

Preparing research proposals for the HWS Institutional Review Board: An informal guide for faculty and students

Ron Gerrard, HWS Psychology Department
on behalf of the Hobart and William Smith Institutional Review Board

Hobart and William Smith colleges, like all educational institutions receiving federal research money, is required by law to have an Institutional Research Board (IRB) to protect the welfare of its research subjects. It does so by evaluating proposed research projects to make sure they meet accepted legal and ethical standards.

As someone who has both served on the IRB and submitted research proposals to be evaluated by the IRB, I have experienced the review process from both sides. I understand the effort required by researchers to prepare IRB proposals, as well as their concern that the review process might seriously delay the start (and therefore the completion) of intended research projects. Researchers are understandably frustrated when their proposals are returned from the IRB with requests for revisions, especially when the reasoning behind such requests seems arcane or unclear.

On the other hand, as an IRB member required to carefully read and evaluate several dozen proposals a year, it is frustrating to see the same sorts of easily avoidable errors appear over and over again, proposal after proposal. My goal in preparing this handout is to better communication between the two sides, hopefully improving the quality of proposal and reducing frustration all around. I hope to give researchers a glimpse into the mindset of the IRB as it reads various types of proposals, yielding a better sense how and why different issues are considered by the committee in judging proposed research. Along the way, I will try to pass on practical advice for preparing research proposals successfully.

Let me start with a general observation. In my experience, few of the proposals reviewed by the IRB raise what I would consider “extreme” ethical issues. Serious issues, yes – but not the sort of life and death issues that might be considered by a Medical School’s review board for example. In my time on the committee, no research project has been completely blocked by the IRB because of ethical problems, and only a very small number have even required substantive changes to the research protocol.

In short, most issues with the IRB proposals do not arise from researchers being reckless or wanting to do seriously risky things to the people in their studies. The problems instead are of two types. First, there are often minor ethical issues related to such issues as informed consent, anonymity and confidentiality of data, and so on. These issues will be addressed later in the handout as I discuss various aspects of research proposals in more detail. The second problem arises from the preparation of the proposals themselves. Very often, it is simply unclear to the committee what exactly is being proposed because the proposals are poorly written, incomplete, or internally inconsistent.

In practice, the two types of problems are not easily distinguishable. When a researcher submits a proposal missing a key piece of information for example, it is often unclear whether that represents a genuine problem with the research design or merely an oversight in preparing the research proposal. No matter. Either will result in the same outcome, the proposal being returned with a request for revisions. Researchers must not only design their studies to be ethical, but also be able to convey the information effectively to the IRB. I will discuss the various parts of a research proposal momentarily, but will begin with a few general suggestions first.

- (1) Read all application forms and relevant supplementary material carefully. The IRB website (http://www.hws.edu/offices/provost/gov_reviewboard.aspx) has copies of all IRB application forms, plus several types of helpful additional material. The present handout (which should also be read carefully, by the way!) is intended to supplement the material on the web site, not supplant it.
- (2) If you are unsure, ask. If the material on the web site does not address your questions, feel free to contact the IRB before preparing your proposal. A brief e-mail or phone call to an IRB member can potentially save hours of work preparing a proposal that is inappropriate to your goals, or perhaps entirely unnecessary. Talking with an IRB member may also give you a better sense of what might or might not be considered potential ethical issues by the IRB when reading your proposal
- (3) Prepare the application with the care you would any other piece of serious writing. It is surprising how often the IRB receives proposals that seem to have been written with no more care than a hastily prepared e-mail. The IRB has received handwritten proposals, proposals containing the word “esperiment” (sic) in the title, and many other examples of similarly lazy writing and proofreading. A carelessly prepared proposal is very likely to be sent back for revisions, and it will usually save researchers considerable time and effort to prepare a good proposal the first time around.
- (4) Resist the temptation to copy large parts of the proposal from previous proposals. Especially for beginning researchers, it can be useful to look at previous successful proposals and use them as models for your own. There is nothing wrong with this, but the IRB has noticed a tendency for many proposals to repeat material from previous proposals verbatim (e.g., every student proposal from a course will have exactly the same wording for certain sections of the paper). This is problematic. Every research project is different, and copying words and procedures from previous studies can lead to difficulties. A researcher may write (copy) that “the data will remain anonymous” for example, when in fact they were never anonymous to begin with. (See later section on anonymity and confidentiality). Or a researcher may write (copy) that “the data will be destroyed at the end of the experiment,” when in fact this is neither necessary nor desirable in the research being proposed. Many other instances could be cited.

At a deeper level, copying material from previous proposals may indicate that a researcher has not sufficiently considered the specifics of his or her own study, preferring a ‘ready-made’ solution to potential ethical issues rather than one tailored to the needs of

the individual experiment. Researchers should always carefully consider both the ethical and scientific aspects of any potential study, integrating them as effectively as possible in the proposal to the IRB.

In preparing whether and how to present your material to the IRB, you should carefully consider several issues.

First, decide whether a proposal to the IRB is necessary

Federal regulations and HWS policy require that the IRB approve all research with human subjects. You should realize however that not all types of information gathering nor all procedures that might be done to individuals are considered ‘human research’ by law and IRB policy. Some activities that seem like human research may not technically be considered as such, and thus may not require IRB review.

The relevant federal regulations define research as “a systematic investigation designed to develop or contribute to generalizable knowledge” and a human subject as “a living individual about whom an investigator... conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” These quotes, while awkward, are essentially intended to delineate activities which require IRB review from those which do not.

In practice there are gray areas, areas or activities where it is unclear whether IRB review is required or not. Examples of such gray areas include historical / biographical research, or investigations conducted secondary to some other purpose such as counseling or therapeutic intervention. If you’re unsure whether a potential research project might require review, contact the IRB. Here I will only discuss the most common gray area, namely research associated with educational practices (teaching, classroom activities, etc.)

By definition, educational practices are intended to educate (i.e. to pass along existing knowledge), not to develop or contribute to new knowledge. Thus, standard educational practices are not considered research by the federal regulations, and do not require IRB review. This statement applies even when the procedures are in some way scientific or raise ethical issues. Suppose for example, that an instructor in a genetics course wishes to have students donate small blood samples to be analyzed in a laboratory exercise. Clearly this is scientific and raises potential ethical issues. But as long as the purpose is educational though - to teach students genetic analysis rather than to develop new knowledge of genetics – the activity is not considered research and is outside the purview of the IRB. Similarly, a psychology instructor would not need IRB approval to administer a personality test to his or her students, as long as the goal was to teach students about personality assessment, not to develop or contribute to our understanding of personality.

I use these examples to illustrate that some ‘research-like’ activity can be considered educational, and thus not require IRB review. The opposite is also true: Some ‘education-like’ activity is considered human research, and does require IRB review. If a faculty member wished to

systematically compare the effectiveness of two different teaching strategies, then this is an attempt to develop new knowledge, not just teach students. A study by the faculty member which evaluated the two strategies would thus be considered research by federal guidelines and HWS policy, and would have to be approved by the IRB.

In considering whether a classroom activity is considered human research or not, here are a few useful questions to ask. First, is the purpose to convey existing knowledge and methods rather than to contribute to new knowledge? Does the activity involve only class members, rather than outside individuals? Will the research results be shared only with class members, not published or presented elsewhere? If the answer to all three questions is yes, then the activity is almost certainly considered educational and would not need IRB consideration. If however the answer to any question is no, then the activity, even if performed as part of class requirements, would likely be considered research and would need IRB approval. To use a common example, student experiments in psychology lab courses, where subjects are typically recruited from other courses, are clearly research as defined by the federal regulations.

If you are unsure whether an educational or other activity requires submission to the IRB, what should you do? Here, I can only repeat my advice from earlier: If you are unsure, *ask*. Furthermore, you should ask as early in the planning process as possible. If the project does not require IRB approval, it will certainly be in your best interests to discover that fact before you've prepared a research proposal rather than after.

I also wish to stress another point. Just because an activity does not require approval by the IRB does not mean there are no ethical or legal issues involved. You should be aware of and sensitive to these issues, as well as all relevant laws and policies. You are legally responsible for obeying such laws and policies, whether or not the activity in question has been reviewed by the IRB.

If a proposal to the IRB is necessary, decide which form to use

Once you are sure your research requires IRB approval, the next step is to decide which of the various IRB forms is appropriate for your project. The IRB uses four different proposal forms appropriate for different types of research projects involving different types of risks. The IRB web site has a "Determination Tree" or flow chart which you should follow carefully in deciding which form is appropriate (see http://www.hws.edu/pdfs/Decision_Tree.pdf). The present discussion is not intended as a substitute for this material, only as a guide to a few of the more important points.

The four forms used by the IRB are labeled forms A, B, C, and D. The four categories derive from two underlying variables: whether the research is being conducted for a course, and whether the research requires full formal review by the entire IRB. The latter issue is determined largely by the potential risks associated with different types of research. 'Risk' as used here is determined by several variables, including the specifics of the research procedure, the characteristics of the subject population, and the handling and intended use of the data. These issues will be fleshed out in the discussion below.

The first issue is whether the research is being done for a course or not. (Note though that ‘course’ here refers only to regularly scheduled HWS courses; Independent study projects, Honors projects, and Masters theses are not considered courses for present purposes). The rationale for distinguishing course-based from non-course-based research is as follows. Course-based research in practice means student research. Because student researchers are generally beginning researchers, this means that they may be less familiar with relevant ethical issues than are faculty. The assumption (fair or not) is that student researchers are more likely to take ethical risks than faculty researchers. By this argument, student research should be scrutinized more carefully and be subject to additional restrictions.

On the other hand, course-based student research is presumably being closely supervised by faculty mentors, most of whom are experienced ethics-savvy researchers themselves. This would suggest that some of the IRB’s research oversight responsibility could be shared with faculty under certain circumstances. The tension between these two ideas – that student research is potentially riskier, but potentially subject to greater supervision – led the IRB to distinguish course-based from non-course-based research in our evaluation process. The practical differences between the two types of research will be clarified after discussing the other difference between various types of research proposal, namely risk and issues related to whether review of a proposal by the full IRB is necessary.

As noted earlier, certain types of activity such as educational practices do not require a submission to the IRB at all. In other cases, the nature of the research is such that it may *potentially* be exempt from IRB review, but the issues are less clear cut and the IRB requires additional information to decide the issue. For such cases, the IRB uses two slightly abbreviated forms to determine whether review by the full committee is necessary (Form B, “Application for Exemption from IRB Review for Research with Human Subjects,”; Form D, “Application for Exemption from IRB review for Course-Based Student Research with Human Subjects”). The term “Exemption” in the title of the forms means that the research need not be reviewed by the full IRB, not that you do not have to submit a form to the IRB at all. In practice, application for exemption means that the proposal will only be reviewed by the IRB chair, not the entire committee.

What sorts of research are potentially subject to Form B and D exemptions? Here, you should closely examine the Decision Tree and specific forms to check all the details, but the key points are as follows. To be potentially eligible for exemption, the proposed research must meet *at least* the following two criteria:

- (1) The research must not involve protected categories of subjects. By law, certain types of individuals are considered more vulnerable as research subjects than are most people. Examples of such categories include minors (under 18 years old); pregnant women or fetuses; institutionalized individuals (e.g. prisoners); individuals with psychiatric, cognitive or developmental disorders; or individuals under the influence of alcohol or drugs. Research involving any protected class of subject requires review by the full IRB.

- (2) The research must involve extremely low risk to subjects. This means not only physical risk, but also psychological, social, legal, or financial risk. Any study which involves greater likelihood or magnitude of risk than that ordinarily encountered in daily life is ineligible for exemption and requires review by the full IRB.

The two criteria are just the starting point for deciding whether a study is exempt from full review. There are also additional criteria which differ somewhat between course-based and non-coursed based research, and you should check the appropriate forms carefully for details.

A few differences between course-based exemption (Form D) and non-course-based exemption (Form B) deserve special mention. First, course-based exemption requires that the faculty supervisor has completed an online Human Participant Protections Education Training course offered by the federal government. The goal is to insure that faculty are qualified to judge the ethical issues in their students' projects, and thus serve as effective ethical advisors.. A link to the ethics course can be found on the IRB web site. The course is free of charge and takes approximately two hours to complete.

A second important difference between course-based and non-course-based research concerns how data can be used once it is collected. Observations or data collected under a course-based exemption must either be destroyed or stored in a form where the data cannot be linked to individual subjects. Furthermore, the data cannot be used in a faculty research study nor published or publicly presented outside the HWS community without further approval by the IRB. The rationale for this policy is that dissemination of the results outside HWS poses additional risks not considered in the original proposal (essentially, threats to privacy) and thus requires additional IRB consideration. The data can later be published or used for other purposes if there is IRB approval, provided that there were no promises made to subjects to the contrary (e.g. on the consent form).

What are the practical consequences of exemption from review (forms B and D) compared to regular review (forms A and C)? There are several. First, exemption from review is generally quicker. Because only the IRB chair has to review the proposal, a decision can sometimes happen in just a few days (though that obviously depends on how busy the chair is with other matters). In contrast, regular review requires a formal meeting of the entire IRB, which normally occurs at two week intervals. Another difference is that the chair cannot outright reject a proposal submitted for exemption. If there are potential problems with the proposal, the chair will simply refer it to the entire committee for full review. Only after a proposal has been reviewed by the full IRB can it be officially rejected, a circumstance which fortunately is quite rare.

The last key difference between exemption and regular review is that exemption is permanent. If a research project is deemed exempt under Form B or D, it is considered exempt forever and never needs to be submitted to the IRB again unless there are changes to the study. This contrasts with regular IRB proposals (Forms A and C) which by law require annual reconsideration and re-approval of the research. A special abbreviated version of Form A is used for annual renewal of previously approved projects.

Parts of a research proposal

Although the various IRB forms differ in detail and serve different purposes as noted above, they for the most part ask for the same sorts of information. Some parts of the forms are completely straightforward (boxes to be checked indicating whether participants are adults or children, whether they will be recruited from HWS or elsewhere, etc.). Only the other, potentially tricky parts of the research proposal will be discussed here.

Cover page:

The cover page of an IRB proposal asks for the names of the principal investigator and other researchers, the title of the research project, and the anticipated dates for starting and completing the research project. Just a few key points should be noted. First, the term ‘principal investigator’ does not imply that this is the person who does the most work or should get most of the credit for the project. Its only significance is that this is the person the IRB will correspond with in discussing and formally approving the proposal. For record-keeping purposes, we ask that principal investigators who submit more than one proposal at about the same time should make sure they each have distinct titles (i.e., they are not all called “Independent study” or “Sociology Research Project,” etc.).

Second, by federal regulations, IRB approval of a research project can be granted for only one year. (Though *exemption* from IRB review is permanent; see earlier discussion). Thus, when forms A and C ask for anticipated starting and completion dates, the dates should be less than one year from each other. If you plan to start August 1 of one year for example, your completion date should be listed as no later than July 31 of the following year. The completion date represents the date that data must be collected, not the date that results must be analyzed, published, or presented. Multi-year projects can be renewed annually using a special version of Form A (“Form A - Continuation”) as noted earlier.

Purpose of the investigation:

Here, you need only provide enough background information that the IRB can understand the rationale and objectives of the study. It is not intended as a full historical or theoretical review of a field, as might occur in a published research article. This section of the proposal can and generally should be fairly brief.

Description of methodology:

In this section of the proposal, you should describe your methodology clearly and directly, in language that non-specialists can understand. Issues can arise in this section when the description of the procedures is incomplete or unclear (e.g., the proposal says that “participants will be taped” but doesn’t say whether this means video tape or audio tape). Another common problem is when various parts of the proposal are inconsistent with each other (e.g., the method section says that participants will be between 17 and 25 years old while the checked box indicates that only adults (18+) will be tested; or the consent form says that it will take five

minutes to complete a survey when it is obvious looking at the survey that it will take half an hour). You should be especially clear and explicit in describing potentially ethically sensitive aspects of the research, and attach copies of all forms (questionnaires, surveys, etc.) which will be used in the study.

Oftentimes, a research project may involve several similar experiments differing only in minor details, not affecting the ethical aspects of research. If so, a single research proposal and description of methodology is normally sufficient, with the planned variations of the experiment summarized.

Participant incentives:

You should indicate whether incentives will be offered to subjects for participating in the study, and if so describe them. The most common incentive is some sort of extra course credit, and this is an area where problems can arise. You should be aware of two issues. First, a researcher cannot give course credit; only a course instructor can give course credit. Therefore the researcher should not promise course credit which he or she might not be able to deliver.

The second concern is that the incentives not be coercive, or research participation a *de facto* requirement to pass a course. Research participation is supposed to be voluntary, and individuals should not be compelled to participate if they don't feel comfortable doing so. The IRB therefore requires that if extra credit is being offered, alternate means of earning the credit be offered for students who don't wish to participate as research subjects. If you are recruiting from a class that offers extra credit, you should make sure the instructor is aware of and agrees to this policy. (The policy has been officially adopted by the HWS Psychology department, but may be unfamiliar to instructors in other departments).

You should briefly make note of both the above issues (that extra credit is at the discretion of course instructors, and that if extra credit is offered, alternate means of earning the credit will be made available) in both the research proposal and in the consent form given to participants. This can be accomplished in the consent form by saying something like:

“You may be entitled to receive extra credit in a course for participating in this study. The availability and amount of extra credit is at the discretion of the course instructor, who you should consult if you have questions about the extra credit policy. If extra credit is being offered, the instructor will also offer other means of earning the extra credit for students who do not wish to participate in research.”

Note that the word may is crucial in the first sentence. If a researcher said that “you will be entitled to receive extra credit...,” this would be seen as making a promise that the researcher couldn't guarantee, and the IRB would request that the consent form be revised.

Potential harm to participants:

In this section you should clearly and honestly describe any potential risks to subjects. This includes not only physical risks, but also psychological, social, legal, or financial risks. Thus,

potential embarrassment or emotional discomfort is considered a risk, as is the potential that private information might somehow be released.

In answering this section, researchers should ask themselves “What is the worst that could possibly happen in the study”? If any subject might plausibly have some negative reaction to your procedures, you should mention that possibility here. You should be proactive in identifying and addressing potential ethical issues, and err on the side of caution. You should also be aware that different subjects can have very different reactions to the same procedures. Though many subjects would feel comfortable answering questions about highly personal matters, others would not and such questions should pose a plausible risk in such a study.

In evaluating the risks in a study, the IRB considers (1) the likelihood and the severity of the potential harm to subjects, (2) whether the researcher has done everything reasonable to minimize the risks, and (3) whether subjects have been meaningfully informed of the risks. Even unlikely risks may be unacceptable if the potential harm is great. Even if you feel an issue is unlikely or relatively minor, it is generally better to acknowledge and deal with it than to ignore it and assume it won't be noticed. In one of my experiments for example, I wanted subjects to watch a flashing display on a computer screen. I anticipated the IRB would be concerned that such a display might cause seizures, headaches, or other complications. Though I felt such problems were very unlikely, I modified the consent form to pre-screen subjects for such issues and the proposal sailed through without difficulty.

Participant deception

In this section of the proposal, you must describe and justify any deception used in the study. Note that deception is not outright prohibited by the IRB. Deception can be used provided it is justified, necessary for the purposes of the study, and not used to expose subjects to risks without their consent. If deception is used, the subject must be fully debriefed (told the truth) immediately after the study. A written debriefing statement must be included in the proposal any time the proposed research involves deception.

Voluntary participation and informed consent:

Arguably, informed consent is the most important single step in assuring the welfare of research participants. If individual are realistically informed about the relevant aspects of the research (including all potential risks) then presumably they will protect themselves by making intelligent decisions about whether they wish to participate. The IRB accordingly requires written informed consent from all participants except under very specific circumstances (e.g., certain types of truly anonymous surveys, observations of naturally occurring public behavior, or cases where obtaining consent might pose some risk to subjects). If the participant is a minor, informed consent must be obtained from a parent or guardian.

The IRB web site has a sample consent form which you should look at carefully (though not slavishly copy). The key issues are as follows:

- The consent form should describe the purpose of the study and the procedures to be

used in plain, jargon-free language. You do not need to describe your specific hypothesis, but participants should know what they will be expected to do (answer a survey, watch a computer screen, give a blood sample, etc.). You should be especially careful to describe any risks in the experiment (even minor or potential ones) and describe how the anonymity or confidentiality of the data will be protected.

- You should describe any incentives for participation (including extra credit –see earlier section) and note that participants can withdraw from the study at any time without penalty
- .
- You should state that the research has been approved by the HWS Institutional Review Board (don't abbreviate as 'IRB; participants won't know what 'IRB' stands for) and note that participants can contact the chair of the IRB if they have comments about the study or questions about their rights as research subjects. Contact information for the IRB chair (name, phone number, e-mail address) should be provided.
- Contact information for all researchers (name, phone number, e-mail address) should also be provided, and you should tell participants that they can contact the researchers at any time if they have questions or concerns about the study.
- The consent form should explicitly state that the participant agrees to participate in the study, and that they have been offered a copy of the informed consent form. (You should of course make sure that you have extra copies to give them). The consent form should be signed and dated by both the participant and at least one researcher.

Anonymity and confidentiality of data

In my experience, issues related to anonymity and confidentiality seem to cause more confusion in IRB proposals than any other topic. The issues are often minor, but they have delayed many a proposal that is otherwise unproblematic. You should pay especially close attention to this part of your proposal, and make sure the information in this section is consistent with that in the consent form and other parts of the proposal.

The first thing is to clearly understand the terms *anonymity* and *confidentiality*. If data are “anonymous”, this means that nobody, not even the researcher, would be capable of linking a subject's data to that person's name or identity. Essentially, this means the researcher does not know which subject provided which data. “Confidentiality” on the other hand means that the researcher is potentially capable of linking data to names or identities, but makes sure that this information is kept private. In other words, the researcher may or does know which subject provided which data, but does not divulge subjects' information to others.

In practice, anonymity really only applies to studies where subjects complete a survey or provide other information without their names or other identifying information every being attached to the data. If for example subjects complete a survey (without names) and then all subjects place the survey sheets in a shared envelope, the researcher will not know which subject completed which survey. The data are thus anonymous.

If however there is any way that individual subjects can be identified and linked to their data, the data should no longer be considered anonymous. This would obviously apply if subjects wrote their names or other identifiers on the data sheets, but can occur in other ways also. If a researcher directly interacts with or observes subjects for example (e.g., the procedure involves face to face interviewing), then this would allow the subjects to be identified visually. Similarly, video or audio taping of subjects during a study would potentially allow them to be identified that way. In no such cases can data ever be anonymous. The most the researcher can do is protect the confidentiality of the data, i.e., make sure that identifying information is not shared with others.

A few examples may help make the distinction clearer. Let's suppose again that subjects fill out surveys (without names) and place their data sheets in a shared envelope as in the first example. This time though, the researcher also has subjects write their names on a separate sheet of paper so that they can get extra credit for their courses. Are the data still anonymous? The answer is yes. The key issue is whether identities can be linked to data, and in this case they cannot. Simply using subjects' names for other purposes such as recruitment or extra credit does not affect the anonymity of the data.

Now suppose the survey doesn't ask for names, but does ask for other personal information (age, gender, ethnicity, major, hometown, etc.). Are the data still anonymous? Perhaps not. In such cases, the key issues are the type(s) of information asked for, the number of subjects in the sample, and whether the subjects are known to the researcher(s). Suppose for example that 20 students from a single HWS course participate in a survey. Here, having someone report that she is a "Hispanic female" or a "junior economics major" would very likely allow the researcher to identify the individual in question. In practice, not everyone would be anonymous in this circumstance. If, on the other hand, the survey was sent to a sample of several hundred students whose personal characteristics were unknown to the researcher, then the researcher would not be able to accurately identify individual subjects. Here, the data would truly be anonymous.

What if the data sheet contains the subject's name, but the researcher crosses out the name so it can't be read and replaces it with an arbitrary code number? Are the data now anonymous? The answer is no. Although someone reading the data sheet would not know the subject's identity, the researcher still would. While replacing identifiable information (names) with non-identifiable information (code numbers) is a useful way to protect confidentiality, it still does not make the data anonymous. This is somewhat similar to a subject being video or audio taped, then the researcher preparing a written transcripts of what was said and then destroying the tape. Someone reading the transcript would not know the subject's identity, but the researcher still would. Keeping transcripts rather than tapes will help preserve confidentiality (assuming the transcripts don't contain identifying information) but the data are still not anonymous.

It is the expectation of the IRB that if data are not anonymous, researchers will take reasonable steps to safeguard the confidentiality of the data. Such steps might include (for example) use of code numbers rather than names on data sheets, making sure that only the researchers have access to the data, keeping the data in a safe location, and never revealing personally identifiable information in any written report of the research. The steps taken to protect confidentiality

should be spelled out in the research proposal, and conveyed to subjects on the informed consent form.

You should also know that it is possible for subjects to waive their right to confidentiality. This requires explicit written consent from the subject, describing the specific way(s) in which their data or personal information will be used and any risks the subjects might incur from such use. An example could be a historical research project, where some individuals might prefer that their real names be used. This would be possible, as long as written consent was given. Another example would be a researcher who wants to show the video of subjects' performance in the experiment at research conferences, or in his or her classes. Provided the subject is informed of the possible risks (that he or she would be seen by strangers, might be recognized, etc.) and consents in writing to allow such use of the video, then the video can be shown. Waivers of confidentiality should be sought only when there is good reason, and the terms of the arrangement spelled out very explicitly to subjects. Participants are of course entitled to deny such waivers if they so choose, and their wishes in this regard must be respected.

A few last points about confidentiality should be noted. In some studies, subjects may reveal information not only about themselves, but also other individuals such as family, friends, or members of the HWS community. It is the IRB's view that the right of confidentiality extends not only to research subjects, but to these other individuals as well. Researchers doing studies where this is an issue should briefly describe how they will protect the confidentiality of such third parties (for example, noting that their names or other identifying information will not be used in the research report).

Another issue concerns confidentiality of legally sensitive information, that is information that might put subjects or others at legal risk. In a study of illegal drug use for example, a subject's information could conceivably be used in a drug case. If a researcher was interviewing doctors about medical errors, then this information could conceivably be used in malpractice suits. Though most such scenarios are unlikely, you should understand that the law gives no special protection to researchers allowing them to withhold information collected about subjects in their research. You could be subpoenaed to testify or ordered to turn over your data, and failure to cooperate could subject you to criminal sanctions. What to do in such cases?

Unless you wish to go to jail to protect your subjects, the IRB suggests that you tell subjects that you will "protect the confidentiality of the data to the full extent allowed by law". (This phrase should go on the consent form). This means that you won't reveal any information unless legally ordered to do so, but would in that case. Of course, subjects should always be made aware of potential legal risks associated with research participation. An even better solution to the problem would be to re-design the research, collecting data in a way that was truly anonymous. If you as a researcher do not know what data came from what individual, the information couldn't be used against any individual no matter who might wish to do so.

Assurance statement:

The final step in preparing a research proposal is signing and dating the assurance statement on the last page. Note that in doing so you promise to inform the IRB if there are any changes to the

research protocol, or any unexpected events that might pose risks to subjects. Such unexpected events don't need to involve actual harm, but only potential risk. If for example you had a laptop stolen that contained personal information about subjects, this would expose them to risk (a breach of confidentiality) even if no subjects had actually been harmed yet. The assurance statement is a promise that you will continue to monitor the ethical aspects of your research carefully, and report any ethical complications to the IRB promptly.

The final step: submitting the proposal to the IRB

Just a few points should be noted about the actual submission process. First, you must submit both a signed paper copy and an electronic copy of the proposal. The paper version is required by law, and the electronic version is for distribution to the committee members. Both versions should match exactly and be submitted to the individual listed on the IRB web site. You will receive an e-mail acknowledgement that your materials have been received by the IRB.

The scheduled meeting dates of the IRB are listed on the IRB web site. For proposals requiring full review (forms A and C), the IRB requires proposal be submitted two weeks before a scheduled meeting date to be assured of consideration at that time. Depending on the committee's workload, proposals submitted less than two weeks in advance can sometimes be considered, but this can't be guaranteed and shouldn't be presumed by researchers. (Submission of Form B proposals and form D proposals, which don't require review by the full committee, are independent of the IRB meeting schedule and should be submitted as soon as they are ready). Researchers should always take into account IRB review time when planning research projects with human subjects.

Once the IRB has reviewed your proposal, you will be notified promptly whether the research has been approved or rejected, or whether revisions to the proposal are needed. (Requests for revisions are far more common than outright rejections). If the IRB does request revisions, it will specify the particular issues that need to be addressed, and the procedure for re-submission. If the needed revisions are relatively minor, they can often be approved quickly by the IRB chair; if they are more substantive, the revised proposal must be considered by the entire IRB at a later meeting. In either case, the issues raised by the IRB should be addressed clearly and explicitly on the revised submission.

I will conclude by reiterating how much the IRB values the effort and thoughtful consideration that most faculty and students put into preparation of their research proposals. Although the handout has occasionally emphasized various bad practices seen in some proposals, most problems I've described are minor and easily avoidable with modest care and attention. The IRB views ethics in research as a cooperative process between researchers and ourselves, and hopes that this handout will facilitate that cooperation. The IRB welcomes comments and questions from faculty and students, and looks forward to your future research endeavors.