Workbook

Citizens' Dialogue on
Privacy and the Use of Personal Information
For Health Research in Canada

Spring 2005

McMaster University
Canadian Policy Research Networks Inc.

This workbook was prepared by McMaster University in collaboration with Canadian Policy Research Networks (CPRN). CPRN is a national not-for-profit, policy think-tank. CPRN uses public dialogues to involve citizens or stakeholders in research and policy discussions. You can obtain more information about CPRN on the internet at www.cprn.org

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Dear Participant,

Thank you for agreeing to take part in the Citizens' Dialogue on Privacy and the Use of Personal Information for Health Research in Canada. The purpose of this project is to better understand Canadians' views and expectations about the use of their personal information for health research.

We hope to learn what you believe is most important with respect to privacy and health research. During the discussion, you will have the opportunity to explore some of the issues and challenges associated with using personal information in research.

This project is being run by researchers from McMaster University in Hamilton Ontario, working with the Canadian Policy Research Networks (CPRN). CPRN is a national, independent, not-for-profit organization. The project is being funded by the Canadian Institutes of Health Research (CIHR) and Health Canada.

There will be a total of eight dialogue sessions held across Canada. After all of the groups have met, McMaster and CPRN will prepare a report for CIHR. You will get your own copy of this report. This report will also be put on the CPRN website for all Canadians to read.

The information from the report will be used to help governments and research organizations develop policies and procedures about how personal information will be collected, used and stored for health research.

To help you get ready for the dialogue, this workbook provides you with some background information on privacy and health research. As a starting point for your discussions with each other, the workbook also presents three possible approaches to address the challenges facing society in dealing with privacy and health research.

On behalf of the research team members at McMaster University, the CPRN, and York University, we would like to thank you for taking part in this project.

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Introduction

The Issue

In Canada, we value personal privacy. Privacy is recognized as a basic human right in the Universal Declaration of Human Rights.

We also value health and research that helps improve our health and the health care system.

As part of this project, we conducted a survey of 1100 people across Canada.[1] We found:

- On the one hand, 89% of respondents said they would be concerned if laws protecting the right to control access to personal health information made it hard or impossible to do health research; and,
- At the same time, 82% said they would be concerned if agreeing to health research made it hard to control how their own health information was being used.

Sometimes, health research comes in conflict with personal privacy when the research is done without getting permission from individuals to do the research. In some cases, the invasion of privacy may be so small that it is not a concern. In other cases, because of privacy concerns, some research may need to be changed or it may not be allowed to go forward at all.

The changing nature of health research – and in how we use information generally in our society – increases the tension between health research and privacy.

In Canada we have federal and provincial laws that govern how we collect, use, and give out personal information. Most of the time, giving out someone's health information without his or her permission is considered an unreasonable invasion of privacy. However, our laws do make exceptions, under certain conditions, for information to be used for purposes that can help society in general. This includes some types of health research.

People in health care and health research respect and value the right to privacy. All health care and health research organizations have ethics guidelines and processes in place to protect privacy. Universities, hospitals, and other health care organizations have Research Ethics Boards (REBs) that must approve all research being done before it may begin. The role of the REB is to protect the rights of research participants, including their privacy.

[1] McMaster University worked with the Institute for Social Research at York University in Toronto. The survey results noted in this workbook are preliminary, based on the responses from 505 Canadians.

Purpose of the Dialogue

The purpose of this dialogue is to better understand Canadians' views and expectations about the use of their personal information in health research. We want to learn how you as citizens would like to see this issue managed more generally. We will be talking about different approaches to getting consent for use of personal information for health research.

We would like to know:

- What would you most want to see in a consent process for the use of personal information for health research?
- Whether and how your consent preference may vary with the type of information being collected or the purpose for which it will be used?
- What would give you confidence and trust that your information is being used appropriately?

These questions are not easy, and don't have right or wrong answers. They relate to how much value or importance you place on the privacy of your personal information, the potential benefits of health research and how decisions should be made about the use of your personal information. You will be asked to explore different approaches to consent and discuss when they may or may not be appropriate. You will also be presented with different ways to control the use of your information. These approaches are presented as a starting point only, to get discussion going. You do not have to choose among them.

The dialogue will give you a chance to learn more about this issue and think about your views and the views of others. This dialogue is not about making technical decisions, but about determining what is most important to you as a group, and what choices you would make under what conditions.

Background

The kind of research we will be talking about in this workbook does not involve experiments with people (e.g. clinical trials to test new drugs). Instead this research collects information from thousands of people's health records to study things like:

- patterns of disease in a community, or
- patterns of medical care in a region or province and, how those patterns affect wait times, health care costs, and health outcomes.

To do this, many health research projects are done by looking at existing information from medical charts in doctors' offices, from billing records for medical tests and/or from summaries of hospital stays.

When this type of research is done, researchers are not interested in each patient's name or address. They only want to know things that will help them learn more about the problem. Any personal information, such as name, address, telephone number, and health card number is removed before the researcher gets the information or shortly after. In this way, it is hard to identify each person being studied.

Health Research is Changing

Health research is changing in many ways with the common goal to improve health. Some ways that affect the issue of privacy include:

- New sources of information for health research
- Using new technology to obtain and store information
- Linking health information with other personal information
- Creating working partnerships with the private sector (called "public-private partnerships")

New Sources of Health Information

Sometimes researchers need know more information than can be found in existing records. This may happen if they want to follow the health and health care of people with specific medical conditions such as diabetes, or treatments such as hip replacement, over 10 to 20 years or even longer. They may also become aware of new questions that need to be explored, as their studies progress.

As a result, researchers are creating *registries* to collect and store personal information of people with a common condition such as diabetes.

- People are added to the registry as they come to get health care.
- Some of the information in a registry comes from health records such as the results of blood tests done every 6 months for people with diabetes to see how their blood sugar levels change over time.

- A registry can also collect information about lifestyle which may not be found in a health record. For example, they could compare blood sugar levels of diabetics who exercise frequently with those who exercise rarely or never.
- Sometimes, a registry may contain tissue samples (which include your DNA) to learn more about genetic problems and how they affect certain people and not others. Right now, this is rarely done, except for cancer clinics that may keep samples like biopsies, with plans to research how genetic differences affect whether or not people get certain types of cancer.

The researcher may also be the treating physician in the clinic. In other cases, the clinic physician may simply identify people who could be eligible to enter the registry.

New Technology

New technology offers many ways for research to improve health. Large amounts of information can be stored in computer systems now. This can make it easier for researchers in different institutions, universities and countries around the world to share and compare information. This increased ease of communication now makes it even more important to have laws, rules and steps to follow when using and sharing this information.

In 2002, the Romanow Commission on the Future of Health Care in Canada recommended a personal electronic health record system be created, along with clear rules to protect the privacy of health information. With this type of system, each Canadian would have only one health record. You could access your own health information more easily and any health care provider you see anywhere in Canada could pull up your complete health record. An electronic health record system would also make it easier to collect information for health research, track disease trends and monitor the health of Canadians.

Some people in the government are now working on making this happen. However, having an electronic health record makes it hard to draw the line between health care and health research. You give information to health care providers such as doctors and nurses to get better health care. This information may also be used for improving quality of health care, evaluating programs and research.

Some studies show that Canadians support the move to electronic health records. In the McMaster survey:

- 72% supported the development of a common electronic health record
- Of these, 88% supported using the common electronic health record for health research.

Linking Health Information with Other Personal Information

We now know that health is closely linked with other things such as lifestyle, education, income, and the work people do. To study this, researchers need to

combine health information with other personal information such as level of income or education to see how they affect health.

The McMaster survey found that the public would like more control over what information is used and combined. For example:

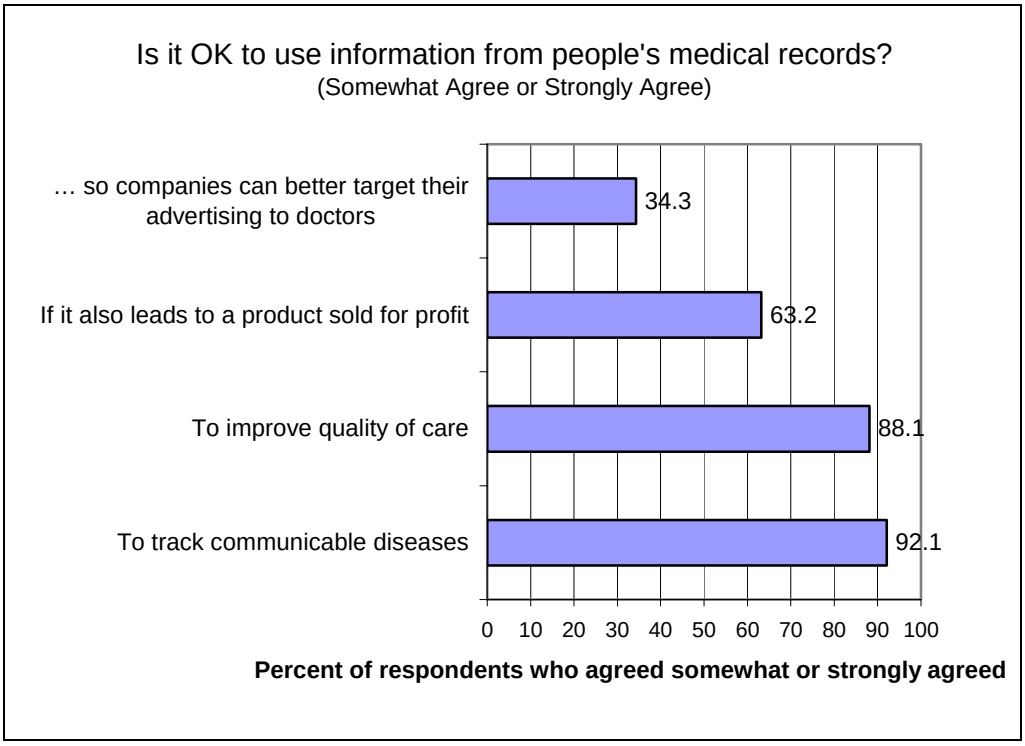
- 1 in 4 people (26%) said information about their income should not be linked to their health record and another 4 in 10 (39%) said this should be linked only after getting permission.
- 1 in 10 people (10%) said information about their education should not be linked to their health record and 4 in 10 (40%) said this should be linked only after getting permission.

This survey also found that the amount of control people want over their information depends on the type of disease being studied. For example:

- 64% wanted researchers to get their permission first for research about diseases such as alcoholism or chronic depression
- 52% wanted researchers to get their permission first for research about health problems such as high blood pressure or diabetes.

Public-Private Partnerships

More and more, researchers are being encouraged to seek funding from the private or business sectors to fund their research. This presents some issues for sharing personal information. In the McMaster University survey, the following graph shows how people felt about having personal information shared. You can see that there is less support when the research has something to do with making a profit.



How are Decisions Made about Use of Personal Information for Health Research ?

In Canada, there are laws and guidelines that determine how personal information should be used. While each province has its own laws on this subject, they are all based on ten common principles.(You can see the ten principles in the Appendix, at the back of this workbook.) Two of these principles are especially important for this dialogue:

Each person needs to be informed about the research and give his or her consent freely

Before taking part in a research study, each person needs to be told what the research study is about, why it is being done and what personal information is needed. Each person has the right to say "yes" or "no" to the study without any impact on their health care.

Most of the time, you have to sign a consent form before any of your personal health information can be collected, stored, used, or released to others for any purpose other than direct patient care and treatment.

There must be safeguards in place to protect personal information

Personal information needs to be protected from use or sharing with others without consent, unless the law requires or permits it. Safeguards include:

- locked doors and filing cabinets (physical safeguards);
- electronic passwords on computer files (technical safeguards); and
- policies and procedures that state exactly who can and cannot look at or use the data (procedural safeguards).

When can research be done without getting consent?

Most privacy laws in Canada state that academic research is one area where personal information may be used without consent but only under certain conditions. Academic research refers to research that is done at universities or similar institutions.

In order to use personal information without consent, the research must meet these conditions:

- Personal information is needed to do the research. It cannot be done without personal details or the information cannot be grouped together to give meaningful results.
- It is very hard or impossible to get each person's consent to conduct the research. This means that either:
    - It would be so expensive to get consent from each person that the research could not be done.
    - The research would not give the correct results if people who were missing from the study were different from those who agreed to

participate. For example, some studies have shown that the people who do not agree to participate in a research study are sicker. When this happens, people using the results of this study could make the wrong conclusion about managing their own patients because of the missing information.

- Adequate safeguards are used and the researcher does not try to contact the person.
- The public interest in the research is greater than the public interest in protecting the rights of each person.
    - For example, a Research Ethics Board may decide it is more important that researchers get information about **all** stroke patients across **all** hospitals in a province (not just from the patients who consented) so that the right recommendations can be made for buying equipment for the whole province.

When do researchers have to get consent?

Although it may not be written in the law, it is generally the policy of research ethics boards that researchers must get consent to use personal information when:

- Tissue samples are involved – especially when the results of tissue testing are combined with information from the health record.
- The researchers expect that some invention from the study may be sold for profit.

Who decides that consent is needed or not needed for each study?

Each university, hospital and health care organization has a **Research Ethics Board**. Researchers must submit their research proposal to the REB to be approved before the research is allowed to begin.

The role of the REB is to protect patients' rights. This includes their right to privacy. Each Board is made up of experts in research methods, ethics, law, and members of the general public. About half of the members are researchers or scientific experts. Members volunteer their time on these Boards. Members work very hard and give many extra hours of time each month to review and discuss each research proposal. Right now there is no common training offered or required for REB members.

Each Board meets to review and discuss research proposals from researchers in their own institutions. The REB looks at the purpose and design of the research and makes sure that the research meets a need and maintains high quality.

Each REB decides how to apply the privacy laws and guidelines as they relate to research. This is one reason why decisions may be different from one location to another. There is no information collected on how many studies across Canada are done where consent is needed and how many are done where consent is not needed.

The REB may decide to set restrictions or conditions on how the information can be used and reported. For example, the REB may state if the information can be:

- used for anything more than the proposed study;
- released to other people or organizations; or
- how long the information should be kept and under what safeguards.

After the study has started, the researcher must report any changes in how information is collected, stored and used to the REB.

In Quebec, a Director of Professional Services coordinates and supervises all scientific and professional activities in a hospital or medical organization. This Director decides when consent for use of personal information in research is needed. Directors in Quebec use criteria similar to what the REBs use to make these decisions.

What guidelines and standards are there for health research?

In Canada, there are four agencies funded by the federal government that pay for research involving people.[2] They follow guidelines for research involving people and for the protection of personal information that reflect respect for human dignity. This includes respecting the right of a person to make free and informed decisions about whether or not to participate in research and respect for privacy and confidentiality.

Universities, hospitals and other institutions that receive funding from these public agencies must follow these guidelines in all their research, not just the projects funded by the granting agencies. If they do not follow these guidelines, the granting agency can stop all money to the researcher or to the institution for both current and future research projects.

In Quebec, each university health centre must follow the **Guidelines for Research Ethics and Scientific Integrity** to make sure the research is ethical and has scientific value.

In Canada, some government and research bodies are working on national research standards for everyone to follow. They are also working on having inspections and accreditation of research institutions, so people will know that someone outside the organization has reviewed their practises and agreed they follow the ethics guidelines. Privacy protection will be one standard. There is no firm date when these standards will be ready.

What if I have a concern?

Each province and the federal government has an Information and Privacy Commissioner or Ombudsman. Their task is to make sure that privacy laws are

[2] These are: The Canadian Institutes for Health Research, the Social Sciences and Humanities Research Council, the National Science and Engineering Research Council, and the Canadian Health Services Research Foundation.

followed. Any person who has a concern about the use of his or her personal information can complain to the Privacy Commissioner's Office. This may lead to an investigation. Most complaints are resolved through mediation. The Privacy Commissioner in each province can also check up on how any organization uses and stores personal information, even if a formal complaint is not made.

Summary of Existing Controls

We have talked about several ways to control how your personal information is used:

- Controls that you have:
  - Your right to consent before your information can be used for research
  - Your right at any time to remove your information
  - Your right to see how an organization is using your personal information and to challenge this
  - Your right to complain to a Privacy Commissioner if you feel a person or an organization may be using your information in a wrong manner
- Controls put in the hands of others:
  - Research Ethics Boards that must approve research projects before they can start and review the progress of each project
  - Federal and Provincial Privacy Commissioners, who have the power to inspect how organizations collect, use, and release information

No one method of controlling information use is perfect. When combined, though, these controls provide layers of protection that help address weaknesses in the one method or another.

Possible Additional Controls

Below, we describe three things that decision makers are considering as possible additional controls.

1. Improving people's ability to look at who has used their information and why

You have the right to look at your health record and find out what has been done with your personal health information. Right now, though, it is hard to find these details without a lot of effort on your part.

One idea is to build into the electronic health record a way to find out who has looked at your personal health information and why. For example, you could see when the information was used in a study to improve the quality of care, or for different research projects.

Another idea would be to have health care organizations that have registries keep a log book of research projects that have used information from these registries.

2. Use small groups of "affected people" to review research proposals

Another approach is to have small groups of people who may be affected by the research review the research proposal. These groups could talk to the researchers

and raise any concerns they may have. They could also recommend changes to the Research Ethics Boards and review the research follow-up and final reports.

Groups like these are sometimes used now, but not very often. One idea is to have these types of groups meet regularly to review research proposals. The results of these meetings could also be made available for the public to read.

3. Use an expert patient advocate

Some people feel that Research Ethics Boards may support the interests of researchers more than the interests of research participants. One idea is to hire an expert who understands how research works but is not employed by the research organization. This hired person would monitor the research process and stand up for patients as advocates. A Privacy Commissioner is an example of this type of person. Right now, monitoring the research uses of personal information is only one small piece of the work they do, so one possibility would be to expand their role in this area, so they can monitor more closely how the information is being used.

What are other countries doing?

Countries such as the United Kingdom, Australia, most European countries, and the United States have information protection laws very similar to what we have in Canada.

These countries are also trying to decide when consent is needed for research, when it can be set aside, and new ways of approaching consent. Many experts in ethics, law, philosophy, and health sciences are talking about this in countries around the world. The United Kingdom has also consulted with the public about what directions to take.

Opportunities and Challenges

Changes in health research offer important opportunities for better research, and therefore better health for all Canadians. They also raise concerns over privacy, confidentiality and security of personal health information.

This is why this dialogue is being held. We need to collectively work through all of the issues that surround privacy and health research to make sure that the guidelines and laws put in place best meet the needs and values of Canadians.

Managing Your Information – Who's Involved

People/Organizations who have your information

Oversight Role

Funders of Research

Your Doctor

Pharmacy

Labs

Hospitals

Clinics

REBs

Health Researcher

REBs

Universities

REBs

Health Research Institutes

You and your information

Provincial Health Ministries (Health Insurance)

Private Sector

Public Sector Research Institutes (CIHR +)

Canadian Institute for Health Information (CIHI)

Privacy Commissioners/ Ombudsman

Agenda for the Day

Welcome and Introductions

Overview of the Issues

Initial Thoughts: Questionnaire

Morning Questions
What do we most want to see in a consent process for the use of personal information for health research?

Would your consent preference be affected by:

- **the type of information gathered or**
- **the purpose for which it is used?**

Lunch

Afternoon Question
What would give you confidence and trust that your information is being used appropriately?

Closing Thoughts: Questionnaire

Identifying the most important insights from the day

Closing Comments

Summary of Three Approaches to Consent

Approach 1

Emphasize individual control through consent for each project
Information kept in any health record about you is your personal information. You should control what happens to it.
Using this approach:

- For each research project, you would be told who wants to use your information and how they are going to use it.
- You would need to give written permission for every project before your information can be used for any research project.
- A Research Ethics Board could make an exception to this when it takes into account the effect of the research on individual privacy and decide that the public benefit of the research is greater than the need to ask for consent.

Approach 2

Emphasize efficient research by not requiring consent
Personal information can be a great source of health research data. It should be easy for researchers to collect and use. It should not cost a lot of money to collect. The more information that can be collected for a study, the better it is for the research. Also, with more information, more questions can be answered to improve health.
Using this approach:

- Your information would be automatically available for research, unless you ask for it to be removed. When you do this, you are "opting out" of the research.
- There would be some sort of notice that your information was being used in this way.

Approach 3

Broad consent
As more and more information gets collected on each one of us, the requests from researchers to use your information will grow.
Using this approach:

- You would give your written consent for your personal information to be used for the types of health research you are comfortable with. This could be any and all research, or you can put limits around how and why your information is used.
- You would decide the boundaries.

This allows the research process to be more efficient, but still gives you some control over use of your information.

Using Dialogue

Debate vs. Dialogue

Our meeting today is designed to be a **DIALOGUE.**

Dialogue is a special kind of conversation that involves working together to overcome differences to find and build on common ground. Dialogue is very different from **debate**, as described below.

Debate	Dialogue
• Assumes there is one right answer (and you have it)	• Assumes that others have pieces of the answer
• Attempts to prove the other side wrong	• Attempts to find common understanding
• Objective is to win	• Objective is to find common ground
• Listening to find flaws	• Listening to understand
• Defends personal assumptions	• Explores and tests personal assumptions
• Criticizes others' point of view	• Examines all points of view
• Defends one's views against others	• Admits that others' thinking can improve one's own
• Searches for weaknesses and flaws in the others' positions	• Searches for strengths and value in the others' positions
• Seeks an outcome that agrees with your position	• Seeks an outcome that creates new common ground

Ground-rules for Dialogue

1. The purpose of dialogue is to understand and to learn from one another (you cannot “win” a dialogue).

2. All dialogue participants speak for themselves, not as representatives of any particular interest.

3. Treat everyone in a dialogue as an equal: leave role, status and stereotypes at the door.

4. Be open and listen to others even when you disagree, and suspend judgment (try not to rush to judgment).

5. Search for assumptions (especially your own).

6. Listen with empathy to the views of others: acknowledge you have heard the other <u>especially</u> when you disagree.

7. Look for common ground.

8. Express disagreement in terms of ideas, not personality or motives.

9. Keep dialogue and decision-making as separate activities (dialogue should always come before decision-making).

10. All points of view deserve respect and all will be recorded (without attribution).

Three Approaches to Consent

Approach 1: Emphasize Individual Control, Through Consent for Each Project

What does this mean?

Information kept in any health record about you is your personal information. You should control what happens to it.

Using this approach:

- For each research project, you would be told who wants to use your information and how they are going to use it.
- You would need to give written permission for every project before your information can be used for any research project.
- A Research Ethics Board could make an exception to this when it takes into account the effect of the research on individual privacy and decide that the public benefit of the research is greater than the need to ask for consent.

The REB has a job to protect your rights as a research participant. This includes protecting your privacy. Any time a REB feels consent is not needed, it has rules to follow.

This is the approach most often used today for research.

How does it work?

- All research using personal information must be reviewed by a REB. This is described in detail on pages 10 and 11.
  - If the REB decides your consent is needed, the following steps are taken:
    - Your doctor's office, clinic, health department or whoever holds the information would contact you. They would ask for your permission to have a researcher contact you to explain the project, why they need your information and ask for your consent to use your information.
    - You would be given information about the specific research project. This allows you to ask questions and decide if you want to agree to have your information collected and used.
    - If you decide to let your information be used, you are able change your mind at any time and stop being in the study.
  - If the research proposal meets established rules, the REB can permit the researcher to use the information without getting your individual consent. This is done on a study-by-study basis.
    - When a REB approves a study, the researcher still needs to get permission from your doctor's office or whoever holds the data and describe in writing how this information will be stored and kept.
    - If the researcher is given the information without your consent, he or she is not allowed to contact you directly.

- No matter what, the researcher must show the REB:
  - How information that identifies you, such as your name and address, will be removed from the data collected before it is used; and
  - How the information will be protected from being used for anything else. It can only be used for the purpose stated in the proposal.

Arguments for this approach

Giving consent each time…

- This approach respects my privacy the most. It gives me the most control over how my information gets used.
- This approach is more transparent and makes researchers accountable for their actions. Researchers know they have to explain their research to me and I know who is in charge of my information.
- I have a direct link with researchers. This would make it easy for them to follow-up with me if they need more information or want to do a follow-up study.

When REBs can decide consent is not needed…

- The decision that consent is not needed is made by a REB that has experts in research. Experts will understand all of this much better that I could.

Arguments against this approach

Giving consent each time…

- I do not want to be contacted each time my information might be used. This just takes too much time and money - both for me and the researchers. I would prefer to see public dollars spent on research that improves health, rather than spending it to get consent from each person for each research project.
- Even though the system says people are supposed to be fully informed, this is easier said than done. This information is technical and specialized. Do most people really understand what they are agreeing to?
- I worry that there is no such thing as truly “free” consent. If my doctor asks me to participate in a research study and I refuse, will I still get the same treatment?
- I am concerned that if too many people say “No” to the research, it won’t be possible to do the research. Or, they will get the wrong answer because those who said “No” will be different from those who agreed to let their information be used.

When REBs can decide consent is not needed…

- If the REB decides my consent is not needed, how will I even know that my information is being used without my consent?
- Most of the people who sit on an REB are researchers themselves. Won’t they look at things from the view of the researcher? This may be a conflict of interest.

Approach 2: Emphasize Efficient Research, by Not Requiring Consent

What does this mean?

Personal information can be a great source of health research data. It should be easy for researchers to collect and use. It should not cost a lot of money to collect. The more information that can be collected for a study, the better it is for the research. Also, with more information, more questions can be answered to improve health for more people.

- Your information would be automatically available for research, unless you ask for it to be removed. When you do this, you are "opting out" of the research.
- There would be some sort of notice that your information was being used in this way.

Right now, this is the approach for using and sharing your information by health institutions for quality improvement. It is also used for public health purposes, when reporting on communicable diseases such as SARS and tuberculosis but, for this use, there is no option for opting out.

How would it work?

- There would have to be a notice that your information is being used this way. This could be done many ways:
  - There could be brochures in your doctor's office, pharmacy, or laboratory that describe the research. If you had any questions, you could visit a web site or call someone by telephone.
  - You could also receive a letter in the mail from your doctor, describing how your information will be used for research unless you contact them and say 'No'.
  - You could also get a notice when your health card comes up for renewal.
- If you do **not** want your information made available to researchers or you want to limit its use, you must be given a way to say 'No'. For example, you may not want your information to be used without consent for research that would combine your health information with your education or income or for research for profit.
  - There would have to be an easy way for people to say 'No' or opt-out.
- Each REB would review and approve all research projects to make sure the research was ethical.
  - Any time the REB decided it was in the patient's best interests to give consent for use of personal information, the REB would make sure that the researcher gets consent from each person.
- Any information that can identify you, such as your name, address and health card number would be removed from the information before the researcher gets it, or shortly after.

- This approach **cannot** be used if the researcher:
  - Plans to collect tissue samples like blood; or
  - Plans to contact you and does not already have a relationship with you.

Arguments for this approach

- As a taxpayer, I am already paying to have this information collected and stored. To be as efficient as possible, it should be readily available for research. Resources should be put into improving public health instead of administration.
- Getting consent from everyone involved in every research project may have been the way to go in earlier times, but this is supposed to be a paperless society now. Things are more complicated and move at a faster pace. It is not practical to deal with this kind of administrative burden.
- I do not want to be "hassled" by researchers every time they want to use my data. I have little free time as it is.
- If my doctor or his/her staff think the research is important, and my information can contribute to it, that is good enough for me.
- I would have more confidence in the research results, as almost everyone would be included in the analyses.

Arguments against this approach

- It is not fair to assume that just because I share information with my doctor I am willing to have it used for research. I prefer to know how my information is being used. I may not want it used for some types of research or if some business is going to make money off it.
- I am worried that many people may not be aware that their information is being used for research. Who has time to read every brochure in their doctor's office? What about all the people that rarely go to see a doctor or people who have trouble reading?
- Even if I say "No" for certain types of research, it's going to be too complicated keeping track of this and my information may get used anyway.
- After my information leaves my doctor's office, how can I trust what will be done with it? I don't know any of the people managing or using my data. How am I supposed to know who is accountable?
- It seems that the researchers are in the driver's seat. Putting the responsibility on REBs to make the case for individual consent for particular research projects does not give me enough confidence that my information will be protected.

Approach 3: Broad Consent

What does this mean?

As more and more information is collected on each one of us and databanks which store this information become larger, the requests from researchers to use your information will grow.

- Under this approach, you would give your written consent for your personal information to be used for the types of health research you are comfortable with. This could be any and all research, or you can put limits around how and why your information is used.
- You would decide the boundaries.

This approach to consent is sometimes used for research following treatment of specific medical conditions or treatments over a long period of time, like diabetes, stroke, or hip replacement. You may already have seen this approach being used, if you go to a specialty clinic.

How does it work?

- You would be asked by health care providers or institutions that were doing research to give your written permission for your personal information to be used for a range of research uses.
  - You would be provided with general information about the **types** of research your information could be used for, but not specific research studies.
  - You would have the option of specifying whether you would like to be re-contacted from time to time to renew your consent.
  - It is your decision whether you wish to sign or not and you can withdraw your permission at any time.
- If the research involved tissue samples, like blood, there would be a separate consent process that described the limits of what could be done with the samples.
- There would be a system in place to collect people's consent to use their information.
- The person managing the database would need a system for keeping track of every person who has consented to having their information used and any limits they might have placed on their consent. This could be built into the electronic medical record.
- As with the other approaches, before research can be done using your health information, researchers would need to have their specific research proposals approved by an REB.
  - The REB and the holder of the health information would need to decide if the research falls within the broad consent for use of information. If not, the researchers may need to get individual consent for use of personal information for that project.

- The researchers would need to make sure that safeguards are in place to protect personal information.
- Under broad consent, there will still be times when the law will permit research use of your information without consent, using the same rules as discussed in the Background section of this workbook.

Arguments for this approach

- This approach gives me a role in deciding how I want to take part in the research, without having to be contacted for every research project. It would be less time consuming for me.
- I can put conditions on how and for what purpose my information might be used. This makes sure it gets used only for types of research that I am comfortable with.
- It would save time for researchers, making research quicker to do and less costly. Researchers could use data without having to manage a consent process for each research study.
- It would encourage researchers and health institutions to take a longer term approach to research studies, identifying what kinds of research they are planning to do and why.

Arguments against this approach

- This system is too complicated. It would be too difficult to keep track of each person's restrictions on use of information.
- While this approach does give me greater control over how my information gets used than if my consent is assumed, the consent could be so broad that almost any research could fall within it. Also, if it is <u>too</u> broad, I don't know if I would really understand what I am consenting to.
- This places a lot of responsibility on me to think about what it is I want my health information used for and to keep informed in case there is some new research that I do not want my information used for.
- I worry that there is no such thing as truly "free" consent. If my doctor asks me to participate in a research study and I refuse, will I still get the same treatment?

Appendix

Fair Information Principles

Internationally agreed upon “fair information principles” are at the core of virtually all legislation. An organization that follows these:

1. is accountable for personal information in its custody;
2. identifies, in advance, the purposes for which information is collected;
3. obtains consent – to collect, use or disclose the information;
4. limits collection of personal information to that necessary to accomplish the purpose;
5. limits use, disclosure & retention to the purposes for which the information was collected;
6. ensures information is accurate, complete and current for its intended purposes;
7. employs adequate safeguards – from unauthorized use, disclosure or from corruption;
8. is open about its information use policies and practices;
9. allows people individual access to information about them, and to challenge its accuracy and completeness, and amend as required; and,
10. allows individuals to challenge compliance with these practices.

Adapted from the Canadian Standards Association: Model Code for the Protection of Personal Information.
http://www.csa.ca/standards/privacy/default.asp?load=code&language=English

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