GUIDELINES ON THE RETROSPECTIVE USE OF MEDICAL PATIENT RECORDS FOR RESEARCH PURPOSES

1. Documents relevant to ethical aspects of this type of study

These are not an attempt to provide a complete list of all applicable documents.
More might be added.

The Declaration of Helsinki (Section 8) argues that: "While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and the interests of individual research subjects". Hospital patients are still research subjects even when 'only' their health records are being used. In this context, it would be ideal to ensure that they are aware, even in general, of the potential use of their personal information for research purposes.

The Declaration of Helsinki (Section 23) states that RECs "must take into consideration the laws and regulations of the country or countries in which research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration".

Extract from the 2015 DoH guidelines for ethics in health research (Section 3.3.7)
"Secondary use means use in research of materials or data originally collected for other purposes… the following is recommended:

- The ***nature of the previously obtained consent*** should be determined to ascertain whether subsequent usage was envisaged and whether it falls within the scope of the current proposal. If so, new consent is not required.
- If the ***scope of the current proposal is different***, then new consent may be required.
- ***If samples are anonymous*** and the results of research would not place any individual, family or community at social, psychological, legal, or economic risk of harm, then new consent is not required.
- ***If a link to identifiers exists*** but is not provided to the research team and the results of research will not place any individual, family or community at social, psychological, legal or economic risk of harm, then new consent is not required.
- ***If a link to identifiers exists*** the person who holds the code or link should sign an explicit written agreement not to release the identifiers to the research team. This agreement should accompany the submission to the REC."

Extract from the 2015 DoH guidelines for ethics in health research (Section 3.2.1)
"A REC may approve a waiver of personal informed consent for types of research into e.g., record reviews or such like."

Extract from HPCSA guidelines on the keeping of patient health records (Booklet 9: Section 8)
On data ownership: "a patient health record is owned by the health practitioner or the entity generating such a patient health record."

Extract from HPCSA guidelines on confidentiality, protecting and providing information (Booklet 5)
"8.1.1 Information about patient is requested for a wide variety of purposes including education, research, monitoring and epidemiology, public health surveillance, clinical audit, administration and planning, insurance and employment. Healthcare practitioners have a duty to protect the privacy of patient and respect their autonomy.

8.2.3 Obtaining consent where the disclosure is made for research, educational, training, efficient administration of health services or clinical audit purposes: 8.2.3.1 ***If identifiable data is to be used this can only be done with informed consent of the patient***
8.2.3.2 Use of identifiable patient data is permitted for purposes of the efficient administration of health services and for clinical audits, with the proviso that only information relevant to the purpose of disclosure is revealed, and disclosure is only made to personnel with a direct need for that information."
8.2.3.3 Where de-identified information can serve any of the above purposes, ***it is incumbent on the healthcare provider to de-identify data as soon as possible*** before making use of the data.
8.2.3.4 Where healthcare practitioner have control of personal information about patients, they must not allow anyone access to that information for study, research or medical audit unless the person obtaining access has been properly trained and authorised by a health establishment, a healthcare provider or comparable body and is subject to a duty of confidentiality in their employment or because of their registration with a statutory regulatory body.
9.1.3 Medical research: ***Where research projects depend upon using identifiable information or samples, and it is not practicable to contact patient to seek their consent, the data should be anonymised and this should be drawn to the attention of a research ethics committee.***

The Council for International Organisations of Medical Sciences (2016)
A research ethics committee ***can grant a waiver of informed consent in retrolective research when it is not feasible without the waiver, when it is of significant social value and involves barely minimal risks for participants,*** even when the study includes identifiable data or biological samples.

2. Nelson Mandela University RECH guidelines

Retrospective studies using medical patient records without new consent can be approved IF

- the guidelines stated in the extracts above are met,
- there is no other way to obtain such data with prospective informed consent (inconvenience to the researcher is not an adequate motivation),
- the data will be collected on site (records will not be removed from the hospital), and
- only anonymised information will be extracted with the relevant hospital permissions.

Applications for ethics approval should:

- include a consideration of the individual humans behind the data and their rights, not only the needs of the research students or the discipline or greater society – and applications should reflect sensitivity in this regard,
- demonstrate an awareness of the debates around data ownership and when new consent is required, and
- include reflections on the best possible ethical use of health record data in the context of each research study. This is important because it should not be necessary for a RECH member to explain to the committee why the researcher, and not healthcare practitioner, absolutely has to have their own eyes of the full patient file / record with its identifying information themselves. The written ethics application should provide its own explanation in this regard,
- due consideration has been given to dual roles (i.e., as health professional on site and researcher), and
- a data management plan has been included.

Efforts should be made to alert and educate hospital patients of the potential use of their health records for research purposes, to improve individual self-determination in the use of their medical information.