Informed Consent for Clinical Examinations involving Ionising Radiation

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DECLARATIONS

STATEMENT OF ORIGINALITY

I hereby certify that the work embodied in the thesis is my own work, conducted under normal supervision. The thesis contains no material which has been accepted, or is being examined, for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made. I give consent to the final version of my thesis being made available worldwide when deposited in the University's Digital Repository, subject to the provisions of the Copyright Act 1968 and any approved embargo.

Mr. Cameron YOUNGER		15/11/2019
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THESIS BY PUBLICATION

I hereby certify that this thesis is in the form of a series of five papers. I have included as part of the thesis a written declaration from each co-author, endorsed in writing by the Faculty Assistant Dean (Research Training), attesting to my contribution to any jointly authored papers.

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CO-AUTHOR DECLARATIONS

PUBLICATION 1

By signing below I confirm that Cameron Younger contributed more than 50% to the study design, data analysis and manuscript preparation of the publication below. Associate Professor Helen Warren-Forward, and Dr. Charles Douglas contributed to the manuscript preparation in their role as PhD supervisors.

Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2018). Ionising radiation risk disclosure: When should radiographers assume a duty to inform? *Radiography*, *24*(2), 146-150. https://doi.org/10.1016/j.radi.2017.12.002

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PUBLICATION 2

By signing below I confirm that Cameron Younger contributed more than 50% to the study design, data analysis and manuscript preparation of the publication below. Associate Professor Helen Warren-Forward, and Dr. Charles Douglas contributed to the manuscript preparation in their role as PhD supervisors.

Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2018). Medical imaging and informed consent–Can radiographers and patients agree upon a realistic best practice? *Radiography*, *24*(3), 204-210. https://doi.org/10.1016/j.radi.2018.01.005

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PUBLICATION 3

By signing below I confirm that Cameron Younger contributed more than 50% to the study design, data analysis and manuscript preparation of the publication below. Associate Professor Helen Warren-Forward, and Dr. Charles Douglas contributed to the manuscript preparation in their role as PhD supervisors. Ms. Melanie Wagner contributed to the manuscript preparation as a systematic reviewer.

Younger, C. W. E., Wagner, M. J., Douglas, C., & Warren-Forward, H. (2019). Describing ionising radiation risk in the clinical setting: A systematic review. *Radiography*, *25*(1), 83-90. https://doi.org/10.1016/j.radi.2018.11.002

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By signing below I confirm that Cameron Younger contributed more than 50% to the study design, data analysis and manuscript preparation of the publication below. Associate Professor Helen Warren-Forward, and Dr. Charles Douglas contributed to the manuscript preparation in their role as PhD supervisors. Dr. Sheila Moran contributed to the manuscript preparation as a co-reader and analyst of the interview transcripts.

Younger, C. W. E., Moran, S., Douglas, C., & Warren-Forward, H. (2019). Barriers and pathways to informed consent for ionising radiation imaging examinations: A qualitative study. *Radiography, 25* (4). https://doi.org/10.1016/j.radi.2019.03.001

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PUBLICATION 5

By signing below I confirm that Cameron Younger contributed more than 50% to the study design, data analysis and manuscript preparation of the publication below. Associate Professor Helen Warren-Forward, and Dr. Charles Douglas contributed to the manuscript preparation in their role as PhD supervisors.

Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2019). Informed consent guidelines for ionising radiation examinations: A Delphi study. *Radiography*, (In Press, Corrected Proof). https://doi.org/10.1016/j.radi.2019.08.004

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My beautiful daughter Charlotte, I'm looking forward to spending more time being Dad.

Finally, to Melanie, my wife. I am so sorry for the sacrifices we have made, and I am so thankful for the trust and belief you have shown in me. I can't tell you how much it means to me. Thank you.

ABSTRACT

Background

Ionising radiation can cause biological effects, including the induction of a cancer. In Australia, the legal standard is that a patient, prior to a medical procedure, should be warned of the 'significant' or 'material' risks of that procedure. However, the threshold at which a risk of ionising radiation should be considered 'significant' is unexplored. In addition, there are currently no defined processes to undertake this process.

Aim

The aim of this research was to investigate the question of how and when stochastic radiation risk is communicated to patients, and whether this meets the expectations of all the stakeholders (patients, referrers, radiologists and radiographers) from a legal and ethical perspective. In seeking opinions from the stakeholders a proposed process of informed consent for clinical medical imaging examinations that use ionising radiation was developed. The focus in this research is the disclosure of risk. Key research questions written to focus the research aim included:

- What is a significant risk?
- Is there a threshold of when ionising radiation risk should be disclosed?
- What are the ethical influences for risk disclosure?
- What are the legal requirements for risk disclosure?
- What ionising radiation risk disclosure techniques are advocated?
- Who should be disclosing risk?
- What is the best risk disclosure method?
- What barriers exist to ideal risk disclosure practice?
- What pathways are available for improving the risk disclosure practice?
- What is the ideal risk disclosure process?

Method

A sequential explanatory mixed method, multiphase study was chosen to address the research questions and included four phases:

Phase One involved a comprehensive examination of the legal and ethical influences of the informed consent process, and the guidelines of the professional groups of stakeholders. A systematic review was then undertaken which investigated the advocated risk disclosure methodology. A total of seventeen journal articles were assessed, and the findings synthesised into an advocated methodology.

Phase Two utilised a cross-sectional questionnaire survey to assess the preferences of hypothetical patients for receiving risk disclosure information. The participants included radiographers (n=121), and

members of the public (n=172), in the hypothetical role of a patient. Respondents were asked to identify the most appropriate method and medium to receive ionising radiation risk information, and whom they felt were appropriate professionals to undertake this role. The respondents were also asked to identify the threshold at which an ionising radiation risk became significant.

Phase Three involved a series of semi-structured interviews with professional stakeholders, including radiographers (n=21) and radiologists (n=9), to investigate barriers to the risk disclosure process, and pathways to improve the process. Participants were asked questions about the practice of disclosing ionising radiation risk in the clinical environment. The resultant data was reviewed, and using a nominal method of quantitative transformation, and a set of themes constructed.

Phase Four focussed on process development. A group of expert participants, including radiographers (n=5) and radiologists (n=5), took part in an e-Delphi study to define an ideal risk disclosure process. This three-round, online investigation started with thirty-one statements, which were accepted if an 80% consensus was reached. Future rounds utilised questions that were redeveloped from those that did not reach consensus, or generated from feedback from earlier responses. After three rounds, a series of statements reached consensus or were considered irreconcilable. The resultant consensus statements were synthesised into a process for disclosing ionising radiation risk in clinical examinations. The resultant theoretical process was then considered against a legal, ethical, practical and professional framework.

Results

The results from each of these studies were reported in five publications. In line with a mixed methods design, a meta-synthesis was undertaken to integrate the key results. The research uncovered a number of noteworthy conclusions.

Phase One of the research identified that the Australian legal framework requires disclosure of a significant risk, but there are no guidelines of what constitutes a significant ionising radiation risk. Risk disclosure is currently undertaken infrequently, poorly, and without process. There is very little research into this area, and even less documented examples of clinically-integrated practices. In the Australian legal context, it has been advised that the duty to inform to only be legislated for medical practitioners. This phase also found that when the most-advocated techniques of risk disclosure are synthesised, the result is a pictographic representation of risk.

Phase Two of the research found that there is considerable agreement between radiographers and members of the public on many aspects of risk disclosure. Both groups agreed that human interaction was the preferred communication pathway (but that information in the form of pamphlets was useful). Both groups agreed that risk should be expressed as odds, preferably in a visual format (such as a

pictogram). Both groups identified that radiologists and radiographers were trusted sources to discuss ionising radiation risk, but that members of the public also had trust in the referring physician. Respondents felt that the threshold of what constitutes a significant risk was very low.

Phase Three identified that professional stakeholders supported the notion that the process of risk disclosure was done poorly. Respondents indicated that the process was poorly defined, and that a low threshold was prohibitively impractical, in contrast to the members of the public. A threshold of dose equating to fluoroscopic examinations, and CT examinations, was advocated; with plain radiographic examinations not requiring risk disclosure for non-radiosensitive patients.

Phase Four resulted in a proposed risk disclosure process of informed consent that must begin with the referring physician, and conclude (where necessary) with the radiologist, with the radiographer supporting the process. The resultant process (potentially including the pictographic method) was found to meet all legal and professional guidelines.

Conclusion

The resultant risk disclosure process represents a legal, professionally supported framework. The process meets risk thresholds advocated in previous research, but does not meet the impractical standards of members of the public, as this would be extremely prohibitive for clinical application. The described process could, after clinical testing and assessment, form the basis of a clinical practice guideline. This would, in turn, ensure that Australian patients exposed to significant ionising radiation risk would have the risks disclosed meaningfully and ethically.

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DEFINITIONS

Course of action

A course of action is any procedure, treatment, investigation, examination or synonym thereof and also includes the decision to decline a proposed treatment.

Diagnostic Radiography

Diagnostic radiography refers to the use of x-rays to create a radiograph. It specifically *excludes* fluoroscopy, CT scanning, etc. Diagnostic radiography is part of the subset of techniques in medical imaging. The majority of diagnostic radiography techniques do not utilise contrast media. These examinations without contrast media will be referred to as *plain radiography*.

Medical Imaging

Medical imaging refers to the use of an imaging procedure (x-rays, CT scans, ultrasound, MRI, etc) for the investigation of illness in a patient in a clinical environment. It includes both ionising and non-ionising radiation equipment.

Physician / Doctor / Clinician / Medical Practitioner

Physician, doctor, clinician and medical practitioner are used interchangeably, and refer to a qualified medical doctor who is practicing medicine in a clinical environment. This interchangeability reflects the different terminology used internationally. Note that a *radiologist* is defined separately.

Radiologist

A radiologist is a medical doctor who has completed additional training in the interpretation of medical images. They will be considered as a separate entity to a 'doctor' based on their radiobiology training and knowledge base, and in this research they will always be recognised an exception to the grouping of doctors as a singular group.

Referrer

A referrer is a health care professional who, under Australian law, may request a diagnostic imaging service.[1] In Australia, the primary source of referral is considered to be the general practitioner.[2]

Glossary of Terms

Absorbed Dose

The amount of ionising radiation absorbed is called the absorbed dose. This is measured by the quantity of energy absorbed per unit of mass, with a unit of joules per kilogram, also known as the Gray (Gy).[3]

Carcinogen

A carcinogen is something which can cause cancer.

Carcinogenesis

Carcinogenesis is the creation of a cancer.

Delegatee

A person upon whom a task is delegated.

Effective dose

The dose which, if delivered uniformly to the whole body, would produce the same health consequences as those caused by a dose delivered to one or more specific organs.[4] The unit of effective dose is the Sievert (Sv).

Fluoroscopy

The real-time use of an x-ray source to visualise dynamic body systems.

Iatrogenic Risk

A risk attributable to medical intervention. It is not necessarily related to error, but may be an inherent risk of a procedure or an examination.

Ionising radiation

Radiation that produces ionisation in matter. X-rays are a form of ionising radiation. When ionising radiation passes through the tissues of the body, it has sufficient energy to damage DNA.

Latent Period

The latent period (or latency) is the period between a causative event and the development of an observable effect. In this research, it will exclusively refer to the time interval between irradiation and the appearance of a malignancy (cancer).[3]

Millimort

A millimort (from milli- and mortality) is a unit of risk, defined as one-in-a-thousand chance of death. The unit is based on the *micromort*, a microprobability of death[5, 6].

Non-Ionising radiation

Radiation that does not produce ionisation in matter. In the context of medical imaging, non-ionising radiation includes diagnostic ultrasound and magnetic resonance imaging. When these radiations pass through the tissues of the body they do not have sufficient energy to damage DNA directly.

Prima facie

Prima facie ('at first appearance') signifies that a matter appears to be evident from the facts. In common law jurisdictions, *prima facie* denotes evidence that would be sufficient to prove a particular proposition or fact, unless specifically proven incorrect.

Screening

Unqualified use of the term 'screening' refers to programs that attempt to identify instances of disease in an asymptomatic population.[7] ('Screening' is also used in the context of *fluoroscopy* but in that case will be qualified, as in 'fluoroscopic screening)'

Sievert

A Sievert is an SI unit, and represents one joule of energy per kilogram of material ($J.Kg^{-1}$). The sievert is a measure of the effective dose.

Stochastic Effect (of radiation)

A *stochastic effect* of radiation is a biological effect. The most commonly cited stochastic effect is the development of cancers.[3, 8] The probability of a stochastic effect occurring is a function of radiation dose (without a threshold).[3]

Tissue Effect (of radiation)

A *tissue effect* is a biological effect, for which the *severity* of the effect (and often, *immediacy* of effect) varies with the dose. Tissue effects require a certain threshold dose (approximately 3Gy[9]), before the effects occur. Example tissue effect include cataracts,[3] skin blistering, erythema, desquamation and necrosis.[10] Tissue effects were formerly known as *nonstochastic effects*, and, later, *deterministic effects.*[11]

Tort

A tort is a legal wrong which one person or entity commits against another. The tortious act results in a legal liability, for which the usual remedy is an award of damages[12].

X-Ray

X-ray here refers to the actual physical beam of radiation.

Acronyms and Initialisations

ACPSEM:	Australian College of Physical Scientists and Engineers in Medicine
AEA:	Atomic Energy Agency
AHPRA:	Australian Health Practitioner Regulation Agency
ARPANSA:	Australian Radiation Protection and Nuclear Safety Agency
BEIR:	(Committee of the) Biological Effects of Ionising Radiation
CINAHL:	Cumulative Index to Nursing and Allied Health Literature
CT:	Computed Tomography
EMBASE:	Excerpta Medica dataBASE
HMRI:	Hunter Medical Research Institute
HREC:	Hunter Research Ethics Committee
ICRP:	International Commission on Radiological Protection
LNT:	Linear, No-Threshold
MRI:	Magnetic Resonance Imaging
MRPBA:	Medical Radiation Practice Board of Australia
NAS:	National Academy of Sciences
NGT:	Nominal Group Technique
NSQHS:	National Safety and Quality Health Service
RANZCR:	Royal Australian and New Zealand College of Radiologists
RIMS:	Research Information Management System
TBP:	Thesis by Publication
U/S:	Ultrasound
UNSCEAR:	United Nations Scientific Committee on the Effects of Atomic Radiation
UON:	The University of Newcastle
WHO:	World Health Organisation

SYNOPSIS

The research structure is a sequential, explanatory mixed-method multiphase study.

The aim of this research is to investigate informed consent for a patient considering an ionising radiation medical imaging examination.

In this research, the primary focus on the informed consent aspect will be on the disclosure of risk. The other aspects of informed consent (such as the expected benefit of a proposed examination, or alternate courses of action) are specific to the individual patient, whereas a (population averaged) risk can be calculated with a reasonable degree of confidence.

For the consideration of ionising radiation risk, the primary focus will be on the stochastic effects of radiation to the patient (particularly carcinogenesis). Stochastic risks have a likelihood as a function of dose. As such, stochastic effects of radiation may have no need for risk disclosure at all, or may have a need to be disclosed based on a specific level (or threshold) of dose (and thus, risk).

Risk disclosure must work within a number of parameters, and to align the needs of a number of different stakeholders. This research, therefore, begins with an analysis of *what must be done* by investigating the legal considerations of informed consent.

The next step is to consider *what should be done*, by investigating ethical considerations of informed consent. If these steps can be satisfied, then the next step is to consider *what has been done before*. The findings on previous research is considered, to see how this informs the process.

With this information, the next step is to consider *how it should be done*. The stakeholders in the process should be consulted, so as to investigate practical and agreeable principles and methodologies. These rules, guidelines, viewpoints and practicalities should then be aligned into an ideal practice, or at least a model of best practice. With this information, a process for disclosing the ionising radiation risk of a proposed medical imaging examination can be developed. The investigation framework is planned in Figure 1.

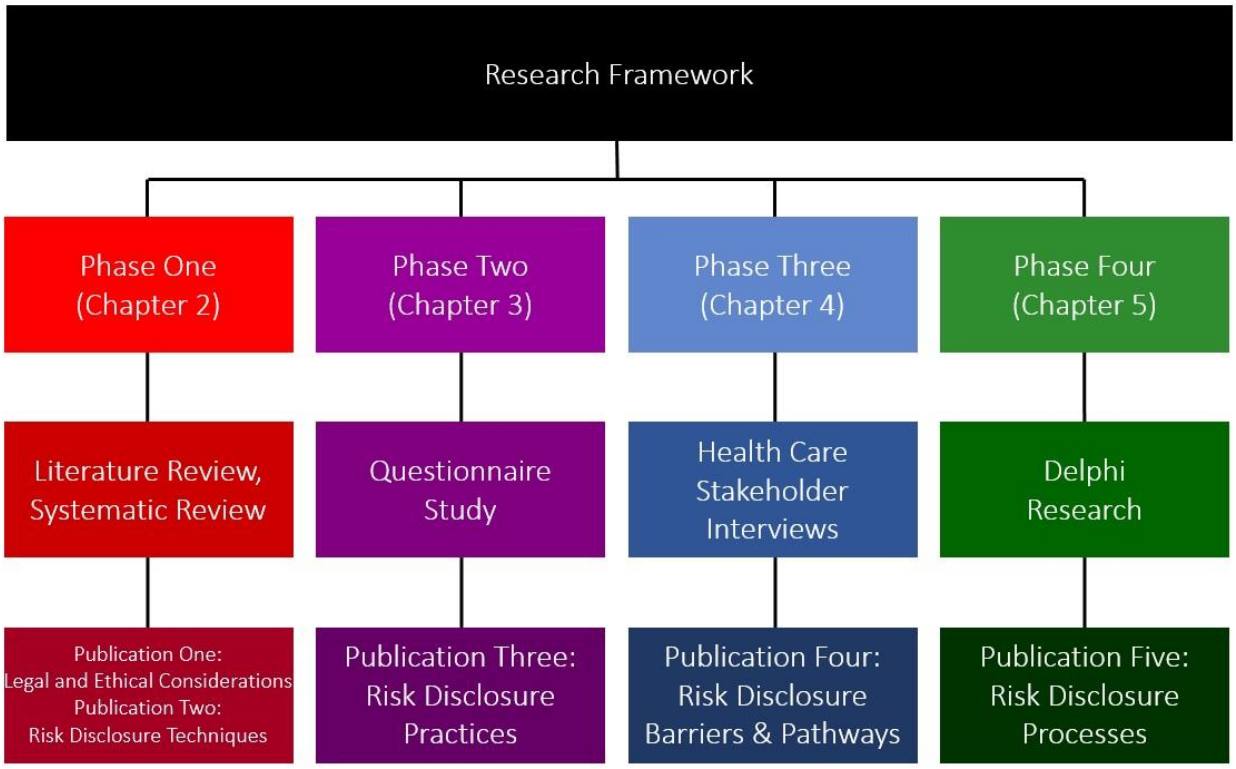

Figure 1: Research Framework.

By undertaking the research in this manner, each step informs the next. The research framework (Figure 1) outlines the sequence of research into distinct phases.

This thesis is presented as a thesis by publication, with the findings supported by five publications on the informed consent process for medical imaging examinations that utilise ionising radiation:

1. Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2018). Ionising radiation risk disclosure: When should radiographers assume a duty to inform? *Radiography*, *24*(2), 146-150. https://doi.org/10.1016/j.radi.2017.12.002
2. Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2018). Medical imaging and informed consent–Can radiographers and patients agree upon a realistic best practice? *Radiography*, *24*(3), 204-210. https://doi.org/10.1016/j.radi.2018.01.005
3. Younger, C. W. E., Wagner, M. J., Douglas, C., & Warren-Forward, H. (2019). Describing ionising radiation risk in the clinical setting: A systematic review. *Radiography*, *25*(1), 83-90. https://doi.org/10.1016/j.radi.2018.11.002
4. Younger, C. W. E., Moran, S., Douglas, C., & Warren-Forward, H. (2019). Barriers and pathways to informed consent for ionising radiation imaging examinations: A qualitative study. *Radiography, 25* (4). https://doi.org/10.1016/j.radi.2019.03.001

5. Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2019). Informed consent guidelines for ionising radiation examinations: A Delphi study. *Radiography*, (In Press, Corrected Proof). https://doi.org/10.1016/j.radi.2019.08.004

Excerpts of this research have been presented at the Australian Society of Medical Imaging and Radiation Therapy's 13th National Conference (March 2018).

1. Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2018). *Informed Consent in Medical Radiation Science* (Oral Presentation)[13].
2. Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2018). *Communication of risk – Do our views match those of our patient?* (Oral Presentation)[13].

Conference Presentation Abstracts for these presentations are shown in Appendix A.

Chapter One: This chapter provides an overview of the research, and the publications linked with each phase of the research process. This chapter describes the background, rationale and objectives for the study. From here, the influences that led to investigation of the topic, and a brief analysis of the problem, are discussed. This is followed by a discussion of the aims and objectives of the research.

Chapter Two: This chapter comprises a review of the literature. First, ionising radiation risks are defined. Second, the stakeholders in the process are identified. Third, ethical concepts of risk disclosure and patient autonomy are investigated. Fourth, the International and Australian legal backgrounds to informed consent are considered.

This chapter includes two published research articles:

Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2018). Ionising radiation risk disclosure: When should radiographers assume a duty to inform? *Radiography*, *24*(2), 146-150. https://doi.org/10.1016/j.radi.2017.12.002

Younger, C. W. E., Wagner, M. J., Douglas, C., & Warren-Forward, H. (2019). Describing ionising radiation risk in the clinical setting: A systematic review. *Radiography*, *25*(1), 83-90. https://doi.org/10.1016/j.radi.2018.11.002

Chapter Three: This chapter investigates the substantive aspects of informed consent for ionising radiation medical imaging examinations. This chapter is based on a questionnaire study. The questionnaire asks respondents about who is the preferred provider of ionising radiation risk, how it should be described, and through which media. It further investigates what respondents consider to be a significant risk (that is, the threshold at which an ionising radiation risk was material to the patient).

This chapter contains one published paper:

Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2018). Medical imaging and informed consent–Can radiographers and patients agree upon a realistic best practice? *Radiography*, *24*(3), 204-210. https://doi.org/10.1016/j.radi.2018.01.005

Chapter Four: This Chapter reports on interviews with radiographers and radiologists and investigates what barriers exist for ideal risk disclosure practice, and what pathways are available for improving the practice. This chapter contains one published paper:

Younger, C. W. E., Moran, S., Douglas, C., & Warren-Forward, H. (2019). Barriers and pathways to informed consent for ionising radiation imaging examinations: A qualitative study. *Radiography, 25* (4). https://doi.org/10.1016/j.radi.2019.03.001

Chapter Five: This chapter investigates the views of radiologists and radiographers about the ideal consent process, from the patient's first interaction until the proposed care is complete. The process was investigated using a Delphi study. This chapter contains one published paper:

Younger, C. W. E., Douglas, C., & Warren-Forward, H. (2019). Informed consent guidelines for ionising radiation examinations: A Delphi study. *Radiography*, (In Press, Corrected Proof). https://doi.org/10.1016/j.radi.2019.08.004

Chapter Six: This chapter revisits the research aim, and the research questions which supported this investigation. A phase-by-phase summary of the research findings are then considered.

Each process recommendation is then discussed in the context of the Australian ethical and legal landscape. These recommendations are then synthesised into a proposed clinical guideline for the informed consent process for ionising radiation medical imaging examinations. This chapter then discusses the strengths and limitations of this research, and avenues for further research and investigation. Integration of the research into a clinical process is then considered.