Ethical Considerations

6

Hesta Friedrich-Nel and Aarthi Ramlaul

6.1 Brief History and Timeline of Research Ethics

The history of ethics can be traced to the time of Socrates (469–399 BC), Plato (427–347 BC) and Aristotle (384–322 BC). Many different views of how best to implement the 'good for all' emerged from BC (before Christ) to AD (Anno Domini) with the advent of Christianity and the biblical commandments. The views continued to develop and evolve through the centuries leading to multiple theories that have shaped the way we perceive ethics today. The need for ethical considerations through formal review gained ground. However, in the nineteenth century experiments on human subjects during World War II (1939–1945) created difficulties. Some of the difficulties were that many participants were not informed that they were part of a research study; they did not provide informed consent [1]. In many instances the vulnerability of a group was used to the advantage of a researcher [2]. In addition, researchers did not as a rule explain the risks associated with the research. Resnik [3] indicated that publications such as the Nuremberg code [4], the Belmont report [5] and the Declaration of Helsinki (first published in 1964) [6] addressed these difficulties by establishing guidelines to protect research participants. The Declaration of Helsinki is recognised as the most authoritative guide on ethical standards for human or clinical research and has been revised several times (1975, 1983, 1989, 1996, 2000, 2008 and 2013) [2].

H. Friedrich-Nel (✉)
Department of Clinical Sciences, Central University of Technology, Bloemfontein, South Africa
e-mail: hfried@cut.ac.za

A. Ramlaul
Diagnostic Radiography and Imaging, School of Health and Social Work, University of Hertfordshire, Hatfield, Hertfordshire, UK
e-mail: a.ramlaul@herts.ac.uk

A. Ramlaul (ed.), *Medical Imaging and Radiotherapy Research: Skills and Strategies*, https://doi.org/10.1007/978-3-030-37944-5_6

Aligned with the Declaration of Helsinki, the World Health Organisation (WHO) [7] and the Health Research Authority (HRA) [8] published key principles that researchers need to consider when conducting clinical research. The WHO defines good clinical research practice (GCP) as a process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human subjects [7]. Good clinical practice (GCP) is an international quality standard that is provided by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This international body defines a set of standards that governments can transpose into regulations for clinical trials involving human participants [7].

Researchers who conduct clinical research need to consider GCP. It gives the assurance that a researcher considers, respects and protects the rights, safety and well-being of research participants [7, 8]. Both the WHO and HRA regard human research as any research project involving individuals in a physical or psychological intervention, observation, collection, storage or dissemination of information. In any of the mentioned circumstances, an individual could be exposed to an unwanted risk.

Figure 6.1 provides a brief overview of the good clinical research principles, which are explained in this chapter. A researcher using human participants must be familiar with and apply these principles in a research project. Research involving human participants, participants who lack capacity, human tissue or radiation, by law will need approval from an appropriately constituted research ethics committee

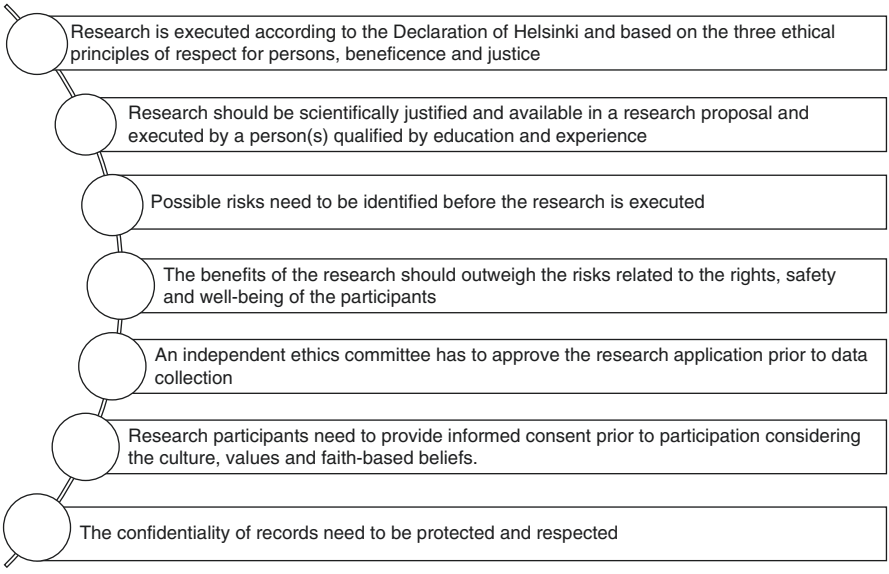

Fig. 6.1 The principles of good clinical research adapted from the European Medicines Agency [9]

(REC). In the UK, this application is made through the Integrated Research Application System (IRAS) and is discussed in Sect. 6.5.

Mainly UK sources are cited in this chapter. Researchers from outside the UK should also access the requirements of their respective countries and universities.

6.2 Ethics in Research

Ethics is a branch of philosophy that deals with making the right decision to justify a moral outcome [10]. Put simply, it means distinguishing between what is considered as 'right' and 'not right'. It deals with critical analysis and evaluation of assumptions we hold and make to decide the best way to deal with problems that arise. Medical ethics is a branch of ethics relevant to healthcare researchers due to their commitment to best practice in their professional roles, responsibilities and accountability.

Ethical decision-making is not a simple process. It involves analysing often large amounts of information and evidence to answer a complex problem. There are no right or wrong answers in solving ethical problems, and herein lies the dilemma of managing ethics related issues. A researcher must ensure that the best possible decision is made based on reasoning following a methodical and rigorous interrogation of an issue at hand. Making these decisions requires a critical thought process. There are several principles and guidelines available that a researcher can consult to help in the decision-making process.

6.3 The Principles of Ethical Conduct

Beauchamp and Childress [11] in their 1979 seminal book *Principles of biomedical ethics* devised four principles that later became known as the Georgetown mantra. These principles are autonomy, beneficence, non-maleficence and justice [11]. Several authors are critical about the reduction of research ethics and professionalism to include only these principles [12]. With this criticism in mind, it is important to note that these principles should be the core when research includes human participants. A researcher must however respond to all ethical principles in executing a research project. These principles are briefly discussed.

Respect for persons indicates that prospective research participants should be treated with autonomy. Autonomy means that individuals have the right to self-determine what happens to them. It implies a rational thought process where a person actively decides whether or not to take part. Informed consent plays a vital role in enabling research participants to exercise their autonomy. Individuals need to be able to choose whether or not they want to participate in ethically approved research. They need to be fully informed before they give consent. They should not get involved until they have granted valid informed consent.

There are two legal aspects regarding consent. The first involves the act of a researcher giving information to a prospective participant. The second involves a

participant agreeing to participate based on an understanding of what the involvement in a study would entail. It is therefore a participant's right to receive information in their own language. It is furthermore a researcher's duty to provide information in such a way so that a prospective participant can make an informed decision whether or not to take part. Researchers must create a balance between right and duty. To give consent, participants must be competent (of sound mind), sufficiently informed (getting the right amount of information) and not be subjected to coercion or influence (no prompting or manipulation). Information must be provided in a way that is comprehensible to them and devoid of technical jargon or confusing language.

There are additional ethical considerations to be made for people under the age of 16 years. For example, parental or guardian consent is required. Depending on the nature of research studies, most undergraduate research studies focus on adults over the age of 18 years because they are not considered a vulnerable group. However, some groups are classified as vulnerable. These groups include pregnant women, children, prisoners, and mentally handicapped persons. Additional measures are needed to protect the rights and welfare of these groups; the principle of 'do no harm' needs to be emphasised. All available information about the benefits and possible risks of a project needs to be communicated to prospective participants prior to them giving consent for participation in research studies.

Beneficence means to do good or prevent harm. The principle involves balancing the benefit and risk associated with the proposed research. A well-designed research ethics application, based on sound scientific and ethical guidelines, is required to ensure that this principle is upheld (see Sect. 6.5). In addition, a researcher needs to be duly qualified to undertake the proposed research in order to protect all participants. In the case of a student performing research, a research supervisor needs to have the necessary qualification with a regulatory or professional body registration.

The principle most closely linked to beneficence is non-maleficence: do no harm or having an obligation not to inflict harm. Beneficence and non-maleficence can be considered as two sides of a coin. Usually 'doing good' and 'not doing harm' often confuse people about where one stops and the other starts. Doing either should lead to good research practice.

The principle of justice means to be treated in a fair manner; a fair process is necessary to select and recruit research participants. Fairness needs to be applied in the procedures to select individuals, and in the recruitment of individuals to participate in a study. The Belmont report [5] identifies individual justice, social justice and equity in the selection of research participants. Individual justice means that the proposed research should not only benefit some patients or select 'undesirable' persons for research with a risk. Social justice refers to specific groups such as vulnerable groups, racial minorities, economically disadvantaged or any group that is easily available in a setting where the research is to be conducted. Equity refers to the fact that no group or individual should be advantaged or disadvantaged through favouritism or discrimination. One common ethical dilemma, in relation to justice,

lies in the fair allocation of resources to a population where the demand outweighs the supply. For example, in the distribution of a new treatment a researcher would have to question how to decide who to treat and who not to treat.

6.4 The Need for Ethical Considerations in Our Roles as Radiographers

Ethical and moral behaviour is an expectation of our practice as radiographers. It enables us to take a rational, coherent and consistent approach to making moral decisions. Ethics are the rules of human conduct. Our roles as student radiographers or qualified practitioners contain the rules for professional conduct. Doing what is ethical according to these rules is doing what is right. In this way ethics is a core professional attribute.

Another need for considering ethical issues is to produce a framework based on principles that can be applied universally in decision-making. Decision-making deals with a critical evaluation of assumptions and arguments. This is also evident during the review of ethics application documents when reviewers must be satisfied that a proposed research study meets ethical principles (see Sect. 6.8). This expectation is written into radiographers code of conduct and statements detailing expectations of proficiency and competence as practitioners. In clinical practice we must do what is right for our patients. In research practice we must do what is right for our research participants. When undertaking a research project or data collection exercise involving human participants, a researcher must understand the basic principles of ethics and how these may apply during a research process.

Medical practice involves scientific facts. At the point of service delivery ethics must be seamlessly blended with scientific facts giving holistic practice and delivery of patient-centred care. Our scope of practice, and our professional role and responsibilities, are set out by professional and regulatory bodies in the country that a practitioner is studying and practising in. There is an expectation of trust, reliability and accountability. A core expectation in relation to professional conduct in research is trustworthiness where participants expect researchers to be 'faithful' to their involvement; this includes the need for privacy and modesty. Participants expect practitioners to be competent. They expect practitioners to be well trained to know what they are doing and that they can be depended on to do the right thing. Trustworthiness is a character trait as it encompasses attributes such as reliability, honesty and dependability.

Radiography practitioners, as members of the allied and/or health professions, have a duty of care to report colleagues who act inappropriately, in both clinical and research capacities. An example of this is if a practitioner was investigating the number of repeated X-ray examinations in a diagnostic imaging department and found that a radiographer persistently and unnecessarily repeated X-ray examinations in order to aim for perfection even though diagnostic quality of the images was not compromised. Another example would be if a patient incorrectly received a therapeutic radiation dose of another patient. These incidences must be reported to

a senior member of staff, even if anonymity has been promised. All individuals have their own beliefs and values, their own biases and prejudices. When a student enrols to study radiography, s/he has to subscribe to the beliefs and values of the discipline. As such conducting research within that field must also be undertaken with the same frame of considerations. Guidelines alone are insufficient; the final responsibility lies with the person conducting the research. Radiographers must therefore work within ethical and legal boundaries of their scope of practice and expectation regarding their role and responsibilities.

6.5 Considerations When Applying for Ethics Approval

The first consideration that any researcher must determine is whether their proposed study is likely to require ethical review. All formal enquiry has some ethical component, even if it is only that researchers conduct themselves honestly in undertaking their study and do not deliberately influence (bias), copy (plagiarise) or even fabricate the work. However, not all clinical studies require ethical review. For example, the research governance framework within England, and to a major extent across the rest of the United Kingdom (UK), involves ethics application through the IRAS system. IRAS is a single system to apply for the permissions and approvals for health and social/community care research in the UK [13]. All applications for research within the National Health Service (NHS) are made via the IRAS and then reviewed by the various research ethics committees (RECs) linked to IRAS. A REC consists of a group of people appointed to review research applications, and to formally assess whether a proposed research adheres to ethical principles. It must conform to recognised ethical standards, which include respecting the dignity, rights, safety and well-being of participants [13]. Similar application processes for ethical approval of research studies are required in countries such as Europe, South Africa, New Zealand, Australia and the United States of America (USA).

Researchers need to follow a clear but rigorous process of determining whether their study requires ethical review. The IRAS website gives detailed guidance on this process. Within the UK, formal NHS ethical review is not required if a proposed study is deemed to be an audit and/or service evaluation and not research. This is dependent upon the intention of a researcher. For example, is the aim of the research to obtain new knowledge through rigorous and systematic approaches (research) or to measure existing practice/undertaking quality assurance? Table 6.1 outlines some of the determinants that can be used in deciding which category a proposed study may fall into and whether it requires formal IRAS ethical review.

While the basic premise of ethical review is to protect every participant from any potential harm, and at the same time respecting their dignity, rights and well-being, it may also seek to safeguard a researcher and/or institution undertaking a study. However, the process of implementation differs around the world. Researchers are encouraged to discuss the requirements for ethics approval as per the regulatory standards in their respective country. If a researcher is a student or member of staff in a university, internal review may also occur within the institution. For academic

Table 6.1 Determining the need for ethical approval

		Researcher's intent	Questions	Data collection	Allocation/ randomisation	Decision
Service evaluation		To evaluate service delivery and/or current care	What is the standard that this service achieves?	Measures current service only; can only be tested on treatments/investigations/ techniques in practice	None	May require NHS Trust R&D review but not usually ethical review
Clinical audit		To evaluate the delivery of current care against best practice	Does the service meet predetermined standard/s?	Measures service against guidance or professional standards; can only be tested on current treatments/investigations/ techniques in practice. Usually involves the analysis of existing data but may include simple interview or questionnaire administration	None	May require NHS Trust R&D review but not usually ethical review
Research	Quantitative approaches	To derive new approaches, knowledge, test hypotheses and interrogate research questions	Based on hypothesis	Evaluation or comparison of new treatments/investigations/techniques using existing or new data. Understanding the implications of new treatments/ investigations/techniques and/or relationships using existing or new data	May use both	Formal NHS Trust R&D and ethical review required
	Qualitative approaches		Research questions to identify and explore themes		May use both	

Adapted from Health Authority Research—Defining Research [8]

or non-clinical research this may be the only review required. In the case of a student or staff member wishing to undertake clinical research in a health and social care setting, an application to IRAS is required. The information in Table 6.1 should help a researcher decide how to proceed with the correct ethics application process. If the research is part of a university degree, in the case of undergraduate and postgraduate radiography courses, students can discuss this with their respective research supervisor in the first instance.

6.6 Key Ethical Considerations

This section provides guidance on the main ethical considerations when making an application for approval. It is presented in alphabetical order for ease of reference.

Anonymity refers to the identity of participants being kept unknown. Anonymity may be achieved in a variety of ways. For example, pseudonyms may be used to protect the identity of participants and/or locations. In addition, codes may be used to identify participants, with the information that relates to these codes (participants) being kept on a separate central list (key). In some cases, however, the identity of a participant is known to a researcher but anonymous to other research participants. For example, in face-to-face interviews, participants cannot be anonymous; however, their identity remains confidential in that they are unknown to others. Their respective identities and views are then 'hidden' in any subsequent report or publication.

Assent is the acceptance to be involved in a research study by a participant under the age of consent for research purposes (16 years and over in the UK). To obtain assent a participant information sheet (PIS) should be age-appropriate with respect to the language and explanations utilised. It has no legal standing; where a participant is old enough to understand what taking part in the research entails, it is good practice to interact with such a young person as an individual as well as with an adult (parent/guardian/legal representative) who gives the formal (legal) consent. It should be noted that research on children should be avoided if the data can be obtained by using only adult participants.

Coercion relates to payments in monetary terms or in goods such as gift vouchers. These are sometimes offered by researchers to thank participants for taking part in their research studies. Payment may also be made to investigators, usually by pharmaceutical companies, for their time in taking part in clinical trials. However, if the level offered is too high, this may be viewed as coercive, in that it may induce investigators to sign up numbers of participants purely for monetary return. A similar situation may happen with participants. Coercion may also take place when researchers, in whatever way, pressurise participants into taking part in research. This can inadvertently occur when researchers attempt to recruit participants for a study without allowing them time to consider the implications of their involvement in the research before they consent to take part. Usually a minimum period of 24 h after initially discussing the research should be given to potential participants to allow them time to consider whether or not they want to take part.

Coercion may also occur in respect of the nature of the relationship between researchers and participants, especially where research is being undertaken by clinical staff or by academics with their own students. It may be difficult for a patient to refuse to participate in a clinical trial if asked to consider this by a surgeon who is going to perform the operation. The same dilemma would occur if a first year student were to be invited by his/her professor to be interviewed as part of the professor's research. In circumstances where participants have a particularly dependent relationship with a researcher, consideration should be given to asking another member of the clinical/research team to take consent.

Confidentiality refers to the duty of a researcher to securely manage the information obtained from or about a research participant. Participants have the right to privacy and confidentiality; they expect professionals to keep their information safe and secure. Researchers must follow the data protection principles and use this in their judgement and decision-making. Like anonymity, confidentiality is a promise that it will not be possible to attribute/connect the findings of the research to the participants themselves, unless they gave permission for this prior to consenting to take part. If a researcher wishes to utilise anonymous direct quotations from participants, it is good practice to obtain express permission from them and to do this prior to them taking part in the research.

Conflicts of interest may arise where there is some form of relationship between various individuals or groups within a study that could possibly affect the outcome of the research through bias or coercion. Such a relationship should be declared and clearly identified in an application and, if appropriate, in the PIS (see PIS below). An example here could be the source and amount of funding provided to a researcher. Participants may not want to take part if they are unhappy about a research funding body. For example, inviting patients that have lung cancer to participate in a research study funded by a tobacco manufacturer. It is also good practice for researchers, particularly undergraduate students, to declare on the PIS if the research is to be done in fulfilment of an academic qualification. In some ways this may have a beneficial impact, with altruistic patients wanting to help students to fulfil their research, although this could also be construed as possibly being coercive.

Consent is the formal acceptance given by a participant to be involved in a research study. Any consent should, as far as possible, be fully informed and written, in that a potential participant should be made aware of what the research is about, and of methods and implications in taking part. This is normally given in the form of a written leaflet (see PIS below) which sets out the details of the proposed research. Informed consent becomes difficult when prospective participants are unable to give consent because of their age (young and old), mental capability, or physical state (e.g., unconscious). In these situations, consent should be obtained as far as possible from the individual concerned. If it cannot be obtained then another person such as a parent/guardian, carer or legal representative may be asked to give consent on behalf of the prospective participant. However, if a participant were to be only temporarily incapacitated it is important that consent be obtained from such a participant once they regain their full faculties.

Written, informed consent is taken as the standard. There are other forms of consent that may occur in research practice. Implied consent occurs when a participant does not expressly give consent, but this is inferred through their actions. In a research sense this generally occurs with survey methods utilising questionnaires, when consent is not specifically asked for by a researcher but is taken to be given (implied) if the questionnaire is returned. Once given, consent does not become permanent; participants may withdraw from a study without being required to give any reason and may also be able to ask that their data are not to be used. This must be indicated on the consent form. However, if data have been anonymised and aggregated it would be difficult for an individual participant's information to be separated out. This may also occur with data obtained from focus groups because it is the group interaction that generates the data; withdrawing one participant's data would therefore make the remaining data difficult to interpret. In cases such as these it needs to be made clear on a PIS that data collected up to the point of withdrawal have to be retained. In addition, ethics approval is only given for any one named project at a time; it does not cover future studies where the subjects being identified have not been clearly stated. Research that evolves from current work requires separate ethics approval and consent from participants at some time in the future. In other words a current authorisation will not apply. As well as the various types of consents, researchers also need to consider who is to take/obtain consent from a participant as there may be issues of coercion and a possibility of power bias, as outlined above. Conversely, a person taking the consent must be aware of the implications of a study to be able to answer any queries, thus enabling each participant, by being fully informed, to decide whether to take part.

Data are needed in research. Researchers must operate in accordance with several legislative acts governing data protection and access to medical records relevant to the country in which research is performed. Researchers should indicate how and where data are to be stored (usually in a locked cabinet or password protected computer), who will have access to the data (usually the researchers), how long data will be stored (a minimum of 3 years if data are to be published), and what will happen to the data post-study (i.e., destruction). Data that are to be sent outside the country in which a study has been done should be anonymised. As outlined in the section on anonymity, the use of codes/keys can be used to separate identifiable data.

Data monitoring committee (DMC) plays an important role in clinical trials. A DMC reviews a study while it is in progress to assess the impact of an intervention (e.g., drug/new technique) upon the participants. If it is shown that serious side-effects are beginning to occur in large numbers, then the trial should be stopped to avoid exposing future participants to harm. On the other hand, when a study shows overwhelming positive results then it might be suggested that enough data have been collected to show benefit, thus it would be unethical to inconvenience or recruit further participants and therefore the study should be stopped.

Data protection regulations apply to how researchers collect and hold information about their participants. On 25 May 2018 the General Data Protection Regulation (GDPR) came into force in the European Union (EU). It pertains to protection of personal information (data). According to the GDPR, one must have a

defined lawful basis to hold and use personal data. Researchers who will be holding and using health information, which is a special category of personal data in GDPR (most researchers producing a PIS), are also required a further condition to this lawful basis. In most cases this condition should be to support 'scientific and historical research'. GDPR also requires that a researcher should be fair and transparent about holding and using personal data. This includes all personal data used to support research. The PIS provides a large part of how to meet fairness and transparency requirements. However, the information provided in the PIS is not the only information a researcher should provide. GDPR demands that all potential research participants can access the information provided and are likely to understand it [14]. Researchers outside of the EU must adhere to the protection of personal information legislation in their country.

Participant information sheet (PIS) is arguably the most important document of a research study. The information contained within it explains and invites participants to participate in a study. It does receive scrutiny at the REC meeting. A clearly written, well defined and appropriate PIS should give participants enough information on the nature of a proposed study for them to be able to make an informed choice about whether or not to take part. Guidelines and a template are provided on the HRA website. The RECs prefer the PIS to be in a specific format, but this is not compulsory. However, if the template is not used, then researchers should make sure that the appropriate sections relevant to their study are included in whatever alternative format they utilise, such as a letter.

A PIS must be written in lay terms and in a language style that is understandable to possible participants. If assent is being sought from a participant under the age of 16/18 years, it is necessary to amend the level of reading ability. For younger children, around 8 years of age, it could be beneficial to use drawings or diagrams to explain the information. Language again may be an issue with respect to multinational studies; a PIS may have been written in another country. The language used within a PIS must be suitable to the audience in the country the research is being carried out in. Therefore, if a PIS is required for non-English speakers it must be translated. Unlike clinical practice, it is not enough to get relatives to translate or act as interpreters for participants. Participants must have the relevant information available directly to them so that they can make an informed choice; professional services should therefore be utilised. With respect to research documentation, applications and in particular a PIS, a researcher should make sure that all paperwork is devoid of errors in spelling and grammar, and that all sections have been completed correctly with the information required, otherwise the decision of the REC may be delayed.

Radiation research refers to studies involving the use of radiation. Such research generates specific sections of an ethics application form to be completed detailing the type of radiation and particularly the dose to be received. This has to be substantiated by a local radiation protection advisor who has to sign the form confirming the proposed level of radiation exposure. Researchers need to provide information on a PIS to participants about any possible radiation effects. The concept of measuring radiation dose in millisieverts (mSv) may probably not be understood by a lay

participant. Thus, it may be useful to use a comparator; the most commonly used being levels/hours of background radiation. Informing patients of the risks of radiation is highlighted within the recent updated Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 [15] and IR(ME)R (NI) 2018 guidelines [16]. There is however limited guidance on what is considered as appropriate comparators so that these can be understood when explaining them to patients and/or research participants. Nonetheless, the basis of IR(ME)R lies in justification of the risks and benefits: researchers are therefore encouraged to use this as a reasonable approach in their explanation to participants.

Respondent distress/expectation refers to the potential for participants to become distressed or expect further information about topics that are highlighted because of their participation within a study. A researcher has to provide details, in an application and on a PIS, on how these situations will be dealt with. This is usually done by giving advice on access to further information and support services or, if appropriately qualified, undertake this directly themselves. In determining the suitability of a PIS an ethics committee may be concerned that a study is not artificially raising participants' expectations of a particular treatment or examination or causing unnecessary anxiety and stress by the information given. For example, a researcher may want to ask patients with prostate cancer their views on which treatment they would prefer (radiotherapy or surgery). However, while both options could be available in one hospital, only surgery may be available in another. For patients in the second hospital equity may not be apparent; it may thus be deemed unethical as the proposed research may be raising expectations that such patients may have a choice of treatment. Researchers should also consider issues like time inconvenience and the sensitivity of the matter being investigated. In addition, with the increasing prevalence of mental health disorders that participants do not need to disclose, a researcher should additionally consider any associated hazards that could arise during a study.

Researcher issues and responsibilities are important when conducting a study. The primary purpose of any research ethics system is to protect each participant. However, researchers also need to be aware that there may be times when their own actions/circumstances need to be considered within a study. This could include visiting a participant in their home or collecting data alone in a city centre. The REC looks for some indication that researchers are aware of these issues (risk assessment undertaken) and that they have put into place a mechanism to protect themselves (e.g., lone-worker policy). This is particularly important for research involving radiation. Prospective researchers must show that they are aware of the implications of their actions about any use of radiation, complying with the principles of ALARA (as low as reasonably achievable) and ALARP (as low as reasonably practicable). In addition, researchers have a responsibility to participants and to society as a whole by the very nature of what they are undertaking. They should not copy (plagiarise) or falsify data, and should act fairly (unbiased) in their approaches to all participants, for good quality findings to be obtained. Otherwise it becomes unethical to subject participants to poor research practice.

Sponsor is often erroneously understood by inexperienced applicants to refer to financial contributions to undertake a study. They are sometimes confused regarding

questions as to whether their research has a sponsor. They often answer in the negative due to their misunderstanding of a sponsor. In governance terms a sponsor is taken to be a person or company, usually an employer, who accepts responsibility for the actions of a researcher in respect of any claims for negligence or harm because of such research. In most cases the answer therefore would be in the affirmative, particularly for researchers working within the NHS. In terms of student researchers, their respective university should take responsibility as sponsor. This would be through a research supervisor who is directly employed, rather than a student.

6.7 The Process for Ethical Clearance of a Research Project

Research studies are broadly classified as qualitative and quantitative. Nonetheless, if a study involves human participants (adults and/or children) it requires ethical approval. The main reason is to protect both a participant and researcher. Each participant is protected since an ethics committee considers the risks involved in the proposed research. A researcher is protected because there will be evidence that an ethics committee approved the research project. In other words an approved project adheres to specific standards. Approval from an ethics committee needs to be obtained before data collection can commence.

An ethics committee provides guidelines on the application requirements; this is usually provided as a checklist. Figure 6.2 is based on the main points of such checklists. A researcher must use a checklist as a guideline to complete an application and to provide additional evidence to support the review and approval processes as well as for self-assessment. Submission of a research ethics application and supporting documents for the ethics committee approval is commonly done via online platforms. This means that it is easy to verify that all required documents were submitted. The committee administration can verify if an application is incomplete and notify the researcher.

Submissions can be classified as research with a risk or a minimal risk project. Research with a risk may involve prospective interventions with human subjects. A project with a minimal risk may be a retrospective study using information from a patient's records. Once submitted, an ethics committee refers the complete submission to one or two independent reviewers. The reviewers may use the principles in Fig. 6.2 to approve a project, request modifications or, in rare cases, may even reject an application. The role of an ethics committee is to ratify reviewers' reports at a meeting where a final decision is captured. A researcher receives written notice with the reviewers' consolidated feedback. Once a project is approved, a researcher is notified in writing with an ethics approval reference number linked to the project.

Ethics committees usually provide helpful resources; for example, templates and examples are usually available on their websites so that a researcher can prepare a submission for the approval process. Good practice is to access the online submission site of your university to verify the deadline date for submission of documents,

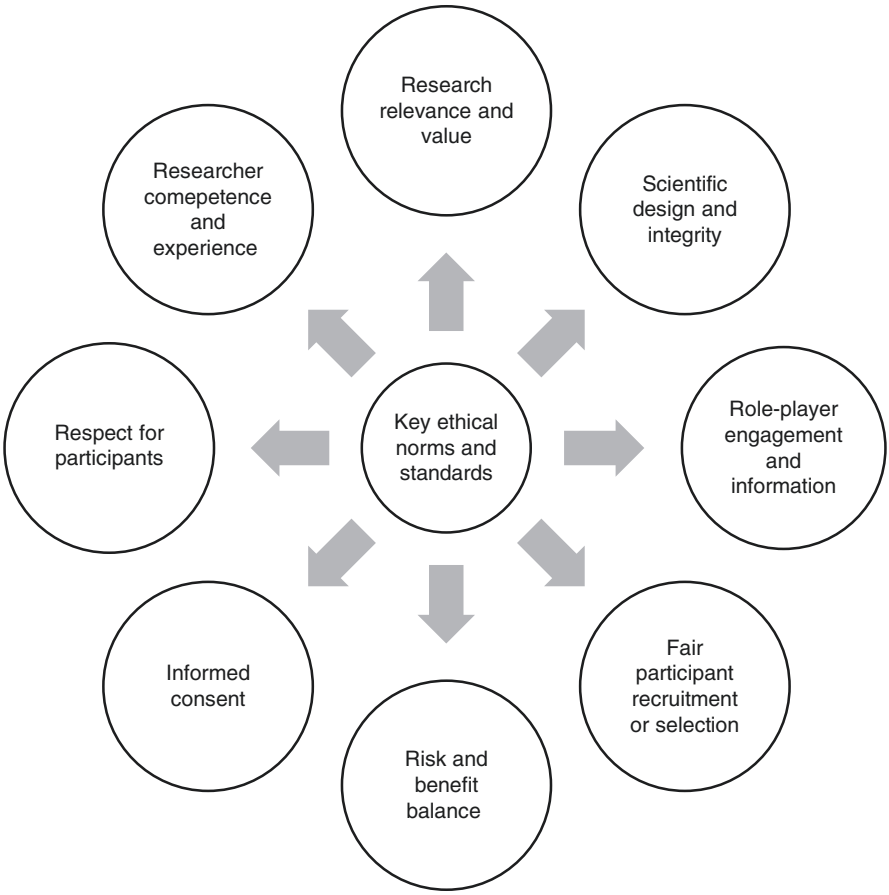

Fig. 6.2 Criteria for approval of applications

to identify the specific requirements, to make a list of the documents needed and to access templates (e.g., PIS). A formal application to the RECs is a lengthy process which takes time, so it is wise to plan ahead. As a researcher you should create a folder with all the documents ready to upload. Each ethics committee may use a different checklist, and these requirements may also be university or country specific. However, the information broadly corresponds with the criteria for approval of a project as given in Fig. 6.2.

The scientific design of a research ethics application requires sound alignment between the research title, aim, objectives, and methodology. In the selection of participants, the recruitment procedures and information to potential participants need to be clearly outlined. For example, inclusion and exclusion criteria or if any potential participants belong to a vulnerable group. The possible risks and benefits of the proposed research must be highlighted. The informed consent process must be clear and explained in terms that a lay person can understand. An ethics

application must clearly indicate privacy and confidentiality matters, and whether participants will receive compensation and the projected cost of the proposed research. A researcher must state how the participants will be informed regarding the outcome of the research, plans for the safe keeping of records and length of time of retention of such records. It should be clear that a researcher, sometimes with the guidance of a supervisor, has the required competency to perform the proposed research. One example is to indicate competency to interview research participants.

In addition, the research procedures must be clear and aligned with the research title and inclusion of participants. This includes the data collection process and analysis. An example here would be a survey of patients' experiences of a colonoscopy examination or of a radiotherapy planning session, where it was proposed to interview the patients 15 min after the end of the examination/session. Patients are unlikely to be able to answer questions at this time as they will be recovering from their examination. Such a hypothetical study might be better served by a questionnaire for each participating patient to complete in their own time, or interviewing patients after a suitable time period.

Lastly, undergraduate students often misunderstand the requirement for permission with the requirement of consent. Consent applies to research participants: once they have formally agreed to participate means they have consented. Permission on the other hand refers to approval to gain access to participants. For example, in a university setting this would need to be the course or programme leader of a student population (diagnostic radiography, radiotherapy, physiotherapy and so on) that a researcher wishes to recruit for a study. Students are required to write to their respective course/programme leader or dean of the faculty to ask for permission to access their students. In a hospital setting, students are required to write to the department manager or lead superintendent of that specific clinical area to ask their permission to approach either the radiographers and/or patients. Depending on the nature of a study, the local R and D department of the trust may also have to be consulted. A department manager and research supervisors should be able to advise students further in this regard. The term R and D is used generically to describe research and development offices or departments within either NHS organisations or universities [13].

6.8 Dealing with Reviewer Feedback

Reviewers provide written feedback on an application. This feedback is linked to the criteria for approval of projects (Fig. 6.2). It is however seldom a pleasant experience for a researcher to receive feedback from reviewers, specifically if the outcome of the ethics committee is that an application needs to be modified and resubmitted. A researcher must keep in mind that the purpose of the reviewers' feedback is to improve the submitted application, and address areas of concern so that the project responds to all ethical principles. The feedback should never be personalised. If a researcher must resubmit an application and supporting

documents to an ethics committee for final approval of the project, it is good practice to highlight the changes within the application. A cover letter to accompany the resubmission should indicate the changes and responses to the reviewers' comments as this may be helpful for them to review the changes. This step may even speed up the approval process. In some cases, a researcher, with a supervisor's support, may explain with the necessary evidence that it is not possible for some of the recommended changes to be executed as per the reviewers' feedback.

Reviewers also comment on administrative aspects such as an incomplete submission. For example, some documents not uploaded or incorrectly uploaded and/or missing permissions; a common one is where a supervisor did not give permission for the research project. Other matters relate to the inclusion and exclusion selection criteria of research participants being unclear; the PIS being unavailable in the languages spoken within the research environment, and the layman summary of the project being done in technical and academic language. Reviewers may also request revisions if the risks associated with the proposed research have not been comprehensively addressed and the data collection method and the data collection tool are not aligned with the aim of the proposed study. Lastly, reviewers may request a revision of a project's timelines as these may not be feasible to conduct the proposed study.

In the end, the most successful application is the one in which the ethical implications are carefully considered and addressed, and supported by applicable documentation.

6.9 Conclusion

The origin of research principles of good clinical research practice, why ethical approval is required, and guidance on the process involved to obtaining ethical clearance, are covered in this chapter. Differentiation is provided to help researchers determine whether their respective study will be considered as research, audit or service evaluation and the need for ethics approval. The specific ethical considerations in our roles as radiographers were presented as well as considerations that should be made when devising ethics application documents. Common pitfalls that reviewers comment on were shared with the integration of good practice tips to ensure successful outcomes during a review process.

References

1. Beecher HK. Ethics and clinical research. N Engl J Med. 1966;274:1354–60. https://doi.org/10.1056/NEJM196606162742405.
2. Dhai A. The research ethics evolution: from Nuremberg to Helsinki. S Afr Med J. 2014;104(3):178–80.
3. Resnik DB. Research ethics timeline (1932 to present). National Institute of Environmental Health Sciences; 2019. https://www.niehs.nih.gov/research/resources/bioethics/timeline/index.cfm.

4. Nuremberg Military Tribunals. The medical case. In: Trials of war criminals before the Nuremberg military tribunals under control council law no. 10, vol. 2. Washington, DC: US Government Printing Office; 1949. p. 181–2. https://www.loc.gov/rr/frd/Military_Law/pdf/NT_war-criminals_Vol-II.pdf. Accessed 23 Oct 2015.
5. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. The Belmont report: ethical principles and guidelines for the protection of human subjects of research. 1979. https://www.hhs.gov/ohrp/policy/belmont.html. Accessed 21 Oct 2015.
6. World Medical Association. WMA declaration of Helsinki—ethical principles for medical research involving human subjects. Revised October 2013. http://www.wma.net/en/30publications/10policies/b3/index.html. Accessed 23 Oct 2015.
7. WHO (World Health Organisation). Handbook for good clinical research practice (GCP) guidance for implementation from the World Health Organization. Geneva: WHO; 2002. https://www.who.int/medicines/areas/quality_safety/safety_efficacy/gcp1.pdf.
8. Health Research Authority. Defining research. 2018. http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf. Accessed 10 May 2019.
9. European Medicines Agency. Guidance on good clinical practice (E6). 2016. https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/. Accessed 16 May 2019.
10. Ramlaul A, Gregory T. Ethical and legal considerations in professional practice. In: Ramlaul A, Vosper V, editors. Patient-centred care in medical imaging and radiotherapy. Oxford: Elsevier; 2013. p. 257–70.
11. Beauchamp TL, Childress JF. Principles of biomedical ethics. 6th ed. New York: Oxford University Press; 2009.
12. Tsay C. Revisiting the ethics of research on human subjects. AMA J Ethics. 2015;17(12):1105–7.
13. Integrated Research Application System. Streamlining the research application process. 2019. https://www.myresearchproject.org.uk/. Accessed 10 May 2019.
14. Health Research Authority. Consent and participant information guidance. 2019. http://www.hra-decisiontools.org.uk/consent/. Accessed 10 May 2019.
15. The ionising radiation (medical exposure) regulations 2017 No. 1322. http://www.legislation.gov.uk/uksi/2017/1322/contents/made. Accessed 11 Feb 2019.
16. The ionising radiation (medical exposure) (amendment) regulations 2018 No. 121. http://www.legislation.gov.uk/uksi/2018/121/made. Accessed 30 May 2019.