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Assisting you to advance with ethics in research: an introduction to ethical governance and application procedures

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Abstract

Ethics and ethical behaviour are the fundamental pillars of a civilised society. The focus on ethical behaviour is indispensable in certain fields such as medicine, finance, or law. In fact, ethics gets precedence with anything that would include, affect, transform, or influence upon individuals, communities or any living creatures. Many institutions within Europe have set up their own committees to focus on or approve activities that have ethical impact. In contrast, lesser-developed countries (worldwide) are trying to set up these committees to govern their academia and research. As the first European consortium established to assist academic integrity, European Network for Academic Integrity (ENAI), we felt the importance of guiding those institutions and communities that are trying to conduct research with ethical principles. We have established an ethical advisory working group within ENAI with the aim to promote ethics within curriculum, research and institutional policies. We are constantly researching available data on this subject and committed to help the academia to convey and conduct ethical behaviour. Upon preliminary review and discussion, the group found a disparity in understanding, practice and teaching approaches to ethical applications of research projects among peers. Therefore, this short paper preliminarily aims to critically review the available information on ethics, the history behind establishing ethical principles and its international guidelines to govern research.

The paper is based on the workshop conducted in the 5th International conference Plagiarism across Europe and Beyond, in Mykolas Romeris University, Lithuania in 2019. During the workshop, we have detailed a) basic needs of an ethical committee within an institution; b) a typical ethical approval process (with examples from three different universities); and c) the ways to obtain informed consent with some examples. These are summarised in this paper with some example comparisons of ethical approval processes from different universities. We believe this paper will provide guidelines on preparing and training both researchers and research students in appropriately upholding ethical practices through ethical approval processes.

Keywords: Higher education, Ethical codes, Ethics committee, Post-secondary education, Academia, Ethics, Institutional policies, Research ethics



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Introduction

Ethics and ethical behaviour (often linked to “responsible practice”) are the fundamental pillars of a civilised society. Ethical behaviour with integrity is important to maintain academic and research activities. It affects everything we do, and gets precedence with anything that would include/affect, transform, or impact upon individuals, communities or any living creatures. In other words, ethics would help us improve our living standards (LaFollette, 2007). The focus on ethical behaviour is indispensable in certain fields such as medicine, finance, or law, but is also gaining recognition in all disciplines engaged in research. Therefore, institutions are expected to develop ethical guidelines in research to maintain quality, initiate/own integrity and above all be transparent to be successful by limiting any allegation of misconduct (Flite and Harman, 2013). This is especially true for higher education organisations that promote research and scholarly activities. Many European institutions have developed their own regulations for ethics by incorporating international codes (Getz, 1990). The lesser developed countries are trying to set up these committees to govern their academia and research. World Health Organization has stated that adhering to “*ethical principles ... [is central and important]... in order to protect the dignity, rights and welfare of research participants*” (WHO, 2021). Ethical guidelines taught to students can help develop ethical researchers and members of society who uphold values of ethical principles in practice.

As the first European-wide consortium established to assist academic integrity (European Network for Academic Integrity – ENAI), we felt the importance of guiding those institutions and communities that are trying to teach, research, and include ethical principles by providing overarching understanding of ethical guidelines that may influence policy. Therefore, we set up an advisory working group within ENAI in 2018 to support matters related to ethics, ethical committees and assisting on ethics related teaching activities.

Upon preliminary review and discussion, the group found a disparity in understanding, practice and teaching approaches to ethical applications among peers. This became the premise for this research paper. We first carried out a literature survey to review and summarise existing ethical governance (with historical perspectives) and procedures that are already in place to guide researchers in different discipline areas. By doing so, we attempted to consolidate, document and provide important steps in a typical ethical application process with example procedures from different universities. Finally, we attempted to provide insights and findings from practical workshops carried out at the 5th International Conference Plagiarism across Europe and Beyond, in Mykolas Romeris University, Lithuania in 2019, focussing on:

- highlighting the basic needs of an ethical committee within an institution,
- discussing and sharing examples of a typical ethical approval process,
- providing guidelines on the ways to teach research ethics with some examples.

We believe this paper provides guidelines on preparing and training both researchers and research students in appropriately upholding ethical practices through ethical approval processes.

Background literature survey

Responsible research practice (RRP) is scrutinised by the aspects of ethical principles and professional standards (WHO’s Code of Conduct for responsible Research, 2017).

The Singapore statement on research integrity (The Singapore Statement on Research integrity, 2010) has provided an internationally acceptable guidance for RRP. The statement is based on maintaining honesty, accountability, professional courtesy in all aspects of research and maintaining fairness during collaborations. In other words, it does not simply focus on the procedural part of the research, instead covers wider aspects of “integrity” beyond the operational aspects (Israel and Drenth, 2016).

Institutions should focus on providing ethical guidance based on principles and values reflecting upon all aspects/stages of research (from the funding application/project development stage upto or beyond project closing stage). Figure 1 summarizes the different aspects/stages of a typical research and highlights the needs of RRP in compliance with ethical governance at each stage with examples (the figure is based on Resnik, 2020; Žukauskas et al., 2018; Anderson, 2011; Fouka and Mantzorou, 2011).

Individual responsibilities to enhance RRP

As explained in Fig. 1, a successfully governed research should consider ethics at the planning stages prior to research. Many international guidance are compatible in enforcing/recommending 14 different “responsibilities” that were first highlighted in the Singapore Statement (2010) for researchers to follow and achieve competency in RRP. In order to understand the purpose and the expectation of these ethical guidelines, we have carried out an initial literature survey on expected individual responsibilities. These are summarised in Table 1.

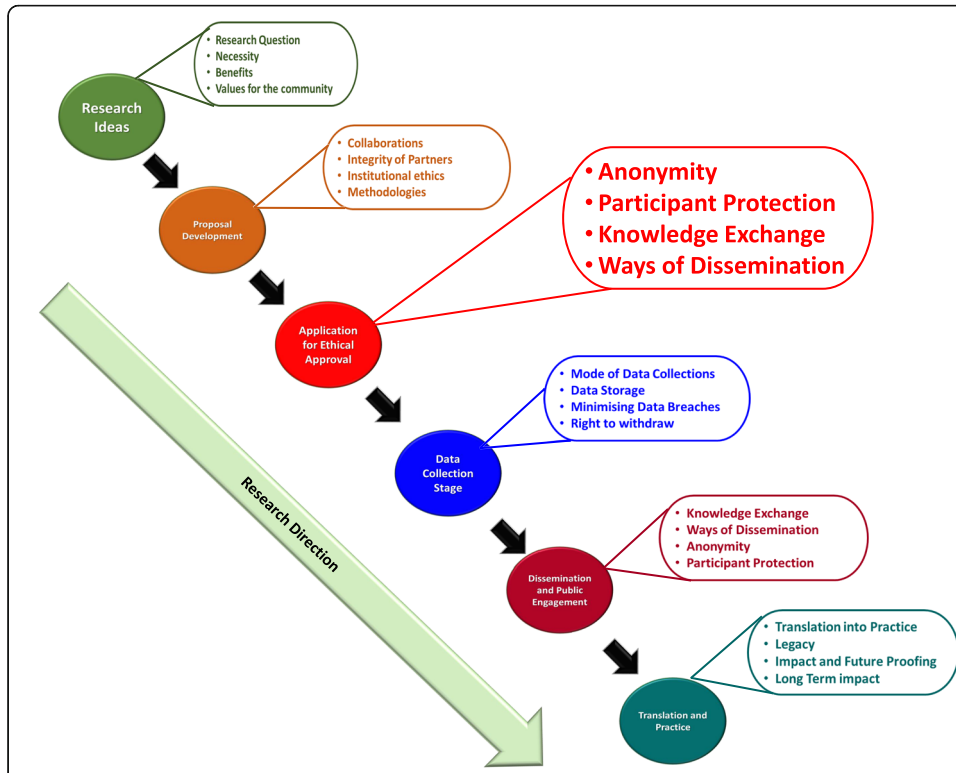


Fig. 1 Summary of the enabling ethical governance at different stages of research. Note that it is imperative for researchers to proactively consider the ethical implications before, during and after the actual research process. The summary shows that RRP should be in line with ethical considerations even long before the ethical approval stage

Table 1 Summary of agreed responsibilities for researchers to ensure RRP

Researcher responsibilities	RRP enhancements
Upholding Integrity at all stages of research	Proper research design in consideration of all stakeholders.
Adherence to Regulations	Forward planning in accordance with local/institutional ethical policies
Appropriateness of research methods	Applying appropriate methodologies including participant selection, informed consents, right to withdrawal etc.
Accurate record keeping	Long-term competency checks, data handling/storage by avoiding/minimising data breaches. Also methodological changes to address any efficiency issues.
Openness in research findings	Maintaining transparency, measuring the benefits against risks
Responsible authorships	Truthful representation related to contributions by avoiding authorship malpractices
Proper attribution	Respecting contributions and acknowledging attributions
Rigorous evaluation in peer review	Critical analysis of all aspects within research and taking appropriate measures to attribute issues
Disclosing conflicts of interests	Truthful reporting of funding sources, potential conflicts, addressing allegations of misconduct and other irresponsible research practices
Responsible Public communication	Reporting the findings highlighting both the advantages and disadvantages
Transparency in research	Ensures the research integrity at all stages
Prompt actions against misconducts	Minimising the chances of any research/professional misconducts whilst protecting the whistle blowers
Creating a sustainable research environments	Encouraging integrity through education, maintaining clear policies, and standards

Table is based on The Singapore Statement on Research Integrity (2020)

By following these directives, researchers can carry out accountable research by maximising ethical self-governance whilst minimising misconducts. In our own experiences of working with many researchers, their focus usually revolves around ethical “clearance” rather than behaviour. In other words, they perceive this as a paper exercise rather than trying to “own” ethical behaviour in everything they do. Although the ethical principles and responsibilities are explicitly highlighted in the majority of international guidelines [such as UK’s Research Governance Policy (NICE, 2018), Australian Government’s National Statement on Ethical Conduct in Human Research (Difn website^a - National Statement on Ethical Conduct in Human Research (NSECHR), 2018), the Singapore Statement (2010) etc.]; and the importance of holistic approach has been argued in ethical decision making, many researchers and/or institutions only focus on ethics linked to the procedural aspects.

Studies in the past have also highlighted inconsistencies in institutional guidelines pointing to the fact that these inconsistencies may hinder the predicted research progress (Desmond & Dierickx 2021; Alba et al., 2020; Dellaportas et al., 2014; Speight 2016). It may also be possible that these were and still are linked to the institutional perceptions/expectations or the pre-empting contextual conditions that are imposed by individual countries. In fact, it is interesting to note many research organisations and HE institutions establish their own policies based on these directives.

Research governance - origins, expectations and practices

Ethical governance in clinical medicine helps us by providing a structure for analysis and decision-making. By providing workable definitions of benefits and risks as well as

the guidance for evaluating/balancing benefits over risks, it supports the researchers to protect the participants and the general population.

According to the definition given by National Institute of Clinical care Excellence, UK (NICE 2018), “*research governance can be defined as the broad range of regulations, principles and standards of good practice that ensure high quality research*”. As stated above, our literature-based research survey showed that most of the ethical definitions are basically evolved from the medical field and other disciplines have utilised these principles to develop their own ethical guidance. Interestingly, historical data show that the medical research has been “self-governed” or in other words implicated by the moral behaviour of individual researchers (Fox 2017; Shaw et al., 2005; Getz, 1990). For example, early human vaccination trials conducted in 1700s used the immediate family members as test subjects (Fox, 2017). Here the moral justification might have been the fact that the subjects who would have been at *risk* were either the scientists themselves or their immediate families but those who would reap the *benefits* from the vaccination were the general public/wider communities. However, according to the current ethical principles, this assumption is entirely not acceptable.

Historically, ambiguous decision-making and resultant incidences of research misconduct have led to the need for ethical research governance in as early as the 1940’s. For instance, the importance of an international governance was realised only after the World War II, when people were astonished to note the unethical research practices carried out by Nazi scientists. As a result of this, in 1947 the Nuremberg code was published. The code mainly focussed on the following:

- (a) Informed consent and further insisted the research involving humans should be based on prior animal work,
- (b) The anticipated benefits should outweigh the risk,
- (c) Research should be carried out only by qualified scientists must conduct research,
- (d) Avoiding physical and mental suffering and.
- (e) Avoiding human research that would result in which death or disability.

(Weindling, 2001).

Unfortunately, it was reported that many researchers in the USA and elsewhere considered the Nuremberg code as a document condemning the Nazi atrocities, rather than a code for ethical governance and therefore ignored these directives (Ghooi, 2011). It was only in 1964 that the World Medical Association published the Helsinki Declaration, which set the stage for ethical governance and the implementation of the Institutional Review Board (IRB) process (Shamoo and Irving, 1993). This declaration was based on Nuremberg code. In addition, the declaration also paved the way for enforcing research being conducted in accordance with these guidelines.

Incidentally, the focus on research/ethical governance gained its momentum in 1974. As a result of this, a report on ethical principles and guidelines for the protection of human subjects of research was published in 1979 (The Belmont Report, 1979). This report paved the way to the current forms of ethical governance in biomedical and behavioural research by providing guidance.

Since 1994, the WHO itself has been providing several guidance to health care policy-makers, researchers and other stakeholders detailing the key concepts in medical ethics. These are specific to applying ethical principles in global public health.

Likewise, World Organization for Animal Health (WOAH), and International Convention for the Protection of Animals (ICPA) provide guidance on animal welfare in research. Due to this continuous guidance, together with accepted practices, there are internationally established ethical guidelines to carry out medical research. Our literature survey further identified freely available guidance from independent organisations such as COPE (Committee of Publication Ethics) and ALLEA (All European Academics) which provide support for maintaining research ethics in other fields such as education, sociology, psychology etc. In reality, ethical governance is practiced differently in different countries. In the UK, there is a clinical excellence research governance, which oversees all NHS related medical research (Mulholland and Bell, 2005). Although, the governance in other disciplines is not entirely centralised, many research funding councils and organisations [such as UKRI (UK-Research and Innovation; BBSC (Biotechnology and Biological Sciences Research Council; MRC (Medical Research Council); EPSRC (Economic and Social Research Council)] provide ethical governance and expect institutional adherence and monitoring. They expect local institutional (i.e. university/institutional) research governance for day-to-day monitoring of the research conducted within the organisation and report back to these funding bodies, monthly or annually (Department of Health, 2005). Likewise, there are nationally coordinated/regulated ethics governing bodies such as the US Office for Human Research Protections (US-OHRP), National Institute of Health (NIH) and the Canadian Institutes for Health Research (CIHR) in the USA and Canada respectively (Mulholland and Bell, 2005). The OHRP in the USA formally reviews all research activities involving human subjects. On the other hand, in Canada, CIHR works with the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC). They together have produced a Tri-Council Policy Statement (TCPS) (Stephenson et al., 2020) as ethical governance. All Canadian institutions are expected to adhere to this policy for conducting research. As for Australia, the research is governed by the Australian code for the responsible conduct of research (2008). It identifies the responsibilities of institutions and researchers in all areas of research. The code has been jointly developed by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC) and Universities Australia (UA). This information is summarized in Table 2.

Basic structure of an institutional ethical advisory committee (EAC)

The WHO published an article defining the basic concepts of an ethical advisory committee in 2009 (WHO, 2009 - see above). According to this, many countries have established research governance and monitor the ethical practice in research via national and/or regional review committees. The main aims of research ethics committees include reviewing the study proposals, trying to understand the justifications for human/animal use, weighing the merits and demerits of the usage (linking to risks vs. potential benefits) and ensuring the local, ethical guidelines are followed. Difr website^b - Enago academy Importance of Ethics Committees in Scholarly Research, 2020; Guide for

Table 2 Summary of some prominent governing bodies in research ethics

Country	Governing Body	Research Areas
Global	World Organization for Animal Health (WOAH)	Animal welfare in research
Global	International Convention for the Protection of Animals (ICPA)	Animal welfare in research
Independent	Committee for Publication Ethics (COPE)	Education, Sociology, Psychology etc
Independent	ALLEA (All European Academics)	Education, Sociology, Psychology etc
UK	NHS	Clinical research governance
UK	UK Research and Innovation (UKRI)	Ethical governance
UK	Biotechnology and Biological Sciences Research Council (MMSC)	Ethical governance
UK	(MRC)	Ethical governance
UK	Economic and Social Research Council (EPSRC)	Ethical governance
USA	US Office for Human Research Protections (US-OHRP)	Research ethics involving human subjects
USA	National Institute of Health (NIH)	Research ethics involving human NIH (N.D).
Canada	Canadian Institutes for Health Research (CIHR)	Jointly developed Tri-Council Policy Statement for ethical governance for all types of research.
Canada	Natural Sciences and Engineering Research Council (NSERC)	
Canada	Social Sciences and Humanities Research Council (SSHRC)	
Australia	National Health and Medical Research Council (NHMRC)	Jointly developed Australian code for the responsible conduct of research - all areas of research
Australia	Australian Research Council (ARC)	
Australia	Universities Australia (UA)	

Research Ethics - Council of Europe, 2014). Once the research has started, the committee needs to carry out periodic surveillance to ensure the institutional ethical norms are followed during and beyond the study. They may also be involved in setting up and/or reviewing the institutional policies.

For these aspects, IRB (or institutional ethical advisory committee - IEAC) is essential for local governance to enhance best practices. The advantage of an IRB/EEAC is that they understand the institutional conditions and can closely monitor the ongoing research, including any changes in research directions. On the other hand, the IRB may be overly supportive to accept applications, influenced by the local agenda for achieving research excellence, disregarding ethical issues (Kotecha et al., 2011; Kayser-Jones, 2003) or, they may be influenced by the financial interests in attracting external funding. In this respect, regional and national ethics committees are advantageous to ensure ethical practice. Due to their impartiality, they would provide greater consistency and legitimacy to the research (WHO, 2009). However, the ethical approval process of regional and national ethics committees would be time consuming, as they do not have the local knowledge.

As for membership in the IRBs, most of the guidelines [WHO, NICE, Council of Europe, (2012), European Commission - Facilitating Research Excellence in FP7 (2013) and OHRP] insist on having a variety of representations including experts in different fields of research, and non-experts with the understanding of local, national/

international conflicts of interest. The former would be able to understand/clarify the procedural elements of the research in different fields; whilst the latter would help to make neutral and impartial decisions. These non-experts are usually not affiliated to the institution and consist of individuals representing the broader community (particularly those related to social, legal or cultural considerations). IRBs consisting of these varieties of representation would not only be in a position to understand the study procedures and their potential direct or indirect consequences for participants, but also be able to identify any community, cultural or religious implications of the study.

Understanding the subtle differences between ethics and morals

Interestingly, many ethical guidelines are based on society's moral "beliefs" in such a way that the words "ethics" and "morals" are reciprocally used to define each other. However, there are several subtle differences between them and we have attempted to compare and contrast them herein. In the past, many authors have interchangeably used the words "morals" and "ethics" (Warwick, 2003; Kant, 2018; Hazard, GC (Jr.), 1994, Larry, 1982). However, ethics is linked to rules governed by an external source such as codes of conduct in workplaces (Kuyare et al., 2014). In contrast, morals refer to an individual's own principles regarding right and wrong. Quinn (2011) defines morality as "*rules of conduct describing what people ought and ought not to do in various situations ...*" while ethics is "*...the philosophical study of morality, a rational examination into people's moral beliefs and behaviours*". For instance, in a case of parents demanding that schools overturn a ban on use of corporal punishment of children by schools and teachers (Children's Rights Alliance for England, 2005), the parents believed that teachers should assume the role of parent in schools and use corporal or physical punishment for children who misbehaved. This stemmed from their beliefs and what they felt were motivated by "beliefs of individuals or groups". For example, recent media highlights about some parents opposing LGBT (Lesbian, Gay, Bisexual, and Transgender) education to their children (BBC News, 2019). One parent argued, "Teaching young children about LGBT at a very early stage is 'morally' wrong". She argued "let them learn by themselves as they grow". This behaviour is linked to and governed by the morals of an ethnic community. Thus, morals are linked to the "beliefs of individuals or group". However, when it comes to the LGBT rights these are based on ethical principles of that society and governed by law of the land. However, the rights of children to be protected from "inhuman and degrading" treatment is based on the ethical principles of the society and governed by law of the land. Individuals, especially those who are working in medical or judicial professions have to follow an ethical code laid down by their profession, regardless of their own feelings, time or preferences. For instance, a lawyer is expected to follow the professional ethics and represent a defendant, despite the fact that his morals indicate the defendant is guilty.

In fact, we as a group could not find many scholarly articles clearly comparing or contrasting ethics with morals. However, a table presented by Surbhi (2015) (Difn website^c) tries to differentiate these two terms (see Table 3).

Although Table 3 gives some insight on the differences between these two terms, in practice many use these terms as loosely as possible mainly because of their ambiguity.

Table 3 The key differences between morals and ethics^a

Basis for comparison	Morals	Ethics
Meaning	Morals are the beliefs of the individual or group as to what is right or wrong.	Ethics are the guiding principles, which help the individual or group to decide what is good or bad.
What it is	General principles set by group	Response to a specific situation
Root word	<i>Mos</i> which means custom	<i>Ethikos</i> which means character
Governed by	Social and cultural norms	Individual or Legal and Professional norms
Deals with	Principles of right and wrong	Right and wrong conduct
Applicability in Business	No	Yes
Consistency	Morals may differ from society to society and culture to culture.	Ethics are generally uniform.
Expression	Morals are expressed in the form of general rules and statements.	Ethics are abstract.
Freedom to think and choose	No	Yes

^atable is reproduced from Surbhi (2015)

As a group focussed on the application of these principles, we would recommend to use the term “ethics” and avoid “morals” in research and academia.

Based on the literature survey carried out, we were able to identify the following gaps:

- there is some disparity in existing literature on the importance of ethical guidelines in research
- there is a lack of consensus on what code of conduct should be followed, where it should be derived from and how it should be implemented

The mission of ENAI’s ethical advisory working group

The Ethical Advisory Working Group of ENAI was established in 2018 to promote ethical code of conduct/practice amongst higher educational organisations within Europe and beyond (European Network for Academic Integrity, 2018). We aim to provide unbiased advice and consultancy on embedding ethical principles within all types of academic, research and public engagement activities. Our main objective is to promote ethical principles and share good practice in this field. This advisory group aims to standardise ethical norms and to offer strategic support to activities including (but not exclusive to):

- rendering advice and assistance to develop institutional ethical committees and their regulations in member institutions,
 - sharing good practice in research and academic ethics,
 - acting as a critical guide to institutional review processes, assisting them to maintain/achieve ethical standards,
 - collaborating with similar bodies in establishing collegiate partnerships to enhance awareness and practice in this field,
 - providing support within and outside ENAI to develop materials to enhance teaching activities in this field,
 - organising training for students and early-career researchers about ethical behaviours in form of lectures, seminars, debates and webinars,

- enhancing research and dissemination of the findings in matters and topics related to ethics.

The following sections focus on our suggestions based on collective experiences, review of literature provided in earlier sections and workshop feedback collected:

- a) basic needs of an ethical committee within an institution;
- b) a typical ethical approval process (with examples from three different universities); and
- c) the ways to obtain informed consent with some examples. This would give advice on preparing and training both researchers and research students in appropriately upholding ethical practices through ethical approval processes.

Setting up an institutional ethical committee (ECs)

Institutional Ethical Committees (ECs) are essential to govern every aspect of the activities undertaken by that institute. With regards to higher educational organisations, this is vital to establish ethical behaviour for students and staff to impart research, education and scholarly activities (or everything) they do. These committees should be knowledgeable about international laws relating to different fields of studies (such as science, medicine, business, finance, law, and social sciences). The advantages and disadvantages of institutional, subject specific or common (statutory) ECs are summarised in Fig. 2. Some institutions have developed individual ECs linked to specific fields (or subject areas) whilst others have one institutional committee that overlooks the entire ethical behaviour and approval process. There is no clear preference between the two as both have their own advantages and disadvantages (see Fig. 2). Subject specific ECs are attractive to medical, law and business provisions, as it is perceived the members within respective committees would be able to understand the subject and therefore comprehend the need of the proposed research/activity (Kadam, 2012; Schnyder et al., 2018). However, others argue, due to this “specificity”, the committee would fail to forecast the wider implications of that application. On the other hand, university-wide ECs would look into the wider implications. Yet they find it difficult to understand the purpose and the specific applications of that research. Not everyone understands dynamics of all types of research methodologies, data collection, etc., and therefore there might be a chance of a proposal being rejected merely because the EC could not understand the research applications (Getz, 1990).

Institutional EC- e.g#1	Institutional EC- e.g#2	Institutional EC- e.g#3
One ethical committee to handle all ethical applications	Subject specific ethical committees	One ethical committee for all institutions within a country
<p>Advantages!</p> <ol style="list-style-type: none"> 1. Consistency in decisions 2. Centralised record keeping (best GDPR) 3. Concerted efforts 4. A balanced insights before decisions 	<p>Advantages!</p> <ol style="list-style-type: none"> 1. Quick decisions 2. Easy retrieval for extensions 3. Minimum need for additional information 4. Maximum flexibility 	<p>Advantages!</p> <ol style="list-style-type: none"> 1. Country-wide constancy/record keeping 2. Efficiency – Reducing repetition 3. Enhancing collaborations 4. A balanced insight before decisions
<p>Disadvantages!</p> <ol style="list-style-type: none"> 1. Logistic problems/ unnecessary delays 2. Often additional information needed 3. Minimum flexibility 4. Extensions would be delayed 	<p>Disadvantages!</p> <ol style="list-style-type: none"> 1. No consistency across university 2. Local record keeping (GDPR issues) 3. Varied approach 4. Subject to prejudice 	<p>Disadvantages!</p> <ol style="list-style-type: none"> 1. Logistic problems in organisation 2. Difficult to monitor 3. Delays in decisions 4. Minimum flexibility

Fig. 2 Summary of advantages and disadvantages of three different forms of ethical committees

[N/B for Fig. 2: Examples of different types of ethical application procedures and forms used were discussed with the workshop attendees to enhance their understanding of the differences. GDPR = General Data Protection Regulation].

Although we recommend a designated EC with relevant professional, academic and ethical expertise to deal with particular types of applications, the membership (of any EC) should include some non-experts who would represent the wider community (see above). Having some non-experts in EC would not only help the researchers to consider explaining their research in layperson's terms (by thinking outside the box) but also would ensure efficiency without compromising participants/animal safety. They may even help to address the common ethical issues outside research culture. Some UK universities usually offer this membership to a clergy, councillor or a parliamentarian who does not have any links to the institutions. Most importantly, it is vital for any EC members to undertake further training in addition to previous experience in the relevant field of research ethics.

Another issue that raises concerns is multi-centre research, involving several institutions, where institutionalised ethical approvals are needed from each partner. In some cases, such as clinical research within the UK, a common statutory EC called National Health Services (NHS) Research Ethics Committee (NREC) is in place to cover research ethics involving all partner institutions (NHS, 2018). The process of obtaining approval from this type of EC takes time, therefore advanced planning is needed.

Ethics approval forms and process

During the workshop, we discussed some anonymised application forms obtained from open-access sources for qualitative and quantitative research as examples. Considering research ethics, for the purpose of understanding, we arbitrarily divided this in two categories; research based on (a) quantitative and (b) qualitative methodologies. As their name suggests their research approach is extremely different from each other. The discussion elicited how ECs devise different types of ethical application form/questions. As for qualitative research, these are often conducted as "face-to-face" interviews, which would have implications on volunteer anonymity.

Furthermore, discussions posited when the interviews are replaced by on-line surveys, they have to be administered through registered university staff to maintain confidentiality. This becomes difficult when the research is a multi-centre study. These types of issues are also common in medical research regarding participants' anonymity, confidentiality, and above all their right to withdraw consent to be involved in research.

Storing and protecting data collected in the process of the study is also a point of consideration when applying for approval.

Finally, the ethical processes of invasive (involving human/animals) and non-invasive research (questionnaire based) may slightly differ from one another. Following research areas are considered as investigations that need ethical approval:

- research that involves human participants (see below)
- use of the 'products' of human participants (see below)
- work that potentially impacts on humans (see below)
- research that involves animals

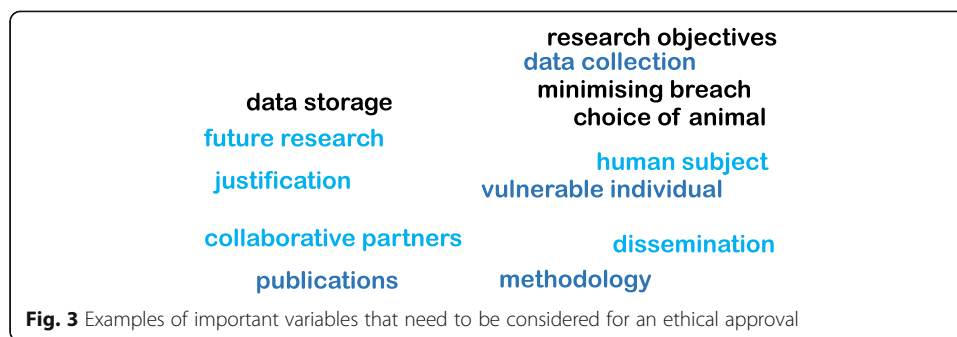


Fig. 3 Examples of important variables that need to be considered for an ethical approval

In addition, it is important to provide a disclaimer even if an ethical approval is deemed unnecessary. Following word cloud (Fig. 3) shows the important variables that need to be considered at the brainstorming stage before an ethical application. It is worth noting the importance of proactive planning predicting the “unexpected” during different phases of a research project (such as planning, execution, publication, and future directions). Some applications (such as working with vulnerable individuals or children) will require safety protection clearance (such as DBS - Disclosure and Barring Service, commonly obtained from the local police). Please see section on Research involving Humans - Informed consents for further discussions.

It is also imperative to report or re-apply for ethical approval for any minor or major post-approval changes to original proposals made. In case of methodological changes, evidence of risk assessments for changes and/or COSHH (Control of Substances Hazardous to Health Regulations) should also be given. Likewise, any new collaborative partners or removal of researchers should also be notified to the IEAC.

Other findings include:

- in case of complete changes in the project, the research must be stopped and new approval should be sought,
- in case of noticing any adverse effects to project participants (human or non-human), these should also be notified to the committee for appropriate clearance to continue the work, and
- the completion of the project must also be notified with the indication whether the researchers may restart the project at a later stage.

Research involving humans - informed consents

While discussing research involving humans and based on literature review, findings highlight the human subjects/volunteers must willingly participate in research after being adequately informed about the project. Therefore, research involving humans and animals takes precedence in obtaining ethical clearance and its strict adherence, one of which is providing a participant information sheet/leaflet. This sheet should contain a full explanation about the research that is being carried out and be given out in lay-person’s terms in writing (Manti and Licari 2018; Hardicre 2014). Measures should also be in place to explain and clarify any doubts from the participants. In addition, there should be a clear statement on how the participants’ anonymity is protected. We

provide below some example questions below to help the researchers to write this participant information sheet:

- What is the purpose of the study?
- Why have they been chosen?
- What will happen if they take part?
- What do they have to do?
- What happens when the research stops?
- What if something goes wrong?
- What will happen to the results of the research study?
- Will taking part be kept confidential?
- How to handle “vulnerable” participants?
- How to mitigate risks to participants?

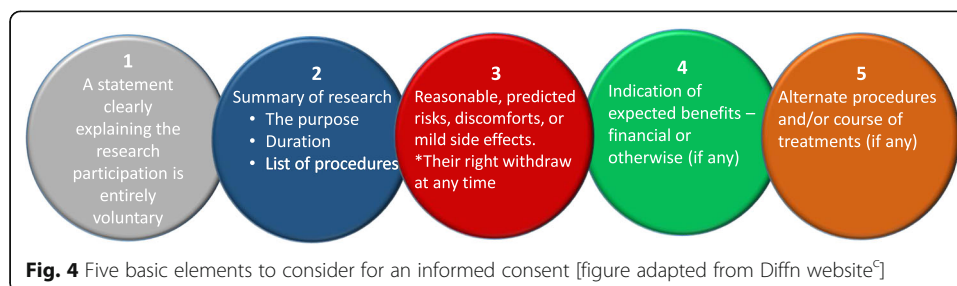
Many institutional ethics committees expect the researchers to produce a FAQ (frequently asked questions) in addition to the information about research. Most importantly, the researchers also need to provide an informed consent form, which should be signed by each human participant. The five elements identified that are needed to be considered for an informed consent statement are summarized in Fig. 4 below (slightly modified from the Federal Policy for the Protection of Human Subjects (2018) - Diffn website^c).

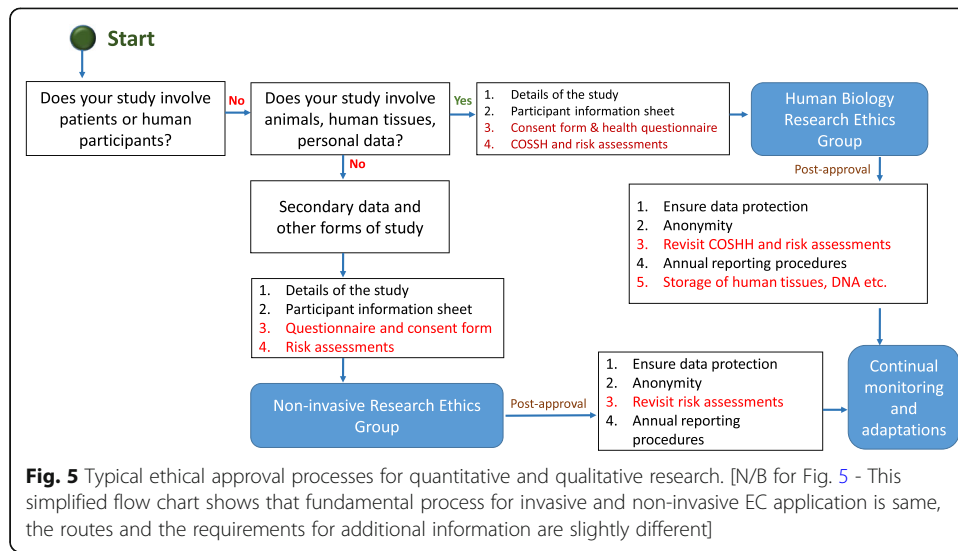
The informed consent form should always contain a clause for the participant to withdraw their consent at any time. Should this happen all the data from that participant should be eliminated from the study without affecting their anonymity.

Typical research ethics approval process

In this section, we provide an example flow chart explaining how researchers may choose the appropriate application and process, as highlighted in Fig. 5. However, it is imperative to note here that these are examples only and some institutions may have one unified application with separate sections to demarcate qualitative and quantitative research criteria.

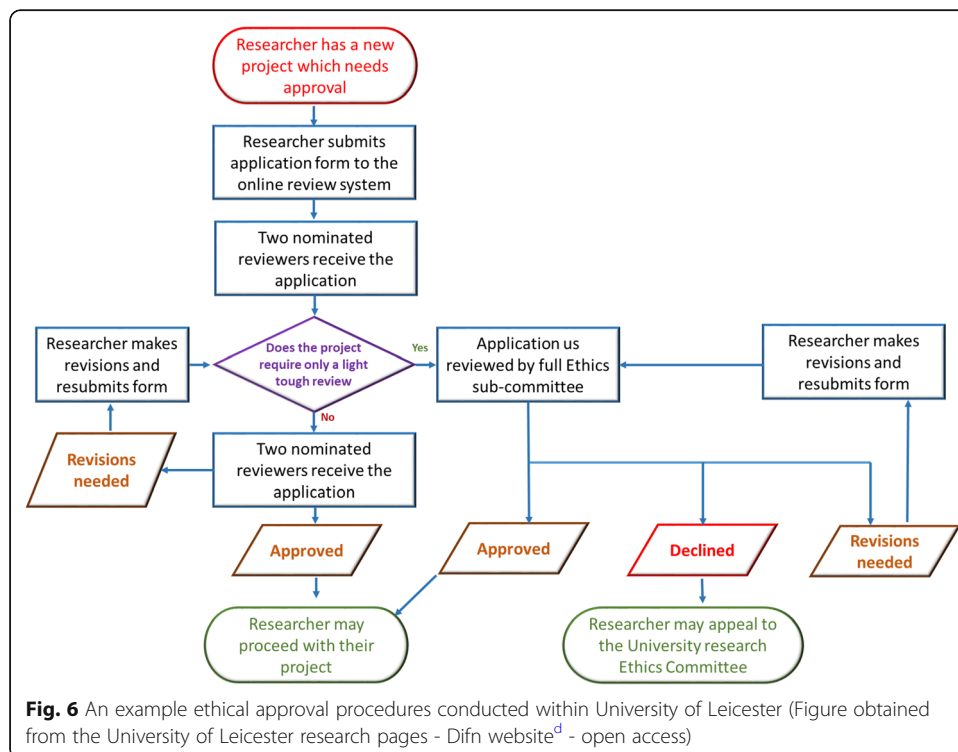
Once the ethical application is submitted, the EC should ensure a clear approval procedure with distinctly defined timeline. An example flow chart showing the procedure for an ethical approval was obtained from University of Leicester as open-access. This is presented in Fig. 6. Further examples of the ethical approval process and governance were discussed in the workshop.





Strategies for ethics educations for students

Student education on the importance of ethics and ethical behaviour in research and scholarly activities is extremely essential. Literature posits in the area of medical research that many universities are incorporating ethics in post-graduate degrees but when it comes to undergraduate degrees, there is less appetite to deliver modules or even lectures focussing on research ethics (Seymour et al., 2004; Willison and O’Regan, 2007). This may be due to the fact that undergraduate degree structure does not really focus on research (DePasse et al., 2016). However, as Orr (2018) suggested, institutions should focus more on educating all students about ethics/ethical behaviour and their



importance in research, than enforcing punitive measures for unethical behaviour. Therefore, as an advisory committee, and based on our preliminary literature survey and workshop results, we strongly recommend incorporating ethical education within undergraduate curriculum. Looking at those institutions which focus on ethical education for both under- and postgraduate courses, their approaches are either (a) a lecture-based delivery, (b) case study based approach or (c) a combined delivery starting with a lecture on basic principles of ethics followed by generating a debate based discussion using interesting case studies. The combined method seems much more effective than the other two as per our findings as explained next.

As many academics who have been involved in teaching ethics and/or research ethics agree, the underlying principles of ethics is often perceived as a boring subject. Therefore, lecture-based delivery may not be suitable. On the other hand, a debate based approach, though attractive and instantly generates student interest, cannot be effective without students understanding the underlying basic principles. In addition, when selecting case studies, it would be advisable to choose cases addressing all different types of ethical dilemmas. As an advisory group within ENAI, we are in the process of collating supporting materials to help to develop institutional policies, creating advisory documents to help in obtaining ethical approvals, and teaching materials to enhance debate-based lesson plans that can be used by the member and other institutions.

Concluding remarks

In summary, our literature survey and workshop findings highlight that researchers should accept that ethics underpins everything we do, especially in research. Although ethical approval is tedious, it is an imperative process in which proactive thinking is essential to identify ethical issues that might affect the project. Our findings further lead us to state that the ethical approval process differs from institution to institution and we strongly recommend the researchers to follow the institutional guidelines and their underlying ethical principles. The ENAI workshop in Vilnius highlighted the importance of ethical governance by establishing ECs, discussed different types of ECs and procedures with some examples and highlighted the importance of student education to impart ethical culture within research communities, an area that needs further study as future scope.

Declarations

The manuscript was entirely written by the corresponding author with contributions from co-authors who have also taken part in the delivery of the workshop. Authors confirm that the data supporting the findings of this study are available within the article. We can also confirm that there are no potential competing interests with other organisations.

Abbreviations

ALLEA: ALL European academics; ARC: Australian research council; BBSC: Biotechnology and biological sciences research council; CIHR: Canadian institutes for health research; COPE: Committee of publication ethics; EC: Ethical committee; ENAI: European network of academic integrity; EPSRC: Economic and social research council; ICPA: International convention for the protection of animals; IEAC: institutional ethical advisory committee; IRB: Institutional review board; IUP: Immaculata university of Pennsylvania; LGBT: Lesbian, gay, bisexual, and transgender; MRC: Medical research council; NHS: National health services; NHAS: National health services nih national institute of health (NIH); NICE: National institute of clinical care excellence; NHMRC: National health and medical research council; NSCERC: Natural sciences and engineering research council; NREC: National research ethics committee; NSECHR: National statement on ethical conduct in human research; RRP: Responsible research practice; SSHRC: Social sciences and humanities research council; TCPS: Tri-council policy statement; WOA: World Organization

for animal health; UA: Universities Australia; UKRI: UK-research and innovation; US-OHRP: US office for human research protections

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Authors' contributions

The manuscript was entirely written by the corresponding author with contributions from co-authors who have equally contributed to presentation of this paper in the 5th international conference named plagiarism across Europe and beyond, in Vilnius, Lithuania. Authors have equally contributed for the information collection, which were then summarised as narrative explanations by the Corresponding author and Dr. Zeenath Reza Khan. Then checked and verified by Dr. Dlabolova and Ms. Králíková. The author(s) read and approved the final manuscript.

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