The Ethics Review Process (by Jennifer Theule; SCCP Student)

Welcome to the HDAP Students' Association - Ethics Review page! We've tried to provide (or provide links to) all the information you'll need to navigate your way through the ethics review process. The information is organized broadly under the following eight questions, just click on your question and voila—you'll be getting ethical approval in no time! If you're totally new to this process, just start at the first question and work your way down, you'll get it.

If you have questions that aren’t being addressed any where on this page, please let us know, just email: hdapstudents@oise.utoronto.ca

Good luck!

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What is an ethics review? / The Basics

An ethics review is a process whereby your research is reviewed by a team of researchers in your (or a related) discipline to make sure that it conforms to a set of ethical standards (For more information on the standards used, please see question #5, What criteria does the Ethics Review Committee use in evaluating my application?).

- An ethics review is a *process*, which means that it takes time. Be patient. Leave yourself lots of time (2-3 months from the time you’ve completed the protocol) for your study to complete the process; some ethically sensitive studies have taken six months or more to get approval (although the average is six weeks). It will also take you about two weeks to a month to prepare the protocol. The Ethics Review Committee only meets once monthly to conduct full reviews. Some months (e.g., August) the review committee doesn’t even meet. You probably should have started this yesterday.

- This process business also means that your study may undergo changes as a result of the ethical review. The Ethics Review Committee may make suggestions for changes, request more information, or just turn your application down. It is quite likely that you will have to resubmit your protocol with changes for it to receive approval. You may not be permitted to do the study that would perfectly answer your questions. Your study would have to have pretty impressive and definitive effects on the advancement of research for the committee to allow you to do things that involve more than a modicum of risk to participants. Be open to and prepared for the committee’s questions and suggestions. When thinking about your research it’s very easy to get caught up in your goals, but if you achieve some distance you’ll see that the well-being of your participants is more important than your research questions.

- Regardless of your topic of study, everyone studying at OISE submits their ethics review *protocol* (this is what the “essay” portion of your application is called) to the Education Ethics Review Committee. This means that you should be very careful to avoid jargon in your protocol. The people reviewing your application may be experts in psychology, sociology, education, or any other discipline studied at OISE, and may not know even the basics about your field.

- OISE (or U of T) aren’t the only people who require ethical reviews. Depending on your topic of study and where you’re conducting your research you may also need to go through an ethics review at a school board, a hospital, or another institution. Leave lots of time for this. Outside institutions differ from the University in the criteria they use in reviewing your study, the amount of time it takes, the format they require, and whether they prefer you get University approval first or last.

- Essentially any student doing a Qualifying Research Paper, a Master’s thesis or a doctoral dissertation needs to submit their research for an ethical review. This is true even if you’re using data your supervisor or others already collected, or if you’re using publicly available information or conducting “assessment activities”.
happen if you conduct research without receiving the appropriate ethical approval (like you may not get your degree).

- If you’ve already started your research and just realized now that you should have gotten ethical approval, don’t despair. First, stop your research if possible and then call the Ethics Review Office. They are pretty understanding people. Then read through the rest of this webpage and prepare an ethics application. Be aware, however, that the Ethics Review Committee may put the kaibash on some of the procedures you’ve already been using and so you may have to change your study somewhat. If you’re reading this in the beginning stages of your research and thinking, “Hey, I’ll do that,” DO NOT think you can get away with submitting your application after you’ve started or finished your research, it is a risky, risky plan, a terrible idea, and just plain wrong.
What type of application should I submit?

For the purposes of OISE students there are seven different types of ethics submissions, they are:

1. Full Reviews
2. Expedited Reviews
3. Administrative Reviews
4. Resubmissions
5. Amendments
6. Annual Renewals
7. Study Completion Reports

If you’re just starting out, the only ones you need to worry about are numbers 1, 2, and 3, the others only apply to people that have already submitted at least once. The last four types of submissions will be briefly reviewed here though, because they’re pretty likely to come up over the course of your academic career.

Full Reviews:

The Full Review is the starting place for all ethics submissions. You should assume that you have to submit a full review unless you meet some pretty specific criteria that you’ll find in the expedited or administrative reviews section. That said, a lot of Master’s level research (theses and QRPs) will qualify for expedited review (a few will qualify for administrative review), most doctoral research will not.

Generally, full reviews are for all research that involves collecting data (not using already collected data).

A full review will take about 2 months at a minimum to make it through the ethics review process. Full reviews are reviewed once a month by the entire Ethics Review Committee. The committee meets once a month, you’ll find a list of their meeting dates at [http://www.rir.utoronto.ca/ethics_hscommittees.html#oise](http://www.rir.utoronto.ca/ethics_hscommittees.html#oise). You will need to submit your ethics review protocol at least two weeks before the scheduled meeting.

You should submit 12 double-sided copies of your full application (including application forms, protocol, appendices, etc.).

Expedited Reviews:

Your ethics review application can be expedited if it is of “minimal risk” to participants (involves no more risk than the person would experience in daily life) and does not involve the collection of sensitive information. If your research involves children it cannot be invasive or stressful; this generally means that your research should only involve naturalistic observation, or the examination of regular school work products.
Almost all research conducted with previously collected data (from your supervisor or a publicly available database) would qualify for expedited review. If you actually must interact with your participants, you probably need to get a full review. For the exact expedited versus full review criteria go to http://www.rir.utoronto.ca/ethics_ercriteria.html.

An expedited review will take a minimum of 2 weeks to make it through the ethics review process. Expedited reviews are accepted weekly. To be reviewed that week, your application must be in by 5 p.m. on Monday. Expedited submissions are reviewed by one Ethics Review Committee member.

You should submit 2 copies of your full application (including application forms, protocol, appendices, etc.).

**Administrative Reviews:**

Administrative Reviews are only for that very small minority of studies that do not involve data collection from/about people, involve data that is publicly available, or constitute quality assurance projects. Essentially, these projects pose no risk. The Ethics Review Office does not provide much information about these types of submissions (in fact the only reference to them is on the OISE/UT Student Research Statement of Intent & Departmental Coordinator’s Checklist) because they are exempt from human subjects review. If your research qualifies for administrative review you do not need to submit an Ethics Review Protocol. You just need to submit the OISE/UT Student Research Statement of Intent & Departmental Coordinator’s Checklist, the Ethics Review Application Cover Sheet, and a one-page description of your project. If the Ethics Review Office agrees that your study does not require review they will issue you a letter of exemption. Be sure to give this letter to Nancy Smart.

**Resubmissions:**

Don’t be upset or surprised if you get a letter or email from the Ethics Review Committee saying that they need a bunch of points addressed before they can approve your protocol: that’s their job. Almost everybody has to make changes and resubmit. Address all the committee’s points in a covering letter, then fix up your protocol and any appendices you’ll be changing (e.g., the informed consent form). Make sure to underline, or highlight in some way the changes you made to the protocol and appendices. Most of the time you can then just resubmit your changes as an expedited review (the letter or email you receive from the committee will detail this). If your changes are minor and short enough they will often even let you resubmit via email. If not, submit two hard copies of the covering letter and revised protocol to the Ethics Review Office. You do not have to get the departmental coordinator or your supervisor to sign off on the protocol again, and you don’t need to submit any non-relevant appendices or forms again.
Amendments:

If you make any changes to the procedures of your study you need to submit an Ethics Amendment. You don’t need to submit an amendment if you suddenly had a breakthrough and just reconceptualized the purpose or implications of your study, or if a brilliant new plan for data analysis just occurred to you. You only need to submit an amendment if something in your study is changing from the perspective of your participants. So, increasing your sample size, adding measures, changing recruitment procedures, broadening inclusion criteria, etc. are the types of activities that require an amendment. Most amendments are considered “minor changes to an already approved protocol” and so qualify for expedited review, regardless of whether you initially submitted a full or expedited review. If your changes are major, however, you may have to submit a full review. An example of a minor change would be adding one more questionnaire on a topic your study already passed review for investigating. Lots of minor changes do not a major change make, so don’t worry if while you’re adding that extra questionnaire you decide you also want to add a few more, extend your observation period, and start recruiting from another source. All the changes can go in one amendment. You should not start using amended procedures until they have received approval.

To submit an amendment use the Ethics Review Application—Amendment form, available at http://www.research.utoronto.ca/forms/ethicsamend.doc. Just briefly describe your changes in the space provided. You will also need to resubmit your protocol (and appendices) with the changes underlined or highlighted, just like for a resubmission. Your supervisor will need to sign this form.

Annual Renewals

If data collection for your study will continue for more than a year you will need to submit an Annual Review. A year is considered to have passed on the anniversary of your ethics approval. You will need to submit a renewal for each year your study continues. If your study goes on for five years or more you will need to submit for a full re-evaluation (since this doesn’t come up in student research much re-evaluation won’t be discussed further).

Two months before your ethics approval is due to expire (the expiry date is exactly one year after the approval date and is written at the top of the Ethics Approval letter) you will get an email from the Ethics Review Office reminding you to submit a renewal. You must submit two copies of the Annual Renewal of Ethics Approval Application (available at http://www.rir.utoronto.ca/forms/ethics_annren.pdf) and your most recently approved protocol with all its appendices at least one month before your approval is due to expire. The form is pretty basic, it just asks about the study’s progress and whether you’ve made any changes.
Study Completion Reports

Once data collection for your study is complete, you need to submit a Study Completion Report. The form is available at http://www.rir.utoronto.ca/forms/ethics_studcomrpt.pdf. The form is very short and easy to complete so there is no reason to forget about this step! You may want to make a note reminding yourself to complete this form somewhere on your calendar about two weeks or a month after data collection should end (since most projects tend to take longer than expected, this should work out just right!). You only need to submit one copy of the form.
How do I submit my application? What’s involved?

The information on this page just refers to first (new) submissions.

An ethics application is a big project. As noted earlier, it can also be a time-consuming project. Be sure to leave enough time for your faculty supervisor and the departmental coordinator to sign and review your protocol. Supervisors vary in the amount of time they need to read these things over (two weeks is generally a good guess though), you should give the departmental coordinator about a week.

The first step in submitting your application is gathering all the relevant forms. Get a copy of the Ethics Review Application Cover Sheet <http://www.rir.utoronto.ca/forms/eracoversheet.doc>, the Ethics Review Protocol Form  <link to http://www.rir.utoronto.ca/forms/ethicsprotocol.doc>, the OISE/UT Student Research Statement of Intent & Departmental Coordinator’s Checklist <http://www.rir.utoronto.ca/forms/oiseut_SOIchecklist.doc>, and the Informed Consent Documents Checklist <http://www.rir.utoronto.ca/forms/oiseut_studchklist2.doc>. You will not need to submit the Ethics Review Protocol Form or the Informed Consent Documents Checklist; these forms are simply to help you create your Ethics Review Protocol and any Informed Consent Letters.

Your submitted application package will consist of the following parts, in this order:
1. The Ethics Review Application Cover Sheet
2. The OISE/UT Student Research Statement of Intent & Departmental Coordinator’s Checklist
3. A brief letter (100 words) justifying why your study qualifies for expedited review (this is obviously just for studies that are applying for expedited review).
4. Your Ethics Review Protocol
5. Any appendices

If submitting a full review, you will submit 12 double-sided copies of this package, if submitting an expedited review, you will submit 2 copies of this package. Once complete your application may be quite large (typically ranging from 20-100 pages), be sure to leave yourself adequate time for copying. You may also want to keep a copy of the submitted package for your records. Take your pile of packages to the Ethics Review Unit at University of Toronto Research Services in Simcoe Hall at 27 King’s College Circle (located between Harbord and College, just West of Queen’s Park). The Ethics Review Unit is located in a hidden little corner of Simcoe Hall so don’t be surprised if you have to spend a little while wandering about the building.
Filling out the Ethics Review Application Cover Sheet:

These guidelines are provided just as general rules, you may be an exception. However, generally…

You are the principal investigator. Include your University mailing address (9th Floor, 252 Bloor Street West, Toronto, ON, M5S1V6).

You do not have any co-investigators.

Check off the Education REB.

Projects have not been submitted to an external agency for funding (even if you have a SSHRC, CIHR, or NSERC scholarship you should probably not check this box as you, not your project is funded in these types of scholarships even though you provide a description of your anticipated line of research).

Check off the third scholarly/scientific review box.

Filling out the Statement of Intent and Department Coordinator’s Checklist:

You may check off more than one “category” in any one box.

The Departmental Coordinator will need to see your entire application to make the determinations necessary to fill out the form.

Submit your full package to Nancy Mayes (the departmental ethics liaison) who will forward it to the Departmental Coordinator.

The last page of this form contains a nice summary of the ethics review process. Do not submit this last page.

Your Ethics Review Protocol:

Your Ethics Review Protocol can be a maximum of 10 pages long (this does not include the previous two forms, references, or appendices).

Number the pages (remember that you will submit double-sided copies so you may want to centre your page numbers or set them to inside/outside).

You do not have to do all sections of the protocol. It is perfectly normal and acceptable to write N/A (not applicable) for many of them.

1. Background, Purpose, Objectives
The committee isn’t all that interested in this information, they’re just using to ensure that there is some justification for your project. Do not include your entire lit review. This section should be 2-3 pages long.

2. Research Methodology
   This should be one of your longer sections. Go through your methodology and procedure in detail. Be sure to briefly mention how commonly your measures are used as well as their reliability and validity. You will probably want to have subsections (e.g., Design, Procedure, Measures, etc.) in this section. Include a copy of each measure in the appendices.

3. Participants
   If there are any special issues with your participants (e.g., competence), describe how you will deal with these problems.

4. Recruitment
   Include a copy of all recruitment materials in an appendix.

5. Risks and Benefits
   Be sure to think of both risks and benefits to participation in your study. Typically, the small compensation fee you provide is not considered a benefit. Try to think of other things, like furthering the field to eventually help others with a given problem, gaining access to a lab website, being provided with a list of resources…

6. Privacy and confidentiality
   Mention when raw data will be destroyed (5 years, 10, more?). Data is generally kept for 10 years. If you need more or less time (e.g., you want to re-analyze the data for your PhD or postdoc) provide this justification.

7. Compensation
   Include anything from toys given to participants to cash.

8. Conflicts of Interest
   In most cases you will write N/A for this section. If it applies to you it is important to address it fully though.

9. Informed Consent Process
   This is one of those really important sections in your protocol, so address it quite thoroughly. Your Letter of Information and consent forms should be included as an appendix. You may have numerous consent forms; one for teachers, one for parents, an assent script for children. Remember that all consent-related forms should be on OISE/UT letterhead and that participants should be given a copy of the form to keep for their own records.

10. Scholarly Review
    In most cases you will write N/A for this section.
11. Additional Ethics Review
Again, this will be N/A for most projects, but if it applies to you include the other research ethics board’s Letter of Approval in an appendix.

12. Contracts
Usually N/A.

13. Clinical Trials
Usually N/A.

Appendices:
Include anything mentioned above in your appendices. They should be labelled A through Z, as appropriate, in the order they are first mentioned in your protocol, so that committee members can easily find what they are looking for. More than one item can go in each appendix (e.g., you can put all your measures in one appendix). You can submit photocopies of your measures to save money (submitting 12 actual protocols for a number of different tests could otherwise get quite expensive!). Generally, you do not need to submit coding manuals, coding forms, or anything that will not be seen by participants. You may want to submit a phone script if you will be speaking to potential participants over the phone. This is often requested by the Research Ethics Board.

At a minimum your appendices should include Letter of Information and/or Consent/assent forms/scripts. If you are recruiting participants you should also include copies of your recruitment materials.

*Informed Consent Materials:*
All consent-related forms should be on OISE/UT letterhead.
Participants should be given a copy of the form to keep for their own records.

If you are not using a written informed consent procedure, be sure to include a justification in your protocol and provide a script for obtaining consent. You should probably have a form that a researcher signs to verify that they obtained the consent verbally or nonverbally.

Be sure to check the Informed Consent Documents Checklist <http://www.rir.utoronto.ca/forms/oiseut_studchklist2.doc> to ensure that your informed consent materials conform to the committee’s standards. Also go to http://www.rir.utoronto.ca/ethics_icrequire.html for more information. For lots of great samples of informed consent materials go to http://www.rir.utoronto.ca/ethics_icexamples.html.
I’ve submitted my application, now what?

After you’ve received approval you can go ahead and start recruiting participants or dealing with your data. Be sure to give a copy of your Letter of Approval to Nancy Smart. She needs to have a copy for your file. Also be sure to keep a copy of the letter in a safe place, if there’s ever a question about whether you received ethical approval, this letter will be very important. The letter also contains your application’s “Protocol Reference Number” which you will need to put on all future amendments, annual renewals, and on your study completion report.

Don’t forget to submit an annual renewal by one month before the anniversary date of your original approval.
What if I want to change something in my study after I’ve already received ethical approval?

If you want to change something after you’ve received approval, you’ll need to submit an ethics amendment. Don’t worry, it’s no big deal. It’s not unusual to find out that the procedures you initially envisioned aren’t working out in the real world, but it’s important you not use your revised procedures until you receive approval for them. For more information, see question #2 “What type of application should I submit?”
What criteria does the Ethics Review Committee use in evaluating my application?

The Ethics Review Committee uses two sets of criteria in evaluating your application. First, they use the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. This document was created by the three major federal granting agencies: the Social Sciences and Humanities Research Council, the Canadian Institute for Health Research, and the Natural Sciences and Engineering Research Council. The Tri-Council Policy Statement can be found at: http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf

The other set of criteria the Ethics Review Committee uses is the University’s Guidelines on the Use of Human Subjects. They can be found at: http://www.library.utoronto.ca/rir/tblconhu.html.

Reading these documents before you submit your protocol can save you precious time by not including procedures that blatantly contradict these criteria.
What if I still need more information?

- The Ethics Review Office is now offering research ethics workshops for students. Go to one. You’ll find posters for upcoming workshops around the department, or go to [http://link.library.utoronto.ca/ethics/workshops/workshops.cfm](http://link.library.utoronto.ca/ethics/workshops/workshops.cfm). You’ll need to register in advance (which you can do by going to the link above).

- Go to the Ethics Review Office’s webpage: [http://www.rir.utoronto.ca/ethics_home.html](http://www.rir.utoronto.ca/ethics_home.html). Almost all of the information on this page was culled from that one.

- Contact Bridgette Murphy, the administrative contact for the Education Ethics Review Committee. She’s a wealth of information and very friendly! 416-946-5606 bridgette.murphy@utoronto.ca

- Talk to Nancy Mayes, the HDAP ethics departmental liaison. She knows lots of stuff, is fabulously helpful, and is especially good at dealing with the departmental coordinator stuff.

- For more information you can also check out HDAP’s Ethics webpage: [http://www.oise.utoronto.ca/depts/ hdap/student_ ethics.html](http://www.oise.utoronto.ca/depts/hdap/student_ethics.html). Please be aware that this page is quite out of date, so in instances where the HDAP page contradicts the Ethics Review Office page or this page, you should probably assume the other page is correct.

- Talk to someone who’s ahead of you in the program. Just about everyone has gone through this process, and although daunting at first, most people eventually succeed.
What should an ethics application look like?

Remember that these are just examples to give you an idea of the structure of the submissions, do not rely on them as ideal prototypes. Some of these submissions may have still required revisions and the uniqueness of your project may make some of these examples not all that useful to you. We have tried to provide examples of the complete submitted package (including all covering letters, forms, etc.), but did not include sample appendices.

1. A Full Review (including a completed Ethics Review Application Cover Sheet, OISE/UT Student Research Statement of Intent & Departmental Coordinator’s Checklist, and an Ethics Review Protocol)


3. An Administrative Review (including an OISE/UT Student Research Statement of Intent & Departmental Coordinator’s Checklist, an Ethics Review Application Cover Sheet, and a one-page description of the project)

4. A Resubmission (including a covering letter and revised protocol)

5. An Amendment (including an Ethics Review Application—Amendment Form and a revised protocol)

6. An Annual Renewal (only the Annual Renewal of Ethics Approval Application form is included—just resubmit the last approved protocol)

7. A Study Completion Report