

# ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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## INTRODUCTION

This memo presents advice based on my experience shepherding institutional review board (IRB) applications prepared by Heller PhD students, mainly for qualitative projects but also for some mixed methods projects. It is written primarily for PhD students and is focused on IRB-relevant issues that arise in qualitative research, but I hope some of the information might be of interest to others in the Heller and larger Brandeis communities who are preparing IRB applications to the Brandeis Committee for Protection of Human Subjects (BCPHS), whether for qualitative, mixed methods or quantitative projects. The aim of this memo is not to be comprehensive, but, rather, to address those issues that, in my experience, arise most frequently.

The first section describes issues to keep in mind when preparing an application to the BCPHS. It is followed by sections on the Initial Application Form, the Protocol and supporting documents, respectively. All the stipulated elements of the Initial Application Form and of the Protocol are included in the BCPHS's wording. Most of the student projects I have overseen have been interview-based studies, so the advice concentrates on this study design, and, to a lesser extent, on organizational or institutional studies and ethnographic research.

The BCPHS's website contains all the necessary forms plus lots of excellent information to guide the preparation of an application. In addition, Morgen Sarpeshkar, the IRB Administrator, is an amazing and generous font of expert advice. If something in this memo diverges from the guidelines, policies or regulations provided on the BSHSP website or by Ms. Sarpeshkar or other BSHSP staff, please ignore it and follow the official advice.

## SOME IMPORTANT THINGS TO KEEP IN MIND

- The IRB is the researcher's friend. It helps each of us to ensure that the research will protect human subjects as well as possible.
- Do not choose not to study a topic and/or a vulnerable population of interest to you because you think that the IRB will not approve the project. The IRB is your partner and will try to help you figure out how to address thorny ethical issues in the project you envision.
- The IRB is, as its website proclaims, "charged with reviewing **all** research involving human subjects conducted at Brandeis University or by a member of the Brandeis community." It is therefore **not** up to the investigator (whether the Principal Investigator or the Student Researcher) to decide whether or not

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*\*My sincere thanks to Morgen Sarpeshkar for her editorial suggestions and for sharing her expertise in many virtual and in-person conversations. I am also deeply grateful to all the students with whom I have discussed IRB applications and whose IRB applications I have read.*

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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- a project fits the federal definition of research or to decide whether or not the project is exempt. Both those decisions are the responsibility of the BCPHS.
- Any research involving human subjects from which findings are presented publically, whether orally or in print, **must** have been conducted with IRB oversight, even if that oversight takes the form of an exemption.
  - It is not possible to obtain IRB review after the fact, so any project involving human subjects must be submitted for review to the BCPHS and approved by it in advance of the start of participant recruitment or data collection. (This bullet and the preceding one are the reasons I do not permit students to do research for a course project absent IRB approval, as it is impossible to tell in advance whether or not the findings will merit dissemination beyond the classroom.)
  - Whereas as scholars we are all ethically bound not to plagiarize, in the case of an IRB protocol it is, in my view, ethically appropriate to borrow without attribution IRB-approved language from a protocol written by someone else that addresses an issue in the protection of humans subjects in research that is also present in your study. This is the **only** time I condone using the words of others without citation, and I do so because it saves the members of the IRB time and energy and fosters clarity of purpose and practice in the ethical conduct of research.
  - The foci of an IRB application are related to the ethical principles laid out in *The Belmont Report*: respect (protection of vulnerable individuals, voluntary participation, fully informed consent, protection of privacy and confidentiality & right to withdraw), beneficence (potential benefits outweigh risks & risks are minimized) and justice (distributing risks & benefits equally).
  - Respect, the first principle of *The Belmont Report*, is often interpreted as meaning that confidentiality must always be promised. This is **not** correct. In some cases it is either impossible or undesirable to keep the identity of study participants and/or organizations private. Moreover, according to some approaches to research, notably those in the spectrum of action or participatory research, it is considered unethical not to credit co-participants. When anonymity of participants cannot be ensured or is not promised for philosophical or other reasons, what is required is that the informed consent process (in the case of action or participatory research this is the process of informed agreement to be co-researchers) makes this absolutely clear so that the prospective study participant (community co-researcher in participatory projects) or appropriate representative of a potential partnering organization knows that the researcher cannot promise to protect confidentiality. The potential participant (or community co-researcher) or institutional partner is then positioned to give fully informed consent (or agreement in the case of community co-researchers).
  - The use of written informed consents is contrary to ethnography's signature data collection method, participant observation, which situates the researcher as much as possible within the lived experience of those whose world is under study. In projects based on participant observation, the researcher does not hide her/his identity as a researcher. Acceptance of the researcher's continued presence by those whose lives s/he is studying constitutes a form of consent,

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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albeit not written. An application for an ethnographic project should request a waiver of informed consent and provide justification for it in the Protocol under item p. "Plans for obtaining and documenting informed consent."

- An IRB application is not the same as either a dissertation proposal or a grant application. For example, the literature review (g. "Results of previous related research" in the Protocol) need not be either as long or as detailed as that in a dissertation proposal. (For grant-funded projects, the grant proposal must be included in the IRB application as a supporting document.)
- All parts of an IRB application must jibe. Thus, for example, if the Initial Application Form indicates in number 8 that 'Handwritten Notes' will be made, then the Protocol must describe this practice among the "Procedures to be performed" in section I. and the Informed Consent Form must also mention that written notes will be made.
- Be sure to follow carefully all the requirements on the BCPHS's "IRB Initial Application Guide and Checklist" concerning font, formatting, etc.
- A request from the BCPHS for revision of an application is a good thing. The BCPHS is assisting the researcher in protecting human subjects as well as possible. In my experience, such requests are usually minor and are always accompanied by detailed advice about what should be done to address the BCPHS's concerns.
- An IRB-approved protocol must be kept active (via annual Continuation Applications, for which the BCPHS sends out email alerts) until all public dissemination of the findings is completed. (In the event the researcher leaves Brandeis while an IRB-approved project is still active, s/he should consult the BCPHS.)
- Answer all emails from the BCPHS as quickly as possible. The IRB staff have more than enough work without having to remind researchers to respond to emails, especially annual emails requesting the submission of either a Continuation Form or a Termination Form.
- When preparing an application to the BCPHS, it is helpful to consult already approved applications that have elements in common with yours, e.g., similar methods, study population or ethical issues. The Heller PhD Program has a file of approved applications, which is located in the Program Office. Heller PhD students should give a hard copy of their approved application, including copies of relevant email correspondence with the BCPHS, to Cheryl Sweeney for inclusion in the file. In addition, they should complete the Application Summary Sheet to assist others who are preparing applications to locate examples of approved applications relevant to their study design and ethical concerns. Some other Brandeis divisions have their own repositories for completed IRB applications, so check with your department or program.

It can happen that the name of an individual or organization is mentioned in an IRB application but the study design and consents include that the name will not appear in any oral or written reports resulting from the research. In that case, if you are depositing a copy of your application in the Heller or other Brandeis repository, you must black out or otherwise delete the

# ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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names of this individual or organization in the copy deposited, as this copy is essentially in the public domain.

## INITIAL APPLICATION FORM

**Top section:** The project title for the purposes of the IRB application need not be exactly the same as that given in the Informed Consent Form, recruitment materials or, indeed, the thesis, dissertation, articles or books based on the project.

A student cannot serve as a Principal Investigator (PI) on an application to the BCPHS. S/he must find a faculty sponsor to serve in that capacity.

In the Status field, a PhD student should enter graduate unless s/he has already passed comps. In that case, PhD candidate is the appropriate response.

Indicate in the appropriate field whether you consider the risk to study participants to be “minimal risk” or “greater than minimal risk.” The BCPHS will make its own judgment. Your choice gives the Committee an opportunity to gauge your assessment of the level of risk. Risks and protections must be discussed in the Protocol and the Informed Consent Form, if any.

For the end date of the analysis, put the anticipated date of the END of the dissemination of the study findings. If the project might develop into a student’s dissertation research, the end date of analysis should be the anticipated date of hooding (receipt of doctoral degree).

**1. Study Purpose:** Check all that apply. If the findings will be used in a course as well as for other purposes do **not** check the ‘Class Assignment Only’ option. Instead check ‘Other’ and enter “Class Assignment” in the associated field. In fact, I hope no student ever checks the ‘Class Assignment Only’ box because it is likely that a project’s findings will be rich and important enough to be presented publicly in some way. Moreover, it is possible that they might be relevant to draw on in a dissertation, even though research done in the context of a course, for example, HS411b Applied Research Seminar: Qualitative, is never sufficient unto itself for a dissertation. It is worth noting that findings from research that merit reporting, whether in a dissertation or elsewhere, need not be substantive, that is, about the topic under study; they can also be methodological or theoretical.

**2. Study Location:** This is straightforward except that it is often difficult, if not impossible, to state in advance all the sites where ethnographic research will be conducted. The description for ethnographic research might be a specific location plus the phrase “and other sites that emerge as appropriate in the course of the research.”

**3. Collaborations/Outside Researchers:** This field is straightforward. In the case of action or participatory research with community co-researchers, the second option seems the appropriate one. The nature of the collaboration should be discussed in the Protocol.

**4. Existing Data:** If you plan to use existing data not in the public domain but have not received permission to do so prior to the submission of your IRB application for the part of the project that involves your own data collection, you might choose to leave

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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the existing data out and check 'No' on the first question. If you do so, I recommend that you indicate somewhere in your Protocol that you are hoping to use existing data relevant to your proposed study and will be submitting a Modification Form and associated amendment to the existing Protocol once you receive permission to use those data. When you receive the requisite authorization, you can prepare and submit the Modification Application.

**5. *Participants to be Recruited:*** Check all that apply. Checking off a characteristic indicates that it is an explicit eligibility criterion. If, for example, some research participants will be members of minorities and they are being interviewed because of this dimension of their identity, 'Minorities' must be checked; if, on the other hand, those research participants who are members of minorities will not have been recruited on this basis, this box should not be checked. (See discussion under item i. "Justification for use of any special/vulnerable subject populations" in the section below on the Protocol.)

**6. *Number of Participants:*** My advice is to insert the word 'approximately' before the estimated maximum number of study participants. Here's why: If in the Protocol for an interview-based study you say you are going to have exactly 7 study participants and you turn out to be lucky enough to find an 8<sup>th</sup> voluntary participant, you cannot interview that person until after you submit a Modification Application to the BCPHS to expand the number of study participants and receive its approval back. Another alternative is to phrase the sample size as a range, for example, 15-30 participants. If you choose this option, be generous in estimating the range's maximum extent to avoid running into the problem just noted. For an ethnographic study, I recommend inserting your best estimation of the number of people with whom you will interact as a participant observer.

**7. *Recruitment Method(s):*** In the disciplines in which ethnographic research is practiced, the term 'recruitment' is not typically used to describe the process by which a researcher enters the field. Rather than the researcher recruiting participants, the people of interest accept the ethnographer. For an ethnographic study, I would recommend entering "participant observation" here.

For qualitative studies that are not based on participant observation, indicate all the methods you intend to use. It is better to include more than one strategy rather than to have to return to the BCPHS with a Modification Application if the initial recruitment method does not yield the anticipated number of study participants. Remember the wording of all recruitment materials must be included in the application among the supporting documents in all the languages to be used. These materials cannot be used until approved by the Committee.

**8. *Data Recording Method(s):*** Again, check all that apply.

**9. *Identifiers to be Collected:*** Again, check all that apply. Remember identifiers can be collected for the sole purpose of contacting study participants as well as in the course

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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of the research itself. For example, in an interview, a study participant might mention another individual's name, which is a personal identifier.

As of 2013, the cover sheet was revised. The new version, the Initial Application Form, includes 'Facial Photographs' among the identifiers to be collected. In ethnographic research conducted using participant observation, it is common that such photographs are taken in a non-surreptitious manner in both public and private contexts. It is also the case, as noted in on page 2, that written consents are not typically used in ethnographic research. If you plan to take photographs of people as part of an ethnographic project, I suggest you check this box and then in the Protocol describe the contexts in which such photographs will be taken and assess the risks associated with them. With respect to facial photographs, an important distinction should be kept in mind, and addressed, if appropriate, in the Protocol, namely, that between a photograph that will be used as data but not shown at a talk or published and a photograph that will be displayed publicly either on a screen or in print. Other issues to consider and address are the age of individuals in facial photographs and whether the occasion was a public or private event.

In the Protocol, how material with identifiers will be safely stored and whether or not identifiers will be removed must be discussed.

**10. Collection Tool(s)/Study Instruments:** If you are doing a qualitative interview-based study, check 'Interview Guide'. I recommend doing the same if the study includes focus groups (a form of group interview). Organizational studies typically involve interviews and/or focus groups. For either an interview-based study or an institutional study, I also recommend that you check 'Other' and write "Field observation" in the adjacent line. This permits you to take notes related to each interview, including about the location and non-verbal communication. Moreover, institutional studies usually involve site visits, that is, field observation or participant observation at the institution(s) of interest.

Increasingly, social media is a source of data. I encourage you to include it by checking 'Other' and entering "Social media" in the associated field. In the Protocol you can explain the nature of the social media being used and how it will be used. For example, collecting data based on participating as a researcher in an online forum, that is, being a virtual participant observer, is different from collecting data via an 'Online Survey', which is the first response option. In an ethnographic project, connecting virtually with people with whom you are conducting face-to-face fieldwork is different from connecting exclusively via the Internet. Being a virtual participant observer on the Internet, which has been variously labeled 'Internet ethnography', 'online ethnography', 'virtual ethnography' (Nicole Constable & Christine Hine) and 'netnography' (Robert Kozinets), is an emerging research practice with its own thorny ethical issues. I recommend that you consult Morgen Sarpeshkar if you plan to use this method.

For a community-based study, I recommend describing it as "Ethnography," and entering that in the box after the response option 'Other'. (In the section on the Protocol, see items k. "Study design" and l. "Procedures to be performed" for additional discussion of interviewing in the context of an ethnographic study.)



## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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In an interview-based study, you might want to use a short questionnaire, which you develop yourself based on your research interests and analysis plans, to gather descriptive/demographic data on study participants in a uniform way. If you choose to do this, check 'Paper Survey'. In addition, I recommend that you follow the astute advice given by Robert Weiss in his book *Learning from Strangers* and use the questionnaire (administered either in hard copy or by reading the questions to the interviewee and entering the answers yourself) at the end of the in-depth interview. The reason for this recommendation is that administering a questionnaire at the start sets the wrong tone and encourages the respondent to provide staccato answers rather than rich and discursive ones to the questions in the in-depth interview.

In the context of an interview study, you might want to use a standardized instrument. The best option to check is 'Standardized Test'. An example of a project in which this would be useful is an interview study related in some way to trauma experiences. The study design would likely be strengthened by the inclusion of an established trauma history measure.

**11. Administration Method(s):** For interview-based studies, check 'In person (1-on-1)'. If focus groups will be used, check 'In person (group)'. For a fully ethnographic project, I recommend not checking any of the boxes here because such studies typically do not include administering any data collection instruments or measures.

I recommend including not only everything you know you will be doing but also what you might be doing. For example, even if you think you will be doing all your interviews in person one-on-one, I would check that plus both 'Telephone/Skype' and 'Email' for two reasons. First, in the event that it is impossible to arrange an in-person interview, you can do one over the phone without first going back to the IRB with a Modification Application. Second, it is useful to include the option of following up shortly after an in-person interview with a thank-you phone call or email in which you can also ask if the interviewee had any additional information or reflections prompted by the interview that s/he would like to share. (In section on the Protocol, see k. "Study Design" for additional discussion of this suggestion.)

In addition, it sometimes happens that the intention is to do in-person, one-on-one interviews but an interviewee wants someone else – or more than one other person – to be present during the interview or someone else just happens to be there at the time of the scheduled interview (this happens especially when interviews are conducted at the interviewee's home). In the latter case, the researcher likely will not know if the interviewee wants that person or those persons to be present or not. In such a case, a strong argument can be made to postpone and reschedule the interview. It is important to think through in advance, in terms of both study goals and human protections, what sorts of circumstances might arise and whether or not the interview will be conducted under circumstances that diverge from those planned. Often it is not appropriate to do so. For example, in a study with women dealing with interpersonal violence, an interview should be rescheduled if a partner is present at the time originally scheduled. Additionally, such an interview should not be conducted in the presence of children.

Although there is no place on the Initial Application Form to address such complexities, they should be addressed in the Protocol.

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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**12. Deception:** I have never read an IRB application for a qualitative or mixed method study that involved deception. At least as I understand qualitative research, it depends on trust between the researcher and the people whose worlds are under study, so I personally would not sign as PI on a Student Researcher's IRB application that involved deception.

**13. Biosafety:** Like deception, this is a study element that has not come up in any of the IRB applications I have read. It could, however, well come up in a mixed methods study of health. A separate IBC Protocol to the Brandeis Institutional Biosafety Committee (IBC) would need to be submitted for such a study and the Protocol number and approval date entered here.

**14. Potential risk exposure:** All studies with human subjects involve some risk, however minimal. Be sure to check all that apply. Remember to address each risk checked here in the study Protocol in item m. "Anticipated risks and benefits to subjects."

Morgen Sarpeshkar aptly notes that "sometimes it's really hard to think of specific types of potential risks . . . . In this case, we encourage researchers to check 'Other' and on the line write 'minimal'." The Protocol should then support the claim that the risk is minimal.

The IRB has no mandate to consider risks to the researcher(s). It is each researcher's obligation to do that her/himself. For example, you might choose not to provide your cell or home phone number on the Informed Consent Form but, instead, choose to use a pay-as-you-go temporary phone number dedicated to the project. Or you might decide not to conduct any interviews in study participants' homes.

**15. Compensation:** Absent grant support for compensation, there is no need to pay study participants. Students often feel it is disrespectful not to provide some form of compensation. I would argue that it is not disrespectful. Genuine non-judgmental interest in others' knowledge, opinions and experiences that is evidenced in the study's topic and goals and will be evidenced in the conduct of the research itself is a form of respect.

According to Morgen Sarpeshkar, "It might be helpful to include a small mention of times when the student might buy the participant a cup of coffee or share a small trinket as a token of appreciation during the interview. These items are not necessarily seen as formal compensation, but more as a gesture of gratitude that is often most consistent with cultural norms/expectations." Since these are not formal compensation, check 'No' here but describe such possibilities in the Protocol.

It is important to note that it is standard practice in ethnographic studies, at least those conducted by anthropologists, not to compensate study participants directly for information; it is, however, common practice for ethnographers to provide other forms of reciprocity. If relevant to the study, this possibility should be discussed in the Protocol.

What is of concern to the BCPHS and other IRBs is that any compensation that is given not be so large that it becomes a form of coercion.



## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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**16. Informed Consent:** Ethnographic studies involve a waiver of informed consent. If the existence of a signed Informed Consent Form itself poses risk to a study participant, a waiver of written informed consent should be requested. For example, if being HIV+ is an eligibility requirement for study participation, the existence of an Informed Consent Form might increase a study participant's level of risk.

In the Protocol, issues such as whether codes will be used to link data to study participants and how signed Informed Consent Forms, if any, will be securely stored should be addressed.

### **Attached Documents**

Check all that apply.

### **THE PROTOCOL**

Aim for completeness with clarity and brevity, as BCPHS members are busy. In fact, the number of IRB applications they must review is constantly increasing. The items below (a-r) are taken directly from the BCPHS's "IRB Initial Application Guide and Checklist" available on its website.

#### **a. Title of study**

For the purposes of the application, the title should be as specific as possible. However, since you do not want to give away either your hypothesis or your preferred words for the topic and concepts under study, you may well want to change the title and descriptions of the issues to be addressed in interviews for the purposes of recruitment material(s) and the Informed Consent Form. For example, in a study that hypothesizes that relational coordination contributes to the integration of two types of services, the Protocol might include that wording in the study title but the Informed Consent Form might describe the research topic without using either the phrase 'relational coordination' or the term 'integration'.

**b. Purpose of study** – describe the overarching goal of what you seek to discover through the proposed research project. Also include the expected benefits obtained by doing the study.

For a pilot or preliminary study conducted by a PhD student, two common goals – and benefits – in addition to that of learning about the topic under study are to hone the Student Researcher's research skills and to clarify research questions for the dissertation and/or to help design a dissertation study.

**c. Sponsor of study** – list any external or internal funding for the project.

This is the appropriate place to discuss any conflicts of interest pertaining to the PI, the Student Researcher or any other research personnel. Be generous or broad in considering what might be considered a real or apparent conflict of interest.

According to Morgen Sarpeshkar,

This might include any relationship that the investigator has with a sponsor, group/organization being researched, identification with a particular

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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community, etc. It's important to remember that just because a relationship may exist does not mean that it is a conflict of interest or that it cannot be managed, but such information is extremely helpful to disclose so that these things can be appropriately taken into account during the review of the application (as they have the possibility to lead to coercion, among other things).

**d. Principal investigator's professional qualifications** – list the professional qualifications, including academic, professional, and/or volunteer activities with regard to the proposed research project. Also include any necessary support services and facilities that exist to support the project. (In student-initiated research projects, this should describe the faculty sponsor's professional qualifications to oversee the student project.)

This should be short and to the point. It is not curriculum vitae. Since a student must always have a faculty member serve as PI, I recommend that s/he obtain a short paragraph from that faculty member rather than spending time writing one her/himself and then getting the PI's approval of it. As an example, here's the one I give to students:

Nina (Cornelia) Kammerer, PhD, MPH, is a Senior Lecturer in the Heller School's PhD Program, in which she teaches two seminars in qualitative research (HS403b and HS411b), and Affiliated Faculty in the Anthropology Department. She is an anthropologist and public health specialist with extensive experience in qualitative and mixed methods research.

**e. Student Researcher's qualifications** (for student-initiated research) – list the relevant courses taken and any other experiences or skills that are applicable to the proposed research.

This section should be thorough but short. Include that the required CITI Training has been completed and the date of completion.

**f. Other Research Personnel** – list all other personnel who will be taking part in the project, their position, role in the project and relevant experience.

Other research personnel are easy to overlook. These include additional research staff to serve as scribes during focus groups, translators for interviews and transcribers of taped interviews and/or focus groups. If a professional transcription firm is hired, a member of its staff is not considered to be research personnel from the IRB's point of view. Presumably the same is true of a translator from a professional translation firm.

If the research plan includes individuals with access to study data, whether considered "research personnel" or not by the IRB, issues of confidentiality should be addressed in section I. on "Procedures to be performed." If there is any chance you will hire someone to serve, for instance, as a translator during an interview, you should say that here and in section I. If not, you would have to go back to the IRB with a Modification Application to add a translator.

For a thesis, whether at the BA, MA or PhD level, a Student Researcher might want to include those committee members who are not serving as the PI, as these

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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professors might be involved in shaping the research in an ongoing fashion and might therefore have reason to consult the data collected.

All research personnel must complete the required CITI Training. If a researcher has not completed the training by the time of the submission of the application, state that s/he will complete the training as soon as possible and submit proof thereof to the IRB prior to beginning to work on the project.

According to Morgen Sarpeshkar, “if another researcher is affiliated with an institution outside of Brandeis and does not want to go through their home IRB or does not have an IRB, they can enter into an Individual Investigator Agreement (IIA).” If this circumstance arises, please talk with her about it.

**g. Results of previous related research** – discuss other research undertaken by others and/or by yourself that places your research in context. This should include a brief discussion of how your project fits within the literature of your field and should include citations (listed in section r). Help the reviewer to become a part of the academic *conversation*.

Remember that this is not the literature review section of a dissertation. The IRB requires this information to ensure that the project is of scholarly value, as research with human subjects that has no promise of benefit is unethical.

**h. Subject characteristics & inclusion/exclusion criteria** – profile the participants you are seeking to be a part of your research.

This item is an example of wording or conceptualization derived from medical/quantitative studies. Often qualitative studies do not have explicit inclusion and exclusion criteria for participants. For example, in ethnographic studies all participants in the world under study, whether a community, ethnic group, organization or type of activity (e.g., users of a given service), are the subjects. Even in interview-based studies, the sampling frame is often not delineated by inclusion/exclusion criteria but instead by range, diversity or theoretical sampling (a term from grounded theory that refers to sampling based on the developing analysis). Indeed, the sampling frame in qualitative studies often cannot be stipulated completely before the research starts. The BCPHS members are well-versed in ethnographic and other sorts of social scientific research in which neither the characteristics nor the basis of selection of participants can be fully described at the outset of the project, so just describe what is known about these at the outset and indicate that other bases of selecting participants might emerge during the course of the research. As the project develops and recruitment patterns evolve, if it becomes clear that the level and/or nature of risks to study participants have altered and consequently procedures to protect against risks need to be amended, the IRB must be notified and these changes reviewed and approved.

**i. Justification for use of any special/vulnerable subject populations**, if applicable – vulnerable populations include children, the decisionally impaired, prisoners, pregnant women, etc.

When members of populations often considered special or vulnerable are explicitly chosen as study participants on the basis of that characteristic, this choice

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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must be justified. You cannot, for example, learn about African Americans' experiences of racism without interviewing African Americans. Sometimes members of special/vulnerable populations are among study participants but not based on that membership. When this is the case, this should be stated. To give an example, you might say the following: "Some of the college students recruited for this study will likely be members of minority groups or have learning or physical disabilities, but they will not be recruited on these bases."

Morgen Sarpeshkar notes that minorities are not always considered special/vulnerable populations. In her words, "Any group of people could be vulnerable given the right circumstances. Investigators should be encouraged to think about the group of people that they are engaging and seek to identify if members of this group would be vulnerable in the situation about which they are being studied."

**j. Recruitment procedures** – describe how you will be finding your research subjects. If applicable, include the recruitment materials you intend to use such as fliers, texts of e-mails or letters, scripts for phone calls, etc. in the supporting documents.

In my experience, recruitment is a dimension that often does not go as planned. For this reason, I encourage applicants to think creatively in advance about multiple realistic strategies for recruitment and to include all of these in the Protocol. Yet again, this is to avoid having to return to the IRB with a Modification Application.

All recruitment materials, such as scripts for face-to-face recruitment, phone scripts, emails, flyers, advertisements and Facebook posts, should be submitted with the Protocol (among the supporting documents), as the wording must be reviewed and approved by the IRB in advance of its use.

Note that when a recruitment invitation is spoken, whether in person or over the phone, it is sometimes difficult, if not impossible, to stick to the exact script. This is especially the case if the researcher already knows the person who is being asked to join the study. For this reason, I encourage you to say something to this effect in the Protocol and to preface the text of the recruitment script, which must be presented in the supporting documents, with a statement such as "The exact wording might change in the delivery but the essence of the message will remain the same."

In an organizational or institutional study, willingness to be the base of participant recruitment must be stated in the letter or memorandum of agreement with the institution that must be included among the supporting documents. Recruitment with the approval and often the help of the organization's management raises special issues in terms of protections that are addressed under item I. "Procedures to be performed" below.

If the letter or memorandum of agreement is not in hand by the time the application is ready for submission, include in the Protocol that a letter is expected and will be submitted as soon as it is received. That way you can get the application in sooner. The IRB might then provide provisional project approval pending submission of the letter/memorandum. Research cannot begin until you have received both IRB approval of the Protocol and acknowledgment of receipt of the letter/ memorandum of agreement for inclusion in its files.

If, on the other hand, an organization or institution is simply a site at which recruitment materials are placed rather than a partner in the research, no official letter

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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or memorandum of agreement is needed. Rather, the Protocol can say something like “Verbal permission will be obtained from an appropriate staff member in advance of posting a recruitment flyer in a public place in institutions such as drop-in centers used by individuals with the characteristics sought among study participants (see flyer in supporting documents).”

All recruitment materials should be submitted among the supporting documents in all languages in which they will appear. If a translation is not finished by the time the rest of the application is ready to submit, indicate in the Protocol that it is in progress and will be submitted as soon as possible. That way, if there is an English language Informed Consent Form, the study can start with that once IRB approval is received. Moreover, the translation can be submitted without doing a Modification Application. Remember that no Informed Consent Form can be used until it has been reviewed and approved by the BCPHS.

Remember also that a recruitment flyer or email can be catchy both in wording and visually.

**k. Study design** – describe the scientific design of your study; include a discussion of the appropriateness of your chosen research methods.

Include all the research methods you might use. For example, if you know you will be doing interviews but think you might want to do focus groups as well, include the focus groups to avoid needing to submit a Modification Application later.

With respect to focus groups, it is good practice to have more than one researcher present, so that one can facilitate the discussion and the other can take notes, especially about dynamics that will not be evident on the tape recording, assuming permission to record was part of the informed consent process. Depending on finances and the nature of the topic under study and of the participants, it might be good to have three researchers present so that the task of taking notes can be divided, with one person focused on the content of what is said and the other on interpersonal dynamics. This would be especially useful if the focus group will not be taped (or as back-up in case the recorder malfunctions). However, these benefits should be weighed against the impact on the focus group of the presence of more than one researcher. If more than one researcher will participate in a focus group, the additional research staff must be described in section f. on “Other Research Personnel.”

Given the growing prevalence of social media, I encourage you to include it as part of your study design. As noted earlier, I suggest that you consult with Morgen Sarpeshkar if you are considering a study design that includes ethnography that is exclusively online.

Interview studies are, in my experience, the most common form of qualitative study proposed by Heller PhD students. The IRB application for such a study must include among the supporting documents either an interview guide or an interview protocol. I want to underscore the difference between the two. An interview guide indicates the topics to be explored and perhaps a few examples of the types of questions that might be asked, whereas an interview protocol (or schedule) has set questions in a set order. I strongly recommend the use of a guide so that interviews can develop in an organic fashion. See the section on supporting documents for

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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additional discussion of the nature of interview guides and an example of an introduction to one.

For interview-based studies, I recommend not only the use of an interview guide but also the inclusion of the following three elements in the study design:

- ***Multiple rather than single interviews.*** If you say you are only going to do one with each interviewee, you can only do one. The kinds of complex and often emotionally difficult topics that students want to investigate are impossible to cover richly and deeply in a single interview. Moreover, trust is needed for study participants to share in that manner, and meeting more than once builds trust, in part because it underscores the seriousness of the researcher's interest in the interviewee's views and experiences.
- ***Follow-up phone call or email after each interview.*** As noted, this practice provides a chance not only to say thank-you again but also to obtain additional input prompted by the interview itself. We often think of additional things to say after the fact, so this is a way to garner that material. It would be possible to try to do so at a second interview somewhat later but the additions and reflections that immediately followed the previous interview might well be forgotten by the interviewee by then.
- ***Permission to re-contact later.*** If we do not build this into our study consent, we do not have the right after the end of the study to get back in touch with the interviewees. This permission seems especially important to write into the study design and the associated Informed Consent Form for a pilot or preliminary project related to a student's intended dissertation project.

If the characteristics of interviewees will be used in analyzing interview data, I recommend that a questionnaire be used with each study participant at the end of the first in-depth interview in order to gather descriptive/demographic data in a uniform fashion. For an explanation of the recommended timing of the administration, see item 10. "Collection Tool(s)/Study Instruments" above in the section on the Initial Application Form.

With respect to ethnographic studies, if you are writing a Protocol for such a study I encourage you not to set precedents unwanted by anthropologists, for whom ethnography is their discipline's signature research method. In particular, I encourage you not to include written consents as part of your study design, as use of these is contrary to the method, which aims to capture life as lived. As noted in the preceding section, in answer to 10. "Collection Tool(s)/Study Instruments" on the Initial Application Form, I encourage you not to check the 'Interview Guide' response option but, instead, to check 'Other' and then write "Ethnography" in the associated field. In the study design section of the Protocol you can then describe the participant observation and the informal and more formal individual and group ethnographic interviews that will be done without obtaining written consents as part of the ongoing ethnographic study. Remember that for an ethnographic study you must request and justify a waiver of consent in the Protocol.



## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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**1. Procedures to be performed** – describe how you will go about your research activities. What you describe in this section should be a realistic description of the steps and actions you will take as you conduct your research. Be as detailed as possible. Be very specific about the data you will be collecting and what you will be doing with it. Specifically discuss your plans for protecting the subjects' privacy. Also discuss your plans for data confidentiality and/or subject anonymity, if applicable. It may be helpful to include a timeline of your research project, flow charts, or a graph, depending on how complex your procedures are.

See numbers 10-11 in the section on the Initial Application Form.

**Recruitment.** In thinking through your recruitment procedures, you need to attend to the issues of voluntariness and confidentiality. Recruitment within an institutional study presents particular problems in this regard. In such studies, the organization's official cooperation must be obtained. That this is the case likely becomes common knowledge within the institution even before the researcher makes it explicit via the study's Informed Consent Form. Thus, the problem of real or perceived coercion arises. In organizational studies, both the official letter of agreement signed by the appropriate member of management (and included among the IRB application supporting materials) and the Informed Consent Form should address the issues of voluntariness/coercion and of confidentiality, the first of which will be addressed here and the second in the subsection below on Confidentiality.

It is good practice for the researcher to draft the letter of agreement both to save busy organization staff the time and trouble and to ensure that the letter covers everything that should be included. For example, both the letter of agreement and the Informed Consent Form might say:

Although [Organization Name] is partnering in this study, it is understood that the researcher(s) will not tell any members of [Organization Name]'s staff who was approached to participate in the study or whether or not they agreed to participate. Moreover, study participants' names and other personally identifying information will not be used in any oral or written presentations of the study findings. In addition, information provided by interviewees will not be presented in a way that would permit someone to discern the identity of the person who provided that information.

**Voluntariness.** Wording such as "participation in the study is entirely voluntary, a study participant is free to choose not to answer any question, to take a break if s/he wants and to withdraw from the study at any time" is commonly used in Protocols and in Informed Consent Forms to affirm voluntariness. Much of this is great, but the last part is untrue and shouldn't be stated in that way, as a participant cannot withdraw from a study after the findings have been made public.

**Confidentiality.** As noted in the earlier section on things to keep in mind, it is not a requirement that names of study participants and partnering institutions be kept confidential. What is required is that individuals who (or organizations which) consent to participate know the level of confidentiality that is being promised. It is vital to

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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recognize that it is unethical to promise a level of protection that cannot be achieved. If the nature of the study context makes it either certain or likely that those who listen to or read study findings will be able to identify individual participants or partnering institutions, the researcher cannot ethically state in either the Protocol or the Informed Consent Form that confidentiality will be protected. Instead, both should say that such protection cannot be promised due to whatever circumstance makes that promise impossible.

In institutional studies, in which recruitment of study participants typically takes place at the institution itself, it might be difficult, if not impossible, to make sure that others do not know which staff members are approached to join the study and which agree to do so. This is especially true in a study of a small organization housed in a single location. Using all the information s/he has in advance of start of the study, the researcher must imaginatively, but as concretely and in as detailed a manner as possible, envision how the research is likely to unfold and then write the Protocol on that basis.

Participatory action research projects typically involve community members as co-researchers. This must be discussed here. Sometimes the applicant will know the names of some or all of the co-researchers in advance of the start of the project and sometimes not. Anyone named as a co-researcher must complete the required CITI Training in advance of the start of her/his engagement in the research.

As noted in item f. "Other Research Personnel," issues of confidentiality relating to research staff beyond the PI and the Student Researcher must be addressed in this section. If the additional research staff has done research before, you can say this and add that s/he has training and experience in conducting ethical research; if not, you can say you will provide the requisite training and that the person will complete the CITI Training, mandated by the BCPHS, prior to starting work on the project. You might also want to have the staff person sign a confidentiality agreement. Here is an example of a one for a transcriptionist.

### TRANSCRIPTION CONFIDENTIALITY STATEMENT

I understand that I am responsible for upholding the privacy of individuals who participate in this research study, for which I am providing transcription services. To fulfill this obligation, I agree to treat as confidential all the information concerning individual study participants that I learn from formal or informal conversations, emails, written materials, computer files, audio recordings and any other sources during the course of my work on this project. I agree to destroy all electronic files and shred all paper files within one month of receiving payment for the transcription services.

**Interviews.** Rather than saying a specific amount of time each interview will last, indicate an approximate duration. If, for example, in the Protocol you say the interview will be a maximum of one and a half hours, you will have to stop at 90 minutes no matter how interesting what the interviewee is saying may be!

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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Similarly, rather than specifying an exact location for interviews, say they will be conducted at a mutually agreed upon location that affords the necessary privacy. You can give examples of such places, for instance, a meeting room in a local library.

Do not say all interviews will be tape recorded; instead say they will be tape recorded if permission is granted to do so. (See item p. below for information about how to obtain such consent.) It is also important to decide in advance what you will do if a potential study participant does not agree to have the interview taped. Will you not accept that person as a study participant? Will you accept the person into the study and do the interview without taping? In that case, will you take notes by hand or computer? Once you have thought through what you will do, include that in the Protocol and in the Informed Consent Form. Also make sure that relevant responses on the Initial Application Form match what is said in the Protocol.

**m. Anticipated risks and benefits to subjects** – describe any potential risks that subjects may encounter by participating in your research project. Such risks may include but are not limited to psychological stress, loss of privacy or confidentiality, social risks, legal risks, economic risks, or physical harm. If you do not feel that any specific risk to subjects exists, please describe the risks as “minimal,” meaning, “not greater than risks encountered in everyday life”.

All research with human subjects involves some risk, however minimal. Therefore do not say there is no risk. If the risk is minimal say so and identify the nature of the minimal risk(s). Whatever the magnitude and nature of the risk(s), say why you consider it to be of that magnitude and that nature.

Just as there are never no risks involved in research with human subjects, so too there are never any assured benefits. Any benefits are possible rather than certain. For example, study participants might welcome the chance to have their knowledge and experiences benefit others in the future through improved services or they might appreciate the opportunity to talk about issues of importance to them and might find that doing so helps them to clarify their thoughts and feelings.

**n. Provisions for managing risk** – describe steps you will take to manage the risks you described in section m.

If a study covers a sensitive topic, for example, mental health issues, substance use, or HIV status, I recommend that the study procedures include providing contact information for local mental health providers to every study participant at the end of the first interview. This normalizes the presentation of this information and also relieves the researcher of the task of judging who might need such information. Even if the researcher is a mental health clinician, that is not the role s/he is enacting during a research interview. Neither do I recommend adopting the practice of leaving it up to the interviewee to ask for information about health professionals, as the person might not feel comfortable asking or the need might arise later.

Frequently used provisions for managing risk include replacing study participants' names with unique codes and removing other personally identifying information from study data other than Informed Consent Forms and contact information. In qualitative projects, including ethnographic research, it is also common that names and identifying information are not removed in the original study materials

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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but are not included in oral and written presentations. Think in advance of writing the Protocol – and the Informed Consent Form, if any – what provisions are appropriate and doable in light of the nature of the study and of the risks it poses.

One issue of concern to the IRB is the time lapse between taping an interview and transcribing it with the removal of personal identifiers. If your study involves taping of interviews and transcription with removal of identifiers followed by destruction of the tape, estimate the time lapses between each of these steps and indicate them in this section. Note, however, that not all studies that involve taping include transcription, removal of identifiers or destruction of tapes. Some studies involve transcription of only selected sections of tapes, some do not involve the removal of identifiers and some do not include destruction of tapes. All, however, should include detailed description of and justification for procedures and discussion of risks and protections.

**o. Cost and compensation to subjects** – describe any costs to participants of the study. Such costs may include participants' time, transportation, etc. Also discuss any form of compensation subjects will receive, along with the terms and conditions of the compensation.

There is always a cost to participants for their participation, if only the time spent doing so. Additionally, some monetary costs might be incurred to get to the location of an interview. On compensation see number 15 in the section above on the Initial Application Form.

**p. Plans for obtaining and documenting informed consent** – describe the circumstances surrounding consent procedures, remembering that obtaining informed consent is a process, not just a moment in time. Describe the setting in which you will be obtaining informed consent, along with any special considerations you will make for vulnerable or non-English speaking populations (e.g. witnesses or translators). If you will be using children as subjects, please describe both the parental consent and the child assent process. If you would like to request a waiver of informed consent, please do so in this section, detailing the reasons why you are applying for the waiver and the conditions in your project that you believe allow you to request the waiver. (If you need to review the conditions under which a waiver applies, please visit [Human Subjects Research 101](#) on the IRB website.)

An important dimension of voluntariness is that the prospective participant actually understands what study participation entails. That means that s/he understands the Informed Consent Form. Stating in the Protocol and the Informed Consent Form that the researcher will read that Form to each prospective participant is fine if that person cannot read, but it is overkill – and insulting – if that person is literate. Moreover, if you say in the Protocol that this is what you will do, this is what you **must** do, even if it turns out to be inappropriate.

If you have no doubt that prospective interviewees will be able to understand the Informed Consent Form on their own, just state that they will be given time to read it and to ask and have answered any questions they might have about the Form or the study itself and will then be asked to sign.

If you think there is a possibility the prospective interviewee might have a bit of trouble understanding the Consent, you might say everything just indicated plus that

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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prior to asking an individual to sign you will ask a few questions to make sure s/he fully understands what study participation entails.

The established format that the BCPHS approves for consent to tape an interview is to have 'yes'/'no' check boxes for that prior to the signature of consent. That signature then endorses the permission or lack of permission to tape at the same time that it constitutes the consent to participate in the study as a whole. Here's an example:

I agree to have the interview(s) tape recorded: ☐ Yes ☐ No

You should think in advance about whether or not you will interview someone who chooses not to let the interview(s) be taped. I advise that you do so; in that case, you will want to take notes during the interview, which is one reason always to mention in the Protocol that you will take notes during interviews and to check the response option 'Handwritten Notes' in item 8 "Data Recording Method(s)" on the Initial Application Form.

For phone interviews, the BCPHS has approved using oral consents for both audiotaping and study participation, with the researcher documenting these in a written log. Just as permitting the continued presence of the researcher in ethnographic projects constitutes ongoing consent, so too does an individual's continued participation in a phone interview after oral consent is given. Note that asking for approval on the part of the IRB to both oral consent for a phone interview and oral consent for the taping of that interview constitutes a request for alteration to documented informed consent procedures and should be identified as such in this section.

Whether or not individuals and institutions in the study will be named in oral or written presentations about the study must be considered in advance, described and justified in the Protocol and appropriately addressed in consent procedures and Informed Consent Forms. Sometimes an individual (or institution) wants to be named. If, however, the inclusion of that person's (or institution's) name would increase the chance that those who listen to or read study findings could discern the identity of one or more study participant who (or institution which) did not agree to being identified, then the name **must not** be included. Decisions must always favor protection. In this case, you would have to go against the wishes of one, the person who (or institution which) wants to be named, to protect another, the person who (or institution which) does not.

If you choose to give study participants the option to be named, you can include 'yes'/'no' check boxes in the Informed Consent Form followed by a line on which the person can write how they would like to be identified. As with the 'yes'/'no' check boxes for permission to audiotape an interview, these check boxes should appear before the line for the signature by which a person voluntarily consents to participate in the study. For organizations, the issue of being named, including how the organization wishes to be identified, should be covered in the letter/memorandum of agreement. In both instances, the possibility that the name will not appear in order to protect the identity of others should be stated.

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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In action research of various types (e.g., community-based, participatory), people considered study participants in other forms of research are considered co-researchers. In projects of this type, the names of co-researchers are typically not protected but instead are public. Such issues must be discussed as the project is set up and in an ongoing way during the life of the project, including data collection, data analysis and presentation of findings. In such cases, it is important to think through collaboratively as much as possible in advance potential problems in terms of decision-making during the project, ownership of data and rights to publication. It might also be important to put decisions about these issues in writing. This would be akin to an Informed Consent Form but might be titled something like Participatory Research Agreement. Given that such an Agreement would have to be reached through the research process, the plans for it should be described in the Protocol together with a promise to submit the agreement to the IRB after it is developed and consensus reached on its wording.

In ethnographic projects, it is sometimes impossible to protect the identity of individuals and institutions. When this is the case, this must be discussed in the Protocol and also with individuals with whom the researcher is doing participant observation.

q. **Plans for data storage** – describe what you will do with the data you collect, where it will be stored, how long it will be kept, and how it will be destroyed. Investigators should be familiar with the [Brandeis University Information Security Plan](#) and should plan their data storage accordingly.

Important issues here include password protection for computer files; external hard drives, if used, stored securely; cloud storage (indicate nature of encryption, e.g., while being uploaded, stored, downloaded); separate storage for materials with names and personal identifiers (e.g., signed Informed Consent Forms and contact information) and data without.

The expectation of data destruction is another example of wording that reflects particular disciplinary views. In anthropology, for example, the expectation is that field notes, photographs and other ethnographic materials will eventually be deposited in an archive, library or museum. The BCPHS has approved such plans for the deposit of ethnographic data. The important point here is that the Protocol should provide evidence of a plan for handling data that is mindful of the need to protect human subjects.

r. **Bibliography/Citations** – include the works you cited in your protocol (particularly from section g.)

### SUPPORTING MATERIALS

This section will not consider every possible type of supporting material. Instead, it will discuss one form of Study Instrument, namely, an Interview Guide, and also Informed Consent Forms. Other study instruments, recruitment materials and the grant proposal have been mentioned where appropriate in the preceding sections.

#### *Interview Guide*



## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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An interview in which a guide is used develops organically, with the timing and phrasing of questions shaped by the flow of the discourse; the researcher can also choose to examine unanticipated topics that emerge in the course of the interview and, if these are productive, incorporate them into future interviews. On the other hand, an interview in which a protocol is used must unfold in accordance with that protocol, adhering to the wording and the order of questions submitted to and approved by the IRB.

The BCPHS is used to seeing Interview Guides that begin with a short description of the nature of the in-depth interviews to be conducted. Here's an example of an introductory paragraph:

The in-depth interviews in this study will cover the same topics but will do so in an organic way. Questions will not be phrased in precisely the same way from one interview to the next; neither will the questions be asked in the same order. What follows are the key topics to be explored and examples of the types of questions that will be asked. It is possible that interviewees will raise unanticipated topics. These emergent topics will be explored at the discretion of the researcher and will be incorporated into future interviews if they prove relevant to the study.

Although this memo is not a guide to conducting in-depth interviews, a few words about the nature of such interviews are in order because a reader who has neither training nor experience might, on the basis of the above description of an Interview Guide, conclude that an in-depth interview is ad hoc. Nothing could be farther from the truth.

To conduct a productive in-depth interview, it is essential that the researcher think carefully in advance about what s/he wants to learn and how to go about doing that. It is particularly important to figure out when and how to introduce topics and, as part of that, precisely how to word questions, including wording to use and wording to avoid. That the phrasing of questions and the order in which they are posed are often not specified in the Interview Guide submitted to the IRB does not mean that they not considered deeply prior to the start of the study and prior to the start of each interview within the study. In fact, some researchers script each interview in advance even though they are prepared to deviate from that script to permit the interview to develop organically.

The aim of an in-depth interview is to learn about people's experiences, opinions, emotions – their world – in their own words. Consequently, it is vital for the researcher to guide the interviewee while also giving her/him the freedom to choose what to say and how to say it, as well as the opportunity to introduce issues the researcher does not know about or consider pertinent. This is tightrope walking and requires care and balance on the researcher's part.

Often part of walking this tightrope is figuring out in advance how to get at a topic of key interest without providing the interviewee the words with which to discuss it. This is one of the reasons I said earlier that you might want to avoid using your study's central analytical concepts or reveal its hypotheses in either the title or the description of the project goals presented in the Informed Consent Form.

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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Let's say, for example, that you are interested in discrimination and stigma experienced by people who are HIV+ and that to do so you choose to interview HIV+ people only (you could choose to interview other people as well, such as service providers, family members or friends of people who are HIV+, but decision-making regarding sampling is beyond the scope of this memo). You have to say in the Informed Consent Form that HIV+ individuals are being sought as study participants, but you do not have to use either the word discrimination or stigma. Instead you might say that interviews will explore the experiences of people who are HIV+.

In each interview you want the interviewee to introduce these terms, if, in fact, they are relevant to the way s/he talks about and understands her/his experiences. That means you have to figure out how to word questions that guide the interviewee towards the topic of interest in the study without providing the terms 'discrimination' or 'stigma'. You might, for instance, ask an interviewee about people's reactions to her/him as someone who has HIV. Note that this question might yield stories of discrimination or stigma, stories of caring or support or stories of behavior unaffected by knowledge of the person's HIV status.

If after you have given the interviewee numerous carefully phrased opportunities to describe behavior or attitudes towards them related to discrimination and stigma, you do not learn anything about these, you might then choose to ask a more direct question. Remember that in that case both your notes and analysis must take into account that you rather than the interviewee introduced the terms 'discrimination' and 'stigma'.

### ***Informed Consent Forms***

The BCPHS's website provides excellent guidance on the informed consent process and Informed Consent Forms. Below I provide advice concerning issues that have arisen repeatedly in Forms I have reviewed for interview-based studies. Some of these reiterate points made in earlier sections of this document.

- The language should be everyday language, clear, succinct and easy to understand.
- The BCPHS requires that Informed Consent Forms be submitted in all the languages that will be used. This is an example of a situation in which it is possible to submit an application before all materials are ready. In all such cases, what is under preparation should be described in the Protocol and its delivery to the IRB promised as soon as possible. If that is done, the Informed Consent Forms in languages other than English can be submitted without doing a Modification Application. Once the IRB acknowledges receipt of these translations, they can be used in the study.
- With regards to interviews, the scope of topics that will be addressed needs to be presented in a way that ensures that the potential participant knows what s/he will be asked about, but it should not be presented in a way that gives away the study's hypotheses.
- Do not say that all information shared will be kept confidential. After all, the point of any study is to have findings to report. What will be kept confidential is not the information but the identity of the study participant, that is, the person

## ADVICE ON PREPARING IRB APPLICATIONS FOR QUALITATIVE RESEARCH

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who provided the information, and of partnering organizations, assuming such confidentiality is promised.

- Do not say that a study participant can withdraw at any time, as s/he cannot withdraw after the findings have been reported.
- You do not have to promise either anonymity or confidentiality, but you do have to state clearly what degree of confidentiality is being offered and steps that will be taken to protect confidentiality to the degree that is offered.
- Whereas risks must be stated, they should not be overblown. What is said in this section must be consistent with the level of risk indicated in the Initial Application Form and in the Protocol. The wording in the Protocol and in the Informed Consent Form need not, however, be identical.
- Permission to tape record interviews should be indicated using 'yes'/'no' check boxes that appear above the signature.
- Remember that what you say should match what you said about procedures and protections in the study Protocol. For example, if in the Protocol you say you will verbally administer a questionnaire about study participant's characteristics at the end of the first interview, you need to say this in the Informed Consent Form when you describe what the study entails.