Facility, service and/or
clinical stream name

# Research Protocol Template: Retrospective Study

**Please read this explanatory information and then delete these blue notes as well as any examples when developing your research protocol.**

This is an example of a lower risk protocol for an analysis of retrospective data. Researchers may use this template and example to develop their own research protocol.

*A well written research protocol is essential for high-quality research. A research protocol generally follows a conventional layout. This research protocol guide aims to offer a generic guide, suitable for a broad range of research in Metro South Health.*

*The preparation of a research protocol is an important first step in the research process for the following reasons:*

1. *It provides the background and justification for the project*
2. *It details the research question, research aims, hypothesis, methodology, risk management including data protection and statistical analysis.*
3. *It* *is the roadmap for the conduct of the research.*
4. *It provides the basis for Human Research Ethics Applications (HREAs).*

*The template contains a broad outline of sections usually expected in a research protocol. It is a guide to the information conventionally required rather than aiming to be definitive. Therefore, not all of the sections will be relevant for every research protocol and may be modified or deleted as applicable.*

**The following resources should be reviewed when preparing your research protocol**

National Statement on Ethical Conduct in Human Research (2023). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra

<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023>

Australian Code for the Responsible Conduct of Research (2018). National Health and Medical Research Council, Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra

<https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>

**Research project title (full)**

The research study title should be descriptive, although clearly and concisely indicating the subject of inquiry.

The title should be consistent across all related documents.

For example: A retrospective review of prescribing habits for sedative agents in an Australian elderly inpatient population

**Study investigators**

It is important to list the investigator affiliations to ensure reviewers are aware of the organisations involved, as this may have implications for data transfer, privacy, and confidentiality.

|  |  |
| --- | --- |
| Principal Investigator: *(for single site studies)*OR | For example:Dr Sirius ResearcherStaff SpecialistPrincess Alexandra Hospital Surgical Unit Ph: 3176 xxxxEmail: Sirius.researcher@health.qld.gov.au |
| Coordinating Principal Investigator: *(for multi-centre studies)* | xxxxx1  |
| Associate Investigator:  | xxxxx1  |

**1**Name, Institution, Department, Contact details

### **Funding** *(if applicable)*

Sources and types of financial, material and other support.

### Introduction

The introduction is a very brief overview of the research project (~250 words). The introduction should be concise but sufficient to orientate the reader to the main purpose of the research, how it will be conducted and its expected benefits.

### Background

The background is an important aspect of a research protocol. In this section the research problem should be described with a summary of relevant published literature to justify the study. A literature review involves finding, reviewing and forming conclusions about the published research to provide clarity of the research problem. A comprehensive literature review should be concise and present the key refences leading to the statement of the aim(s) of the proposed research. This is an opportunity to outline why the research needs to be done.

**For example**: The incidence of head and neck cancers is increasing. From 2009 to 2018, the number of cases diagnosed increased from 3896 to 5212.1 In the curative setting, radiotherapy is used either definitively or as an adjuvant treatment following surgery, with or without concurrent chemotherapy. A ‘typical’ fractionated course of radiotherapy consists of 35 fractions, over 7 weeks, for definitive treatment, and 30-33, over 6-6.5 weeks, for adjuvant setting. Not all patients are suitable for definitive treatment or surgical resection. Factors that needs to be considered include tumour stage, patient preference, geography, fitness, and social support.

There is a wide range of palliative fractionations that require fewer treatments, at the expense of less tumour cell kill, local control, and a potential for increased late toxicity.2 The goal of such treatment is to induce significant and durable tumour regression, with consequent symptom control. An additional radiobiological advantage of shorter treatment is that the treatment will be largely completed before the onset of accelerated tumour repopulation.3 This is particularly significant for the management of advanced stage head and neck cancers in which a high growth rate is frequently observed.4

The optimal dose and fractionation have not been established. A systematic review highlighted a significant variation in practice, with a majority reporting high efficacy and low rate of significant side effects.1 A moderately hypofractionated dose fractionation of 50Gy in 20 fractions has been used in patients not suitable for definitive treatment with chemo-radiotherapy or surgery. This fractionation is frequently used in skin malignancies and seeks a balance between providing durable local control without the requirement for 7 weeks of daily radiotherapy. To our knowledge, the only available literature on the use of this dose fractionation is within a retrospective series by Stevens et al1 of various schedules in which 32 patients received this particular dose fractionation.

### Aim(s)

The aim(s) should be developed from the literature review and state what the research project hopes to accomplish.

**For example:** To review the results of patients with a head and neck malignancy treated with a hypofractionated dose of 50Gy in 20 fractions at the Cancer Hospital.

### Methods

The scientific integrity of the research project and the credibility of the data from the study depend on the study design.

#### 4a. Study type/design

State the design of the research project

**For example:** This is a single institution retrospective data analysis.

#### 4b. Setting

Outline the location of where the research will be undertaken (eg Orthopaedic Unit, Princess Alexandra Hospital).

#### 4b. Participants

This section should describe which potential participants will be selected for data analysis. Be specific regarding the timeframe of records to be reviewed, specifying start and end dates for data capture in dd-mm-yy format and the inclusion and/or exclusion criteria.

##### Inclusion criteria

Inclusion criteria are the ‘characteristics’ that clearly describe the research population that are required for a participant’s data to be included in the research. The criteria may be based on factors such as age, gender, the type and stage of a disease, previous treatment history, and co-morbid medical conditions. If the study only includes adults, state that all participants will be 18 years or older.

##### Exclusion criteria

Provide details of participants who will be considered ineligible to participate and justification for their exclusion.

Include an estimate and a justification for the sample size.

**For example:** This study will review the results of all adult patients treated with 50 Gy in 20 fractions for head and neck cancer between 1st January 2009 to 1st January 2019 at the Princess Alexandra Hospital. We anticipate approximately 100 patients that will meet this criterion. This sample size will provide adequate power (0.8) for an ANOVA comparing 3 groups.

MSH Researchers are eligible for a free consultation plan with QCIF. Please refer to [QCIF Forms](https://support.qcif.edu.au/msh-biostatistics-support) to request an appointment if you require assistance with determining an appropriate sample size.

#### 4c. Data Variables

It is essential to state how the data will be collected and the data source (e.g. ieMR, routinely collected hospital data, other research database). Include the full list of variables that will be accessed for this project. Include the members of the research team and their affiliation, who be accessing the data, completing data extraction and the data analysis.

If accessing medical records or databases for research purposes this requires the approval of the data custodian regardless if research team members have access to same for clinical purposes. Please refer to the Queensland Health Data Custodian List <https://www.health.qld.gov.au/__data/assets/pdf_file/0034/843199/data_custodian_list.pdf>

**For example:** Data will be obtained manually from both the radiation oncology database as well as electronic medical record, iEMR. Data variables that will be included in this study are patient age, comorbidities, smoking history, tumour characteristics (subsite, stage, and treatment technique). Outcome measures are cancer control outcomes and presence of disease. Approval will be sought from the data custodian prior to extraction. The data will be accessed by a MSH Cancer Hospital employee.

### Endpoints

They may include additional clinical, psychological, economic, or safety outcomes (eg treatment related side effects/adverse events).

**For example:** The primary endpoints for this study are treatment response and loco-regional control. Secondary endpoints will be overall survival, disease free survival, acute and late toxicity.

### Data analysis

Describe the statistical analysis that will be undertaken in the study.

**For example:** Depending on normality of the data, continuous variables will be assessed via the independent samples t-test or Mann-Whitney U test and categorical data will be compared using the chi-square test or Fisher’s exact test as appropriate. Kaplan Meier actuarial curves will be constructed for the endpoints of overall survival and disease specific survival. Log-rank test will be used to determine significance of the survival curves. Significance level will be defined as p ≤ 0.05 (2-sided).

### Data Management

This section addresses the storage, retention, disposal, sharing and re-use of data or information. It should address the following questions:

* How and by whom will the data or information be generated, collected and/or accessed?
* Will the data or information be disclosed or shared and, if so, with whom?
	+ Clarify whether data will only be accessible to named investigators.
* Where will the electronic and/or hard copy data be stored?
* In what format will it be analysed and stored, e.g. identifiable, re-identifiable or non-identifiable?
	+ Identifiable: Data that can uniquely identify an individual. Examples of direct identifiers include name, address, driver’s license number, patient UR number and Medicare number.
	+ Re-identifiable: Re-identifiable data, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.
	+ Non-identifiable: data which have never been labelled with individual identifiers for the purpose of research
		- Who will obtain the identifiable data and make it re- or non-identifiable?

*Reference: Health Informatics Services (2021) “De-Identification and Anonymisation of Data Guideline” v1.*

<https://metrosouth.health.qld.gov.au/sites/default/files/content/de-identification-and-anonymisation-of-data-guideline.pdf>

Note: The Queensland Government data retention guidelines state it is 25 years from publication for clinical interventional trials; for paediatric studies it must be kept until the youngest participant has turned 25yrs old; permanently for Phase 1 or genetic focused research; and 7 years for all other types of research. Confirm that the data will be securely disposed of at the end of the retention period.

*Reference: Health Sector (Corporate records) Retention and Disposal Schedule (2023)*

**For example:** The data items will be extracted by Dr Smith and stored in a password protected excel spreadsheet which will be kept on a secure hospital network drive. Participants will only be identified for the purpose of data collection. All extracted data will be made non-identifiable prior to analysis and storage. Data will only be accessible to named investigators. The collected data will be deleted seven years following publication of the research, as per Queensland Health archiving guidelines.

### Ethical issues

State that the research project will be conducted in full conformance with principles of the World Medical Association Declaration of Helsinki, Good Clinical Practice (GCP) and within the laws and regulations of the country in which the research is conducted.

If informed consent cannot be obtained, then please request a waiver of consent to access medical records without participant consent justifying it against the criteria at [2.3.10 of the National Statement (2023) with complete answers to all items from (a) to (i), with specific reference to your project.](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__296)

**For example:** We will be requesting a waiver of consent for this project and believe the activity is not inconsistent with the National Statement (2023) section 2.3.10 because this retrospective study of previously collected clinical data carries no foreseeable risk of harm to participants. It is impracticable to obtain consent due to the large number of records being accessed. Additionally, some of the participants may have deceased. There is no known reason that the participants would not have consented if they had been asked. Non-identifiable patient data will be analysed within the Department. No investigators from outside Queensland Health will be involved in the study.

As per the National Statement (2023):

2.3.10 Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:

a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants

[Insert justification here]

b) the benefits from the research justify any risks of harm associated with not seeking consent

[Insert justification here]

c) it is impracticable to obtain consent (for example, due to the quantity, age, or accessibility of records)

[Insert justification here]

d) there is no known or likely reason for thinking that participants would not have consented if they had been asked

[Insert justification here]

e) there is sufficient protection of their privacy

[Insert justification here]

f) there is an adequate plan to protect the confidentiality of data

[Insert justification here]

g) in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)

[Insert justification here]

h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled

[Insert justification here]

i) the waiver is not prohibited by State, federal, or international law

[Insert justification here]

###  Risk assessment

The researcher will assess the level of risk for participants involved in this study to determine if this study meets the criteria to be submitted for review as a lower risk or higher risk study.

A risk is a potential for harm or discomfort. It involves:

* the likelihood that a harm or discomfort will occur, and
* the severity or magnitude of the harm or discomfort, including their consequences.

While discussion of the risk of harm or discomfort applies to risk to an individual research participant, it can also apply to groups or communities as well as to non-participants such as family members. Risk can be associated with the conduct of research or the proposed outcomes of the research.

Risk in research exists on a continuum with the risk profile of an individual research project falling somewhere along this continuum.

Low risk research describes research, including some types of clinical trials, in which the only foreseeable risk is no greater than discomfort. Accordingly, research in which the risk for participants or others is greater than discomfort is not low risk research. Research in this category is considered higher risk research and carries risk of harm.

*Reference: National Statement on Ethical Conduct in Human Research (2023). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra*

Refer to [Apply for ethics approval | Metro South Health](https://www.metrosouth.health.qld.gov.au/research/research-ethics-and-governance/apply-for-ethics-approval) for information and training which will help you understand, assess and plan for risks in your research project.

### Resource requirements

Outline any resource requirements needed to conduct the research project.

**For example:** This is a retrospective review of existing data. There is no financial cost associated with this project. No additional staff appointments are needed to complete this study. Data will be collected by existing staff members in their own time.

### Dissemination of findings

Identify where the results of the study will be disseminated, e.g., internal presentations, conferences, publications. Confirm that no individually identifiable data will be included in the final research deliverables.

**For example:** The results of this study will be presented at the RANZCR annual scientific meeting, and as a paper for publication in a peer reviewed journal. No individually identifiable data will be included in the final research deliverables, because it will be an aggregate of the overall cohort data.

### References

**For example**

1. Stevens, C. M., Huang, S. H., Fung, S., Bayley, A. J., Cho, J. B., Cummings, B. J., ... & Ringash, J. (2021). Retrospective study of palliative radiotherapy in newly diagnosed head and neck carcinoma. International Journal of Radiation Oncology\* Biology\* Physics, 81(4), 958-963.
2. Staackmann, C., Ribbat-Idel, J., Perner, S., Idel, C., Bruchhage, K. L., Hakim, S. G., ... & Rades, D. (2021). Palliative local radiotherapy for advanced squamous cell carcinoma of the head-and-neck: Prognostic factors of survival. Anticancer Research, 41(6), 3205-3210.