

Guideline for the Reporting of Incidental and Secondary Findings to Study Participants

University of Waterloo Office of Research Ethics

The [Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans](#) (TCPS) states “researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research” if the participant wishes to be informed of these findings ([Article 3.4](#)). **Incidental findings are “discoveries made in the course of research but that are outside the scope of the research”** ([Article 3.4](#), Application) and/or **“results that are outside the original purpose for which a test or procedure was conducted”** ([Presidential Commission for the study of bioethical issues, 2013](#)). Incidental findings may be anticipated or unanticipated, and are different from primary and secondary findings. Each of these is defined below.

- Primary findings: Findings which are the results that are actively sought as the primary target of a test or procedure.
- Anticipated incidental findings: Findings that are known to be associated with a specific test or procedure. These findings do not have to be common or likely to occur. The defining characteristic is the possibility of finding them is known.
- Unanticipated incidental findings: Findings that could not have been anticipated given the current state of scientific knowledge. Researchers cannot plan for these types of findings specifically. However, researchers can consider in advance what they might do if a particular kind of unexpected finding arises, for example, one that could be actionable or lifesaving.
- Material incidental findings: Findings that have been interpreted as having significant welfare implications for the participants. These findings may appear at any stage of the research including, for example, screening for eligibility of inclusion in a study or in collecting baseline information, both of which may involve the participant’s consent.
- Secondary findings: Findings that are not the primary target of the test or procedure; rather, it is an additional result that is actively sought. These findings may be sought deliberately when doing so is recommended by an expert body or by a consensus of practitioners (e.g., Labs conducting genetic sequencing for any purpose must actively look for variants

underlying certain phenotypic traits). Researchers have no obligation to seek out secondary findings.

Purpose of these guidelines

These guidelines have been created to assist University of Waterloo researchers when planning studies that could uncover incidental or secondary findings. These guidelines mainly apply to studies where researchers:

- Collect [physiological or biometric data](#) and/or tissues/specimens/scans/images from participants in their studies;
- Access [biological materials/data](#) (e.g., tissue, specimens, and scans) from existing repositories or banks; or
- Establish and operate specimen/tissue [banks/repositories](#) (i.e., referred to as bank).

Ethical principles associated with incidental and secondary findings

Researchers need to carefully consider the benefits and the risks associated with disclosing incidental and secondary findings to study participants. Although disclosing certain findings might lead to lifesaving interventions or help participants make informed medical decisions, disclosure can also lead to needless testing, costs, anxiety, and distress, with no medical benefit. The [Presidential Commission for the study of bioethical issues \(2013\)](#), outlines the following ethical principles and their application to incidental and secondary findings to help researchers address these considerations:

Principle	Definition	Application
Respect for persons	This principle recognizes the fundamental human capacity for rational self-determination.	Researchers must communicate the fundamental aspects of their research—including the possibility of discovering incidental or secondary findings and the plan for their disclosure or management—so that participants can make informed decisions about whether to enroll.
Beneficence	This principle calls on professionals to take action to ensure the wellbeing of others. Its corollary, non-maleficence, requires not imposing harm on others.	This principle supports returning findings when disclosure might help forestall or prevent harm. By contrast, disclosing an incidental finding for which no preventive or positive action can be taken has the potential to cause anxiety and distress with no corresponding medical benefit.

Justice and fairness	This principle requires fair and equitable distribution of the potential benefits and burdens across society.	The principle of justice and fairness calls upon researchers to take into account how policies for returning incidental and secondary findings could benefit or burden some participants or, alternatively, could burden the research enterprise and the ability to create generalizable knowledge.
Intellectual freedom and responsibility	This principle protects sustained and dedicated creative intellectual exploration that furthers scientific progress, while requiring that researchers take responsibility for their actions	This principle supports affording wide latitude to researchers in pursuing their scientific goals and engaging in intellectual exploration for the good of society, while also expecting that researchers uphold and respect the trust placed in them by participants. Ethical conduct of research with human participants includes acknowledgment and planning for incidental and secondary findings.

Researchers who are privy to medical test results or conduct biometric or physiological measurements can learn things about a research participant they did not expect to learn. In many instances the research being conducted is not meant to be diagnostic and the members of the research team may not be clinicians or physicians. However, as professionals who have expertise in various areas, Waterloo researchers often have the experience and knowledge that allows them to speculate (or even be confident) there could be a concern for a research participant’s health or well-being. In certain situations, researchers must take into account when designing studies the possibility of uncovering an incidental or secondary finding they believe should be reported to the study participant.

Implications associated with incidental and secondary findings

The issues that can result for a research participant, and a researcher or their institution, when sharing individual level research results are challenging. For participants there can be social, health, emotional, and psychological issues and for researchers, or their institution, there can be ethical and legal issues.

The [Network of Applied Genetic Medicine](#) in Quebec produced a report in March 2013 outlining 10 key principles when deciding which research results to return to study participants. A copy of the [summary report](#) is also available. University of Waterloo researchers who collect biometric or physiological data, access a participant’s test results, or analyze tissue or bodily fluids from a biobank that could uncover an incidental finding should become intimately familiar with these guidelines. The 10 principles provide guidance when sharing:

1. General research results
2. Individual results and incidental findings that should be offered
3. Individual results and incidental findings that may be offered

4. Individual results and incidental findings that have implications for family members
5. Individual results and incidental findings concerning a minor
6. Individual results and incidental findings concerning the future adult health of a minor
7. Individual results and incidental finding concerning deceased participants
8. Individual results and incidental findings concerning samples or medical/genetic data deposited in a biobank
9. Population-based research results
10. Longitudinal research results

Informing research participants of the discovery of an incidental or secondary finding

During the planning stages of a study, researchers must consider the possibility, and the probability, that their research could uncover an incidental or secondary finding for any study participant. Researchers need to consider the types of data and information they will be collecting and the likelihood that these results might discover something. At this planning stage, researchers need to begin developing a plan for how they will handle and report an incidental or secondary finding to the Research Ethics Committee and to a study participant.

According to the TCPS guidelines, researchers must inform participants that if, in the course of research, material findings are discovered, they will be informed of the finding if:

- the participant consents to the disclosure; **and**
- the disclosure is deemed advisable by the Research Ethics Committee (REC).

In all cases, a **participant's stated preference to know or not know about findings should be respected**. RECs may grant researchers an exception to this obligation if the researcher satisfies the REC members that the disclosure is deemed impossible or impracticable.

Further guidance from the TCPS outlines that if the REC deems the disclosure to a participant advisable, **the researcher must offer a choice to the participant of whether or not to receive information about findings if the participant has not previously expressed his/her preferences as part of the informed consent process**. If the participant decides to receive the information about his/her findings ([Article 3.1](#)) or an authorized third party exercises the authority in the best interest of the participant ([Article 3.9](#)), the researcher must disclose all known information about those findings to the participant/authorized third party ([Article 3.2](#)).

Researchers may also need to consider if they wish to recommend to the participant that they speak with a health professional (e.g., their family physician) to discuss the possible implications of the finding for their health or well-being or provide a list of options for support. In some cases, research findings may trigger legal reporting obligations and researchers need to be aware of these, for example, evidence of an infectious disease or child abuse ([Article 5.1](#)).

The creation of a plan for reporting findings may not be necessary in all circumstances, particularly those in which there is no ability to identify the donor of the data or biological

sample (e.g., a researcher obtains anonymized blood sample from a biobank for secondary analysis and there is no way to re-identify the sample). If there is uncertainty as to whether a research project warrants a reporting plan, researchers are advised to contact the [Chief Ethics Officer](#) to discuss.

It is important to understand that the intent of informing participants about findings is to not unduly alarm them or to negatively impact the study's recruitment of participants. Therefore, **researchers should only include anticipatory information about incidental or secondary findings in the information consent letter when there is a real possibility (and probability) that:**

- an incidental or secondary finding will be uncovered; **and**
- the finding will be material to the health of a participant; **and**
- there are clinical and therapeutic implications.

If the objectives of the research include secondary findings to support secondary research objectives, this should be disclosed to the participants during the consent process. This disclosure should include the rationale for seeking the secondary research findings.

Questions and answers

1. How will I know if my research may discover an incidental or secondary finding?

Incidental or secondary findings may occur for any type of research but typically these types of findings primarily occur in studies that are investigating the health of individuals or their family. This includes but is not limited to research involving:

- genetic testing;
- imaging, such as MRI scans, CT scans, PET scans and x-rays, and more likely high density images that provide anatomic or physiological data of the type that is used in clinical diagnosis or treatment;
- other procedures such as blood tests, ultrasound, blood pressure, EEG, ECG, heart rate, or other measures for which there is probability that the results or procedures could identify results or incidental findings.

2. I have no idea what an incidental or secondary finding is. Can you give me an example?

Incidental or secondary findings are discoveries made in the course of research, but that are outside the scope of the research ([Article 3.4](#), Application) and/or results that are outside the original purpose for which a test or procedure was conducted ([Presidential Commission for the study of bioethical issues, 2013](#)). For example,

- genetic research may uncover a likelihood the study participant or a members of their biological family may develop a certain medical condition

- research involving [physiological or biometric assessments](#) may uncover physical conditions of which participants are unaware such high blood pressure
- x-rays may uncover a bone fracture the participant is unaware of that is the source of their chronic pain.

A few examples include:

- **Unanticipated discovery:** A team of researchers received funding and approval to test a new analysis method they developed to more readily and easily find certain specific protein in human urine. The rationale for the development of the new analysis method is that certain proteins in human urine are found normally in the human body and other proteins are not. This new test will be able to detect the proteins found with more specificity than previous methods. Other research has shown that if certain types of proteins can be detected early, clinicians will be able to prescribe medications to patients to treat the buildup of protein in the urine. Even though the purpose of the research is to strictly test the new analysis method to see if it works as intended to identify proteins normally found, and nothing more, there is a possibility of an incidental finding as the discovery of certain proteins in a person's urine may be indicative early kidney damage (i.e., proteins not normally found). These findings are unanticipated as the researchers are not looking to discover these other proteins and these discoveries are not associated with their procedures. However, if these other proteins are found and since they indicative of a possible life threatening condition (e.g., kidney damage) the researchers have an obligation to identify the risks of their discoveries in the research ethics application and to ask participants as part of the informed consent process if they wish to learn about their individual urinalysis results.
- **Anticipated discovery:** Researchers were recording heart rate for all participants in a study as part of their usual protocol and for one participant the heart rate recordings were quite irregular (or variable) and not what the researchers had expected to see for a normal healthy young adult male who is 20 years of age. The researchers were concerned this irregularity might be indicative of an arrhythmia or murmur that was unknown to the participant as the participant indicated on the health status form they did not have any cardiac or heart conditions. This discovery is anticipated because the procedure used can also be associated with diagnosing heart conditions.
- **Anticipated discovery:** Participants enrolled in a study had x-rays taken of their elbow as part of the study protocol. The x-rays for several participants showed features that may be indicative of osteoarthritis. Osteoarthritis was one of the exclusion criteria for enrolment in the study. This discovery is anticipated because the procedure used can also be associated with diagnosing osteoarthritis.
- **Secondary discovery:** A laboratory hired to conduct genetic sequencing for any purpose may be required to also actively look for variants underlying certain phenotypic traits.

3. I think I may have discovered an incidental or secondary finding for a study participant. What do I need to do about it?

First, you need to email or phone the [Chief Ethics Officer](#) to report discovery of the finding. This needs to be followed by submission of an incidental finding report (Form 108) to the Office of Research Ethics within 72 hours (3 days) of learning of the finding. The [Chief Ethics Officer](#) will work with you, the researcher, to identify the best course of action. This may include REC review of the finding and (potentially) reporting to a study participant. For example, a determination needs to be made to find out if the finding is material or not. Individual results (i.e., incidental findings) are material, when the following conditions are met:

- they meet generally accepted criteria of scientific and clinical validity (criteria which are widely recognized by the medical community); and
- they have clinical utility for the participant, such that:
 - the benefits associated with the communication of the results outweigh the risks;
 - prevention or treatment is available; and
 - individual, familial, and social factors were considered.

Researchers have an ethical obligation to know (or to find out) if the findings:

- may affect a participant's health and welfare,
- if the finding is scientific and clinically valid, and
- if the finding will have clinical utility for the participant (or their family).

Even though most Waterloo researchers are not physicians or medical professionals, they are experts in their field of study. Waterloo researchers are expected to know (or know who to consult to find out) if their study findings could affect a person's health or welfare, are scientifically and clinically valid, and if the finding has clinical utility for the participant (or their family). Therefore, it is the researcher's responsibility to know in advance (or to find out upon discovery of the finding) if the finding is material (or not) and what this might mean for a study participant.

If upon initial evaluation a life threatening condition is revealed, the researcher must act immediately. For example, a clinician-researcher must administer the required treatment or in the case of a non-clinician researcher or if the situation exceeds the capacity of the researcher, the participant needs to be referred to a professional who is able to provide treatment.

Researchers are expected to consult with a medical professional (e.g., physicians), peers, colleagues, and others to seek advice in making a determination if a finding is material or not. The [Chief Ethics Officer](#), whenever possible, may be able to aid in this determination by consulting with REC members or clinicians or other experts.

4. When am I OBLIGATED to share an incidental or secondary finding with a study participant?

Individual results must be offered to study participants when **all** of the following conditions are met as outlined by the [Network of Applied Genetic Medicine \(RMGA\) principles for the return of research results and incidental findings](#):

- they are **material**, such as when:
 - a. they meet generally accepted criteria of scientific and clinical validity (criteria which are widely recognized by the medical community); **and**
 - b. the research result has been confirmed, **and**
- they have **clinical or therapeutic utility** for the participant, such that:
 - i. the benefits associated with the communication of the results outweigh the risks; **and**
 - ii. prevention or treatment is available; **and**
 - iii. individual, familial, and social factors were considered; **and**
- **exceptions and additional considerations related to the research context have been weighed** such as instances when;
 - a. a research participant's vulnerability or legal capability to consent may require a change or modification to how the finding is reported to the participant or their family ; the best interests of the individual must be paramount;
 - b. anonymized biological samples or anonymized genetic materials or health data are used and it may be impractical or impossible to contact the research participant;
 - c. in a clinical setting there is a higher expectation to share an incidental finding because of the relationship between the researcher-clinician and the participant;
or
 - d. a researcher conducts a longitudinal study with a select group of participants (e.g., those with a rare illness) and has regular contact with the participants this will intensify the expectation and timeliness for sharing incidental findings, **and**
- **REC approval** has been obtained; **and**
- the **participant has consented** to the return of results.

5. When do I NOT need to share incidental and secondary findings with research participants?

There are some exceptions to when a finding does not need to be shared with a participant. These are when:

- the participant has indicated that s/he does not want to be told about the finding;
- the researcher and the REC determine the findings are not material and lack validity and reliability;
- an independent third party has assessed the findings and states they are not material;
or

- the REC judges the risks of disclosing the findings outweigh the benefits.

6. How will I know if the incidental finding is material and needs to be shared with a study participant?

Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant and may appear at any stage of the research including, for example, screening for eligibility of inclusion in a study or in collecting baseline information, both of which may involve the participant's consent ([Proposed changes to TCPS2](#)).

Researchers have a professional obligation to inform participants about what they discovered (or what they think they have discovered). Therefore, it is the researcher's responsibility to know in advance (or to find out upon discovery of the finding) if the finding is material (or not) and what this might mean for a study participant. Further, researchers are expected to know (or to find out) what findings are relevant (i.e., material) and must therefore be reported. If researchers are unsure, they should consult with other clinicians and experts in the field to make this determination.

7. What am I expected to do to confirm a research result?

Confirmation involves validation of the materiality of the finding by a qualified, independent third party. Researchers are expected to consult with medical professionals, peers, colleagues, and others to seek advice on the possibility or probability that their methods, procedures, or measures can be confirmed as an incidental finding and then, if known, to outline this in the research ethics application (Form 101). The [Chief Ethics Officer](#), whenever possible, can aid in this determination by consulting with REC members or others and, in some instances, may be able to assist the researcher in having the finding confirmed by a third party.

8. How do I verify the validity of the result?

The [Network of Applied Genetic Medicine \(RMGA\) principles for the return of research results and incidental findings](#) outline that researchers need to ask themselves: "Does the result meet the generally accepted criteria of scientific and clinical validity?" If the answer is yes or maybe, then an incidental finding may have been found. Researchers are therefore expected to verify the:

- scientific validity of the result by confirming the precision, reliability, accuracy, sensitivity, and specificity of the measure and result that lead to the speculation of the incidental finding, **and**
- clinical validity of the result by confirming the specificity and sensitivity of the measure and result that lead to the speculation of the incidental finding as well as the positive and negative predictive value.

The RMGA recommends that a finding be confirmed by a clinical test after the researcher verifies:

- the scientific and clinical validity of the measure and result, **and**
- the wishes of the participant to be aware of this type of result, **and**
- REB agreement that a validated result may be sent to the participant.

Incidental findings that may require confirmation by a clinical test should only be shared with the REC, and potentially with participants, after each of the steps above have been completed.

9. What do I need to inform the Office of Research Ethics about the incidental or secondary finding? What questions might I be asked?

The [Chief Ethics Officer](#) on behalf of the Research Ethics Committees at uWaterloo will need a response to the following questions as outlined in the incidental finding report form (Form 108):

- Are the incidental or secondary findings material (i.e., do they have significant welfare implications for the participant)?
- Is the incidental or secondary finding based on valid and reliable data?
- Is there a need to independently corroborate the findings?
- Have they been independently confirmed?
- Do these findings have implications for other members of the participant's genetic family?
- Has the participant expressed a wish to know/not know about any possible findings?
- Are the findings able to be treated or ameliorated?
- Will disclosing the findings create unnecessary anguish or harm for participants?
- Was the likelihood of uncovering these findings disclosed to participants as part of the informed consent process?
- Will the participants be able to interpret these findings themselves or will they need assistance (e.g., family physician, genetic counsellor) to understand the implications of these findings?
- How will the finding be communicated to participants taking into consideration their emotional and psychological health?

10. What do I do if an incidental or secondary finding is identified?

You need to contact the [Chief Ethics Officer](#) by phone or email within 24 hours (1 day) of discovering the finding. This needs to be followed by the submission of an incidental finding report (Form 108) to the Office of Research Ethics within 72 hours (3 days) of reporting the finding. The [Chief Ethics Officer](#) will then work with the researcher to identify the best course of action for REC review of the finding and reporting to a study participant.

Information provided to the [Chief Ethics Officer](#) in the incidental findings form (Form 108) must contain a full and complete description of the situation so that an appropriate path forward may be developed. Researchers should consult the [Chief Ethics Officer](#), and colleagues if applicable, to obtain sufficient information to answer the questions in the incidental reporting form (Form 108) and to devise a plan for follow-up that includes:

- a) determining the scientific and clinical validity of the finding, **and**
- b) whether or not it is appropriate to disclose the finding to the participant, **and**
- c) a method to obtain participant consent for this disclosure, **and**
- d) an appropriate method for disclosing the finding to the participant.

Upon receiving the notification of the finding, the [Chief Ethics Officer](#) discusses with the Chair of the appropriate Research Ethics Committee the risks and benefits of disclosing the finding to the study participant. A determination is made and reported back to the researcher on the decision to disclose the finding to the participant and if the plan for communicating the disclosure is appropriate. In some instances, other members or the full Research Ethics Committee may need to be consulted.

11. During our screening process we think we may have found an incidental finding. What do we need to do?

Incidental findings discovered while screening a participant for study eligibility (e.g., measures of blood pressure, genetic testing) must be reported. Researchers are responsible for reporting to the Office of Research Ethics all incidental findings discovered whether they be anticipated and expected or unanticipated or unexpected. Researchers must notify the [Chief Ethics Officer](#) about the discovery of any incidental findings via email or telephone within 24 hours (1 day). In addition, researchers must complete and submit the incidental finding form (Form 108) to the Office of Research Ethics within 72 hours (3 days) of reporting the finding to the Chief Ethics Officer.

12. What do I have to do to report incidental or secondary finding to my study participants?

Great care must be taken as to how incidental findings are reported to study participants. The reporting of these findings must be ethically justified and the process for making the determination and returning the results reviewed and approved by one of Waterloo's two Research Ethics Committees via the Chief Ethics Officer.

Whenever possible, full and informed consent principles obligate researchers to pre-identify likely categories or types of incidental findings which may be uncovered during the course of the research. If known, these should also be noted in the risks section of the application form (Form 101) and in the information consent letter for study participants. If the research protocol involves a real likelihood of uncovering incidental or secondary findings, researchers should, insofar as is practicable and reasonable, ask participants if they would like to be told about the findings as part of the informed consent process.

However, it is important that researchers not unduly alarm participants. Therefore, researchers should only include information about findings in the information consent letter when there is a real possibility (and probability) that:

- an incidental or secondary findings will be uncovered; **and**
- the finding will be material to the health of a participant; **and**
- there are clinical and therapeutic implications.

If the likelihood of discovering an incidental finding is small it may not be necessary to include any statements in the information consent letter especially if the finding is not likely to be material or if, once discovered, there are no therapeutic or clinical implications (i.e., nothing can be done about it). If no incidental or secondary findings are expected researchers have no obligation to ask participants their preference as part of the consent process. However, if an incidental or secondary finding is unexpectedly discovered after the consent process researchers are obligated to contact participants and ask if they would like to be told about this finding.

13. How do I inform a participant about an incidental finding?

Good judgement must dictate how a participant is to be informed about an incidental finding. Researchers need to keep a participant's emotional and psychological health at the forefront of their minds when devising a plan for REC approval that outlines how they will share an incidental finding. A person's emotional health needs to be carefully considered especially when sharing findings that may have negative implications for a person's well-being and welfare (or that of their family). For example, the reporting of a finding should never be provided when resources or supports may not be readily available (e.g., message left on a participant's voice-mail or answering machine on a Friday afternoon). If a finding has serious implications for the participant or their family, the researcher may need to schedule a face-to-face meeting with the participant and their family.

How an incidental finding will be communicated to a participant needs to be included as part of the reporting plan submitted with the research ethics application for anticipated or expected incidental findings or with the incidental finding reporting form (Form 108) if the finding is unanticipated or unexpected.

To discuss appropriate ways to communicate an incidental finding contact the [Chief Ethics Officer](#) for guidance.

14. What needs to be included in a plan for disclosing incidental or secondary findings to participants?

Although the occurrence of incidental or secondary findings may be rare for most types of research conducted at the University of Waterloo, if it is expected that an incidental finding may occur, researchers must submit as part of the research ethics application a plan indicating

for how they will disclose such findings to participants. If researchers are unsure if a plan is needed they should contact the [Chief Ethics Officer](#) to discuss. Researchers can also consult with the [Chief Ethics Officer](#) if they are unsure of the most appropriate method for disclosing findings to participants.

If a plan is needed, there are a number of considerations which need to be outlined in the plan. These include:

- Description of results that may be returned;
- Name of the individual who will have the authority to determine whether the research results or findings meet the criteria outlined;
- Qualifications of the individual identified to return the results to the participant;
- Timing regarding when the results will be returned;
- Mode of communication to be used;
- Plans for pre- and post-counseling for the participant, if appropriate;
- If the participant is a minor or an individual of diminished consent capacity, description of to whom the findings will be returned;
- Description of plans for allowing participants to withdraw;
- Description of the actions that will be taken by the researcher or treatments provided by a health care professional;
- Description of plans for sharing samples with other investigators, if applicable;
- Requests for Waiver of Informed Consent/Authorization, if applicable; and
- A description of the consent process and copy of the form, which should include a section on returning of research results and incidental findings.

These factors need to be outlined so that researchers can outline a proposed course of action if an incidental or secondary finding were to be discovered in their research. All of these questions need to be addressed before outlining if and how a finding should be disclosed to a participant. As part of the review of the research ethics application (Form 101) a Research Ethics Committee will review the plan. The Committee may provide feedback on the plan or request that changes be made. As part of the ethics review process, the Committee must approve of the plan.

15. How will I know if the incidental finding from our imaging is “clinical quality”?

In most research conducted at the University of Waterloo imaging results are not taken for diagnostic purposes and may use non-standard approaches which does not involve clinic or hospital grade equipment. If an incidental finding is speculated the image should be reviewed by a qualified clinician (e.g., board certified radiologist or physician) before the finding is shared with the study participant whenever possible. If a member of the research team is a medical professional (e.g., radiologist or physician) they should review the image to determine if there is a need for the participant to consult with a health professional (e.g., their family physician) about the finding.

The participant's health professional (e.g., physician) may then decide to validate the finding by prescribing that another image be taken using a more standard approach or equipment. This imaging result and the one taken for the research may be added to the person's medical record at the health professional's (e.g., family physician's) discretion. Since many incidental findings may involve restricted or highly restricted identifiable health information, care should be taken to ensure that the planned transfer of data to the participant's health professional complies with [Waterloo data security requirements](#).

Images or reports of those images that are taken by a regulated health professional in a clinic or hospital setting (e.g., x-rays and MRI) would be considered clinical quality. If an incidental finding is speculated, upon viewing the image the medical professional who took the image (or their designate) should be consulted to verify the finding. Alternatively, if a member of the research team is a medical professional (e.g., radiologist or physician) they should review the image to determine if there is a need for the participant to consult with their health professional (e.g., family physician) about the finding. The participant's health professional (e.g., family physician) may choose to add these images to the person's medical record.

16. For how long do I have an obligation to return research results?

Ideally, the obligation should extend through active use of the test/measures/specimens for research. At a minimum, the obligation should extend through the availability of study funding.

17. Do I have an ethical obligation to actively look for an incidental or secondary finding?

Given the current controversy regarding what researchers should or should not do when faced with incidental or secondary findings, coupled with the unique relationship that exists between a researcher and a participant (i.e., as opposed to clinician to patient), researchers do not have a duty or ethical obligation to actively look for incidental or secondary findings.

18. I expect there to be discovery of incidental findings in my research which are likely to be material and which will have clinical or therapeutic utility to participants. What information do I need to include in my ethics application concerning the sharing of incidental findings?

A comprehensive disclosure plan needs to be submitted as part of the ethics application (i.e., Form 101). The plan needs to include all of the following:

- Description of results that may be returned;
- Name of the individual who will have the authority to determine whether the research results or findings meet the criteria outlined;
- Qualifications of the individual identified to return the results to the participant;
- Timing regarding when the results will be returned;
- Mode of communication to be used;

- Plans for pre- and post-counseling for the participant, if appropriate;
- If the participant is a minor or an individual of diminished consent capacity, description of to whom the findings will be returned;
- Description of plans for allowing participants to withdraw;
- Description of the actions that will be taken by the researcher or treatments provided by a health care professional;
- Description of plans for sharing samples with other investigators, if applicable;
- Requests for Waiver of Informed Consent/Authorization, if applicable; and
- A description of the consent process and copy of the form, which should include a section on returning of research results and incidental findings.

19. If I expect an incidental finding which is likely to be material and will have clinical or therapeutic utility is going to be discovered, what information do I need to include in the information consent letter about incidental or secondary findings and the return of research results?

If you expect an incidental or secondary finding to be discovered, the information consent letter must include statements that outline:

- a definition of incidental or secondary findings;
- what results or finding will be offered to participants;
- how findings will be reviewed so that a determination can be made if they are appropriate to return;
- if results will not be provided an explanation as to why;
- disclosure procedures (e.g., genetic counseling);
- possible implications of the findings for the participant or their family members; and
- how participants are to opt in or out of receiving results now or in the future including how participants will be contacted and offered a “result-specific” consent describing implications or ramifications of receiving a result that has been found.

20. What do I do if an incidental finding is identified and the issue of returning findings had not been addressed in the information consent letter?

University of Waterloo researchers need to notify the [Chief Ethics Officer](#) by phone or email within 24 hours (1 day) after learning of the finding. Submission of an incidental finding report (Form 108) to the Office of Research Ethics is to then follow within 72 hours (3 days) of learning of the finding. The [Chief Ethics Officer](#) will work with the researcher to identify the best course of action for review of the finding by one of the Research Ethics Committees and recommendations on reporting to a study participant.

21. Are there any exceptions to the obligation for researchers to disclose material incidental or secondary findings to participants?

Exceptions for disclosing an incidental or secondary finding for research conducted at Waterloo may be rare, but are possible. The [proposed changes to the TCPS2](#) state:

“A researcher may request an exception to the obligation to disclose material incidental findings, based on the impracticability or impossibility of disclosing such findings to the participant. “Impracticable” refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience. Consent may be impossible or impracticable when the group is very large or its members are likely to be deceased, geographically dispersed or difficult to track. The onus is on the researcher to justify to the REB the need for the exception. REBs should decide whether exceptions apply on a case-by-case basis.”

22. I did not expect there to be any incidental findings discovered in my research but something was found for a participant(s). What do I need to say to them?

The following provides an example of text that could be used in an information letter where an individual research result or incidental finding is “deemed” returnable, but the initial informed consent obtained at the time they participated in the study did not outline that incidental findings may be discovered nor did it offer a choice to receive or refuse results or findings.

The information letter needs to address potential risks, benefits, and ramifications of receiving the result/finding, so that the participant may make an informed decision.

While the example follows the standard research consent format, the specific language should not be considered as required template language. Customize the language to describe the unique situation that exists based on the individual subject and the result/finding.

Dear Mr./Ms. X:

You are being contacted by (*the researcher*) to inform you about a result or incidental finding discovered, based on your participation in our research study (*name of research study*). An incidental finding is an unforeseen finding discovered during the course of the research, but does not have anything to do with the goals of the research.

Generally, tests or procedures done for research purposes are not meant to provide clinical information. However, in the event that a researcher discovers a finding they believe may be important for the health or well-being of a study participant or their family, the researcher is expected to contact the participant to inform them of the finding.

A University of Waterloo Research Ethics Committee has assessed the finding in consultation with (*the expert or clinician, for example*) and advised that a member of our research team

contact you to ask if you wish to be informed of the finding. The committee based their determination on a number of criteria including how accurate the test was that identified the result/finding, if a valid test existed to confirm the result/finding and if there were clinical or therapeutic actions that may be taken based on the result/finding.

It is important to remember that (*scans, procedures, tests*) done for research are not meant or designed to diagnose or provide clinical information. Therefore (*we have had the test repeated in a clinical laboratory, OR if you choose to receive the result/finding, additional clinically valid tests, interpreted by qualified clinical professionals, may be required to confirm the result/finding*).

What are the benefits, risks, and implications of receiving the result/finding?

There is no guarantee that you will get any benefit from receiving the result/finding. However, receiving the result could allow you to (*seek clinical care, adopt preventive practices, advise family members of a genetic or hereditary condition, and/or make informed healthcare decisions*).

There is a risk of distress from learning the result. There is a risk that (therapy, treatments, counseling) used to treat the result/finding will not work for you. There is always a risk that the result or finding is determined to be false. Any of these outcomes could cause you or your family emotional or psychological distress, financial hardship. There may be risks from receiving the result/finding that are unknown at this time.

If you choose not to receive the result/finding, are there other choices?

Whether or not you choose to receive the result/finding is voluntary. You will not lose any benefits or rights you would normally have if you choose not to receive the result/finding.

If you do not want to receive the result/finding, (*there are no other choices except not to receiving the result/finding OR you may contact ____ in the future should you change your mind and wish to re-consent to receiving the result/finding*). Your decision will not affect your care or your participation in this research.

If you choose to receive the result/finding, you will be provided with a copy of the (*test results, copy of image*) at no cost to you so that you can take this information to your health professional (e.g., family physician) to discuss.

Who will see information about the result/finding?

Access to information about you as part of the research has been limited to protect your confidentiality. To date, the only individuals who have seen your identifiable protected health information are those authorized to do so.

If you choose to receive the result/finding, (*medical providers such as physicians, counselors, healthcare staff, and medical specialist*) may see or have access to your identifiable protected

health information as part of your clinical care. Your clinical caregivers may include the result/finding in your medical record as part of your clinical care.

If you choose not to receive the result/finding, *(indicate disposition of result/finding i.e., will be destroyed, unless you choose to withdraw the result/finding)*.

We will make every effort to protect your information. However, we are not responsible if you or your family choose to disclose your health or medical information.

What will it cost to receive the result/finding?

You will not be charged to receive the result/finding. If you choose to receive the result/finding, you will decide whether to proceed with further examinations, tests, and/or treatments you and your primary care or specialist determines are medically reasonable and necessary. You and your insurer will bear the costs of such further exams, tests, or treatments.

What else do you need to know?

You are encouraged to discuss the option of receiving the result/finding with your family and primary doctor or medical provider that you trust. Ask any questions that come to mind now. In the future if, you have questions contact_____. If you have questions about your rights as a study participant, contact the Chief Ethics Officer, Office of Research Ethics, University of Waterloo at 519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca.

You are the participant or are authorized to act on behalf of the participant. You have read this information, and you will receive a copy of this form after it is signed.

Decision to receive or refuse receipt of research result or incidental finding:

I choose to receive the result or finding after reading or having this form read to me and having my questions answered.

or

I choose NOT to receive the result or finding after reading or having this form read to me and having my questions answered.

or

I choose to have the result or finding sent directly to my family doctor for his/her opinion after reading or having this form read to me and having my questions answered.

When developing the consent/authorization form, please format to ensure the signature lines fall on a page containing text.

Signature of research participant or *research
participant's legal representative

Date

Printed name of research participant or
*research participant's legal representative

Representative's relationship to
research participant

*(If, applicable) Please explain Representative's relationship to participant and include a description of Representative's authority to act on behalf of participant:

Signature of Principal Investigator or Sub/Co-Investigator

23. My research involves genetic testing. Do I need to be concerned about incidental or secondary findings?

Yes. The [Network of Applied Genetic Medicine \(RMGA\)](#) outlines:

“Because of the nature and quantity of the information analyzed, genetic or genomic research is especially likely to generate material individual results and material incidental findings compared to other research domains. Consequently, in almost all cases, genetics researchers should develop a plan for managing this type of information.”

24. What do I need to do if I come across what I think is an incidental or secondary finding in a participant's genetic test results?

The University of Waterloo recommends researchers follow the [Network of Applied Genetic Medicine \(RMGA\) principles for the return of research results and incidental findings](#).

The US [National Health, Lung, and Blood Institute \(NHLBI\)](#) also provides helpful recommendations on returning individual genetic testing research results to study participants. The NHLBI also provides a [decision tree that outlines when genetic testing results should be shared](#) to aid researchers in this process.

25. Are there any education resources available on incidental and secondary findings in research?

[IRB Primer: Incidental and Secondary Findings](#)

[Researcher Primer: Incidental and Secondary Findings](#)

"Conversation Series" [for Research Participants: A Guide to Incidental Findings](#)

Acknowledgments

Ma'n H. Zawati, LL.B., LL.M., Academic Associate, Lawyer, Centre of Genomics and Policy – McGill University for his valuable advice, input, and guidance in developing these guidelines.

References

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#), December 2010.

Presidential Commission for the Study of Bioethical Issues. (2014). [Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts](#).

PRIM&R (Public Responsibility in Medicine and Research) Webinar: [Ethical Management of Incidental and Secondary Findings](#), October 7, 2014.

Secretariat on Responsible Conduct of Research, Interagency Advisory Panel on Research Ethics. (2013). [Proposed Changes to TCPS2](#).