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BC Cancer Research Ethics Board Guidance for Chart Reviews

The purpose of this guidance is to outline the principles and procedures relating to the ethical review and conduct of chart reviews at BC Cancer. This guidance was largely adapted from information developed by the University of Alberta (https://www.ualberta.ca/research/support/ethics-office/human-research-ethics/information-and-data/health-information/chart-review)

What is a chart review?

A chart review is an evaluation or analysis of a patient's medical record. As the information contained in medical records was originally collected for another purpose (e.g., clinical treatment), when used for research purposes, chart reviews are considered "secondary use of identifiable information for research purposes" (see Chapter 5 – Privacy and Confidentiality, D. Consent and Secondary Use of Information for Research Purposes, Tri-Council Policy Statement: Ethical Conduct for Research Involving Human, "TCPS2, 2018").

What is the difference between a retrospective and prospective chart review?

A ***Retrospective Chart Review*** evaluates patient data that already exists in the subject's medical record at the time the project is submitted for initial REB review. The patient data does not result from the research activity.

A ***Prospective Chart Review*** evaluates patient data that does not yet exist in the subject's medical record at the time the project is submitted for initial REB review.

What to do prior to accessing charts

The use of the health information for quality assurance/improvement activities may not require ethics review, but the use of health information in the conduct of research-related activities does require ethics review. REB review/ and approval, or the determination that the project is indeed QA/QI, and therefore, outside the scope of REB review, should be sought from the REB PRIOR to accessing the charts. In most cases, chart reviews are dealt with via a delegated ethic review process. On rare occasions, such as the collection of sensitive data, the study may have to be reviewed at the full board.

Depending on the custodian of the medical records you wish to access, additional administrative, operational or research agreements must be in place prior to accessing the data. It is the investigator's responsibility to make enquiries and ensure all necessary requirements (particularly in relation to privacy) are met.

Do I need to obtain informed consent when conducting a chart review?

It is a common misconception that consent is not required for chart reviews. For example, just because a chart review may be considered "minimal risk", this does not mean that consent is not required. In all cases, the reasons for not obtaining consent must be addressed. Article 5.5A, TCPS2, states: "Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if

they have satisfied the REB that:

a. identifiable information is essential to the research;
b. the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
c. the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
d. the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
e. it is impossible or impracticable to seek consent from individuals to whom the information relates; and
f. the researchers have obtained any other necessary permission for secondary use of information for research purposes."[1]

It is necessary to explicitly address the above criteria as it relates to the specific research project. It is not acceptable to merely restate the above criteria in the request to not obtain consent prior to accessing the medical records.

Researchers should consider the following when outlining their rationale for not obtaining consent:

- ***Sample size*.** Is the sample size too large to contact all individuals or is it small enough that contacting individuals is feasible?
- ***The age/dates on the medical records.*** Many individuals may be lost to follow up from older medical files whereas it may be possible to contact individuals who recently received medical care. For example, if patients are still being seen in clinic, it is possible to get consent.
- ***The impact of contact for consent.*** Depending on the nature of the medical condition under study, will contact from the research team cause undue stress to the individual?
- ***Consent may introduce bias.*** Where requiring consent may put the scientific integrity at risk.
- ***Consent may lower enrollment numbers.*** It is unlikely that this would be considered ethically justifiable for not obtaining consent.
- ***Impossible or impracticable.*** TCPS2 specifically defines impracticable as referring to "undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience". Researchers must provide substantial evidence that obtaining consent would be unnecessarily intrusive (well beyond "slowing down the process")
- ***Costs.*** The researcher would need to provide evidence that obtaining consent would place undue cost and burden on the team and render the research unfeasible.

Consent is required

Where the above criteria cannot be sufficiently demonstrated, the REB may determine that written informed consent is required. This is almost always the case in **prospective** chart reviews where an investigator intends to review the charts of all of patients within his/her practice. In this situation, the REB will likely determine that the investigator should obtain written informed consent since there will be an opportunity for patients to be consented during a scheduled clinic visit (consent is feasible and practical).

[1] NOTE: TCPS2 Article 3.7A addresses the criteria to obtain a "waiver of consent". The requirements of Article 3.7A, however, DO NOT APPLY to the secondary use of identifiable information (i.e. chart reviews), Article 5.5A applies.

Annual renewals and amendments
Should an annual renewal be necessary, the date range of the initial charts cannot be changed so as to include dates past the date of initial ethics approval. In order to qualify as retrospective, no chart information dated past the date of initial ethics approval can be included. If the investigator proposes to conduct prospective observational research (minimal risk, confined to chart review), then the following consent requirements must be fulfilled: either (1) create a consent form for the prospective data collection or (2) request a waiver of consent which details how all five of the TCPS 2, Article 5.5A conditions for such a waiver are met.

Tips for the Successful Completion of a Chart Review Application in RISe
Please complete sections 4.8 A-E under **4.C. -Clinical Study Type**

- Selecting "Yes" under section 4.8.A (Clinical chart review) will open up Sections 4.8.B and 4.8.C
- Selecting "No" under section 4.8.C (Is this study exclusively retrospective?) and clicking "Continue" will route you to section 5 (Summary of Study and Recruitment)
- Selecting "Yes" under section 4.8.C will open up sections 4.8.D and 4.8.E.

Section 4.8.D – Will you have access to personally identifiable information?

1. Please mark "Yes" if researchers will have access to personal identifiers. This will route you to section A - Retrospective Clinical Chart / Records review and you will need to complete sections A.6-A.6.A to justify the request for a waiver of consent for review by the REB
2. Please mark "No" if researchers will be provided with de-identified data only (i.e., personal identifiers are remove from the dataset provided by another party such as Popdata). This will also route you to section A - Retrospective Clinical Chart / Records review

Section 4.8.E. - Is this a retrospective chart review study for which participant consent will be obtained?

1. Selecting "Yes" under section 4.8.E and clicking "Continue" will route you to section 5 (Summary of Study and Recruitment)
2. Selecting "No" under section 4.8.E will route you to section A (Retrospective Clinical Chart Reviews)

NOTE: Section 4.8.E RISe guidance currently states: "If a retrospective chart review is **retaining** personal identifiers ("yes" in 4.7.D), participant consent is required. Similarly, if a retrospective chart review is being conducted on a small set of charts, looking at a rare disease, consent is required as there is potential for participants to be identified."

This guidance should state "participant consent ***may be*** required in both these situations – all requests for waivers of consent MUST be reviewed by the REB who will make the final decision based on the contextual specifics of the research.

Please contact the REB if you have any questions: reb@bccancer.bc.ca

Resources:
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans:
http://pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

PHSA Research Administration & Services – Research Privacy at PHSA:
http://www.phsa.ca/researcher/ethics-approvals/research-privacy-at-phsa

PHSA Research Administration & Services – Data Access & Management:
http://www.phsa.ca/researcher/resources-support/data-access-management

PHSA Technology Development Office (can help with data transfer agreements):
http://www.bccancer.bc.ca/our-research/research-focus/technology-development

How to Submit a New Human Ethics UBC Clinical Application (covers Chart Reviews):
https://www.rise.ubc.ca/sites/www.rise.ubc.ca/files/documents/How%20to%20Submit%20a%20New%20Human%20Ethics%20CREB%20Application%20%28Dec%202015%29.pdf