incur similar ethical obligations to those of the principal students/supervisors.

8.7: The staff/student/supervisor must provide for participants, and prior to their participation, a clear and fair description of the research/teaching in writing. The student/supervisor must honour all promises and commitments included in that agreement. The student/supervisor must inform all participants, in ways that can be understood by them, of all aspects that might reasonably be expected to influence their willingness to participate, as well as explain all other aspects about which the participants enquire.

8.8: Procedures to protect confidentiality should be outlined in documentation initially given to the participant while informed consent is obtained. Information obtained about a participant during the course of an investigation must be treated as confidential unless otherwise agreed upon in advance. When the possibility exists that others may obtain access to such information, this possibility, together with the plans for protecting confidentiality, should be explained to the participant as part of the procedure for obtaining informed consent. All data obtained should be held in line with the College Data Protection Policy.⁴

8.9: The implications of research with participants of a different cultural background to that of the student/supervisor should be considered at a very early stage. This consideration should include partnership with an informed member of the population from which the research sample is to be drawn, in order to check for foreseeable threats to psychological well-being, health, values and dignity. The proposal should then, after such initial vetting, go to the sub or full Ethics Committee.

8.10: The staff/student/supervisor must respect the individual's freedom to decline to participate in, or to withdraw from the research or teaching situation at any time. The staff/student/supervisor must take particular account of the fact that s/he is normally in a position of authority or influence over the participant during the investigation, and that this may prevent the participant from voicing such wishes.

⁴ All data to be held with the college, College Data Protection Policy

8.11: Researchers and supervisors must familiarise themselves (where required) on college policies and procedures in regard to Children or Vulnerable Adults.

9.0 Loughborough College Ethics Committee - Terms of Reference:

The College seeks to promote and maintain high ethical standards in the conduct of academic activity or professional practice undertaken by staff and students. It aims to ensure the well-being of those involved and to safeguard the standards and reputation of the institution in matters of academic and professional practice.

It is the responsibility of every student and member of staff to ensure that the work they carry out, both academic activity and professional practice, complies with the College Ethical Guidelines.

A record of all decisions is maintained by the Student Registry and the Chair will sign off clearance following committee meetings.

Academic Sub Committee's must lodge all recommendations at the full Ethics Committee and use a cross college sampling methodology to ensure externality to the work of academic departmental ethics sub committees.

To assist in this process, the College has established an Ethics Committee with the following Terms of Reference:

- To consider for approval (or not) applications by both staff and students to undertake research.
- To act in an advisory capacity on ethical matters pertaining to student projects, work placements and any other relevant dimensions of academic activity and professional practice in higher education courses
- To ensure that academic department ethics subcommittee decisions are scrutinised and subject to a process of sampling and verification
- To advise on ethical matters pertaining to the conduct of research, both individual and collaborative.
- To ensure that student research activities are in line with the guidelines and practices on ethical issues of the relevant validating universities or awarding bodies

10.0 Loughborough College Ethical Guidelines:

The following ethical guidelines should be read in conjunction with College policies on Health and Safety, Equal Opportunities and Safeguarding, in relation to individual contracts of employment, and the Data Protection Act 1998.

10.1: All academic activity or professional practice should be conducted within an ethical framework comprising of aspects such as respect for persons, respect for knowledge, and respect for inclusive values.

10.2: For legal reasons, care must be taken when carrying out professional projects or research with anyone under 16 years of age. In the case of any proposed participants who are in a situation or condition of vulnerability, permission must be obtained from the relevant institution and/or, as appropriate, from the parents or guardians of such participants.

10.3: Practitioners, teachers, researchers and students have a responsibility to avoid discrimination against any individual, directly or indirectly, in the planning, conduct and reporting of their academic and professional activities on grounds of gender, race, disability, colour, sexuality, age, nationality, ethnic or national origins, marital status, family or other care responsibility, socio-economic background, trade union activity, political or religious belief.

10.4: All undertakings given to participants in academic activity or professional practice concerning confidentiality and informed consent should be respected.

10.5: Any academic activity or professional practice undertaken at or under the auspices of Loughborough College should be carried out in such a way that it does not put at risk the current or future reputation or legal responsibility of the College.

11.0 Loughborough College Ethics Committee Membership:

- Head or Deputy Head of Higher Education (Chair)
- Minimum of one and a maximum of two representatives from each curriculum team undertaking activities on Higher Education courses which fall within the terms of the College Ethical Guidelines
- Minimum of 2 staff representative must be qualified to undertake and teach research at level 6.
- External experts from professional and or industry partners (where required.)
- Validating University partners (where required.)
- Higher Education Administrator/Registrar (Secretary)
- Safeguarding Lead and Equality & Diversity lead (when required.)

12.0 Loughborough College Academic Departmental Ethics Sub- Committee Membership:

- Curriculum Manager (Chair)
- Minimum of 2 (no maximum) academic staff, two of which must be qualified and experienced at teaching and research at Level 6 Higher Education
- Staff must be qualified generally to undertake activities on Higher Education courses which fall within the terms of the College Ethical Guidelines.
- Staff may be invited and included where they are leading projects on HND/FD level awards
- Higher Education Administrator/Registrar (Secretary)