

**FORM: International Research Appendix C for Expedited/Full Board Studies**

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If you are conducting research outside of the U.S.A, complete this form and upload this completed form into your eIRB+ application Section 5.1.4. This form may also be used for revised submissions (via a Modification in eIRB+) adding international research sites. **Please delete the sample answers below in blue.**

The IRB requests this information to assist it to evaluate the local research context for this study, and to determine whether or not the protocol provides adequate protection of human subjects for the specific local cultural/social/political conditions.

[**Note:** If deemed necessary by the IRB, the information below may be provided to any consultants reviewing the international element of your work.]

**1. LOCATIONS**

(a) **Please indicate the foreign countries and regions where the research will be conducted.**

Click or tap here to enter text.

**2. QUALIFICATIONS**

(a) **Briefly describe the expertise you/key personnel have, or have access to, that prepares you to conduct research in this location(s), and/or with this subject population(s). Please include specific qualifications (e.g., relevant coursework, background, experience, training, previous research visits, your knowledge of local community attitudes and cultural norms, cultural sensitivities necessary to carry out the research, etc...).**

[**Sample Response:** My research agenda for the past fifteen years has involved investigating the experiences of Caribbean immigrants (and their descendants) within the Black Diaspora, specifically those residing in the United States, Canada, and the United Kingdom. My dissertation and research publications all address many aspects of the Caribbean immigrant experience such as: issues of identity formation, racism, ethnocentrism, gender, social class, education, and familial relations.

I lived in London for six months in 1994 and conducted a research project examining the relationship between Caribbean immigrants and native white Britons. Since that time I have made repeated trips to the United Kingdom to conduct follow-up interviews with my initial respondents.

I am extremely aware of the local community attitudes and cultural norms as not only am I a second generation West Indian myself, but I also have family who reside in London. Between my own up-bringing, having learned about British culture from my family, as well as my own extensive experiences with immigrant communities in London, I believe that I am more than equipped with the cultural sensitivities necessary to carry out the research.]

(b) **What is/are the primary language(s) spoken by your prospective research subjects? Do you/key personnel speak this language (or these languages)? What is your level of proficiency?**

Click or tap here to enter text.

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**3. FOREIGN COLLABORATION**

(a) Do you have an official institutional affiliation or collaboration in the country(ies) in which you will be conducting research? If so, please describe.

Click or tap here to enter text.

(b) Does this research require permission from local community groups, institutions, or government agencies, and/or approval from local IRBs or ethics boards?

i. If so, please indicate the status of obtaining the necessary permission or approvals (e.g., letter(s) of cooperation; notice(s) of approval). If applicable, please indicate if the foreign IRB is designated under an approved foreign Federal Wide Assurance (FWA) and provide the assurance number (see also <https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc> for reference).

Click or tap here to enter text.

ii. If not, please provide an explanation (e.g., such entities do not exist in the relevant geographic area or it would be inappropriate to seek permission from such an entity in the local research context. Please note that the IRB is likely to have heightened concerns about the safety of human subjects (and the investigator) if the nature of the research or the context in which it is conducted causes the investigator to be unwilling or unable to seek the relevant permissions generally required by the local authorities).

Click or tap here to enter text.

**[Sample Response:** I have no formal collaborations, and will be conducting independent field work. I've verified with colleagues in the region that local laws only require approval of my study by an IRB in the U.S.]

(c) Please note that it is the protocol investigators' responsibility to be knowledgeable of and adhere to local laws, regulations, and guidelines.

Please check the box below indicating your acknowledgement of this statement:

Acknowledged

**NOTE:** [The International Compilation of Human Subject Research Protections](http://www.hhs.gov/ohrp/international/) is a listing of the laws, regulations, and guidelines that govern human subjects research in many countries around the world. Investigators must review this document to familiarize themselves with these standards for their research study sites, to help assure that those standards are followed appropriately (see also <http://www.hhs.gov/ohrp/international/>).

**4. INFORMED CONSENT PROCESS**

(a) Indicate the literacy level of adults giving informed consent (check all that apply).

- Illiterate
- 3rd Grade Equivalent
- 8th Grade Equivalent
- High School Equivalent or Above

(b) Discuss how you will assure the voluntary and fully informed participation of the research subjects.

Click or tap here to enter text.

**[Sample Response:** Subjects are made explicitly aware of the questions that they will be asked beforehand, as well as reminded that they can refuse to answer certain questions prior to the interview. Those who consent to be interviewed are prepared for minimally invasive questions. There are no known cultural issues that would inhibit voluntary participation, or

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cause individuals to feel obliged to participate.]

- (c) As applicable, indicate the person(s) who translated the informed consent form(s) used for this protocol, his/her qualifications for providing the translations, and a statement attesting that the foreign-language versions are accurate translations of the English versions.

Click or tap here to enter text.

## 5. RISK TO SUBJECTS

**Definition of Minimal Risk:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy 45 CFR 46.102(i)].

[For this definition, “daily life” should be interpreted in the context of healthy individuals in healthy environments.]

- (a) In your opinion, does this research qualify as “no greater than minimal risk to subjects” within the local context, or is it “greater than minimal risk” within this context? Please provide the rationale for this risk assessment, addressing any pertinent local cultural/social/political conditions (e.g., civil unrest).

Click or tap here to enter text.

**[Sample Response:** This study focuses on one among many risks that affect the lives of Indian slum dwellers. Insofar as it is intended to uncover and assist this population in the making of improved adjustments to flooding, it is likely to have significant benefits for them that far outweigh its minimal risks. Since all subjects are volunteers, there is little risk of coerced participation. Since the questions do not single out specific individuals or groups for critical judgment and do not solicit the attribution of blame, there is little risk of retribution. The only discernible risk that participants may face is personal discomfort about revealing and sharing flood experiences. This has been addressed by providing complete freedom for participants to withdraw from the study before, during or after the survey combined with immediate destruction of existing records.]

- (b) Explain how you will identify and minimize any risks posed to subjects, especially those risks in areas such as confidentiality or coercion that are particular to the local research context.

Click or tap here to enter text.

**[Sample Response:** Questions will be asked about current immigration status. While such is potentially problematic, the data collected will be kept completely separate from all identifying characteristics of the subjects, therefore making it quite difficult for the subjects to be placed at risk under UK immigration laws. More importantly, as I am only asking for first names of the subjects, it will be virtually impossible for the UK authorities to make connections between the information gathered and the specific respondent. In instances where subjects have unique names, I will ask them to assign themselves an alias in the effort to ensure their confidentiality.

Please also note that it will be clear to subjects that they are more than welcome to not answer questions that make them uncomfortable. In my experience, subjects who fear exposing themselves to potential legal action simply choose not to answer the immigration status question altogether.

In regards to the data security/confidentiality being sufficient, I have been conducting data collection in this fashion for many years and have not encountered any problems thus far. I conduct all of the interviews myself, thereby ensuring complete confidentiality. I immediately assign codes when labeling the audiotapes, so in the unlikely event that someone gained access to the tapes, the subjects’ individual data is still protected. I also keep the codes I generate in a location separate from the actual tapes to reduce the ability for someone to be able to link the data to individual subjects.

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I understand that given that I am conducting international research, the handling of the tapes are of the utmost importance. The tapes will be kept in my locked office at Oxford for the duration of the research. Upon my returning to the United States, I will be personally bringing the tapes back with me in my carry-on luggage. While this will be somewhat of a burden, confidentiality can only be assured through this method. I do not believe that mailing the tapes back to the U.S. or even placing them in my checked-luggage are viable options.]

For **minimal risk** research, go to and complete **Section 6**.

For **greater than minimal risk** research, go to and complete **Section 7**.

## 6. Research That Involves Minimal Risk To Subjects

- (a) If this protocol will also be approved by an IRB (or equivalent) in the country/region where the work will be done, then please provide the information requested in Section 3.b.

If 6.a is satisfied then please **STOP HERE**.

For minimal risk research where it is not possible to have the work reviewed approved by a foreign IRB (or equivalent), please provide the following information.

- (b) Please list at least two references that provide information about the local research context(s). These references should provide sufficient information for the IRB to affirm that the study design allows for the protection of human subjects for the specific local cultural/social/political conditions.

Click or tap here to enter text.

[Examples include, for instance, peer-reviewed research publications that provide relevant information about the local research context that would assist the IRB in making its determinations. Such may include the protocol investigators' previously published peer-reviewed papers that are directly applicable to the local context for this protocol.]

### Sample Response:

Demack, S., Drew, D. and M. Grimsley. 2000. "Minding the Gap: Ethnic, Gender, and Social Class Differences in Attainment at 16, 1988-1995," *Race, Ethnicity, and Education* 3:117-143.

Modood, Tariq, Berthoud, R. et al. 1997. *Ethnic Minorities in Britain: Diversity and Disadvantage*. London: Policy Studies Institute.

- (c) Please provide a brief description of how these references provide the relevant information. If practicable, please attach the corresponding article, etc...

Click or tap here to enter text.

**[Sample Response:** Both these references explicitly explore the relation of race and the (first generation) immigrant experience within the British context. In addition to race and ethnicity, each publication addresses issues of education, gender, and social class within the Black British population. These are the same issues that this study is attempting to investigate, albeit with a different generation of subjects. The publications also reveal the importance of studying within the context of London, which is an extremely diverse city similar to that of New York. Investigating the experiences of children of immigrants in London is the next step in understanding the assimilation process for not only those people in Britain, but may also provide researchers with information about the effects of global migration in general.]

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**7. RESEARCH THAT INVOLVES GREATER THAN MINIMAL RISK TO SUBJECTS**

- (a) If this protocol will also be approved by an IRB designated under an approved foreign Federal Wide Assurance (FWA) in the country/region where the work will be done, then please provide the information requested in Section 3.c, as well as copy of the protocol submitted for this review. Please submit both the original and English-translated versions (as applicable).

If 7.a is satisfied then please stop here.

For greater than minimal risk research where it is not possible to have the work reviewed under a foreign FWA, please provide the following information.

[Sections 7.b, c are optional supplemental information that may be provided.]

- (b) Please list at least two references that provide information about the local research context(s). These references should provide sufficient information for the IRB to affirm that the study design allows for the protection of human subjects for the specific local cultural/social/political conditions.

Click or tap here to enter text.

[Examples include, for instance, peer-reviewed research publications that provide relevant information about the local research context that would assist the IRB in making its determinations. Such may include the protocol investigators' previously published peer-reviewed papers that are directly applicable to the local context for this protocol.]

- (c) Please provide a brief description of how these references provide the relevant information. If practicable, please attach the corresponding article, etc.

Click or tap here to enter text.

If there is no personal knowledge of the local research context on the part of one or more IRB members for each of the study sites, then, for greater than minimal risk research, IRB consultation with individuals with personal knowledge of the study sites, or review of the study by a local ethics committee or tribal council is warranted. Protocol investigators may assist with this effort by providing the following information if available.

- (d) You may provide the IRB with the contact information for individuals with personal knowledge of the study site(s), such knowledge having been obtained through extended, direct experience with the subject population and their environment, and who have the necessary research expertise to be qualified to provide an informed and independent review of a protocol summary.

- a. Such consultant(s) would be provided with a summary of the protocol containing sufficient information to make a determination as to whether or not the study design allows for the protection of human subjects for the specific local cultural/social/political conditions.
- b. You may provide this summary to the IRB office; otherwise it will be drafted by the IRB administration.
- c. The consultant(s) will review the summary, and the review is to remain confidential. While maintaining final discretion to determine what information is necessary for it to review a protocol, **the IRB will take under advisement any concerns the investigator may have about confidential, proprietary or other sensitive issues relating to his/her research.**
- d. Based on the summary, the consultant(s) will be asked to verify that, in his or her judgment, under the study design and for the social/political/cultural conditions of the study site that (as applicable): (1) selection of subjects is equitable; (2) privacy of subjects is protected and confidentiality of data is maintained; (3) informed consent is sought in a language understandable to the subject(s) and under conditions that minimize the possibility of coercion or undue influence; and (4) appropriate safeguards protect the rights and welfare of vulnerable subjects
- e. A consultant is just that, a person that the IRB may consult. Final determination of whether to approve or not approve

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a protocol remains with the IRB regardless of what a consultant may advise.

- (e) You may provide the IRB with the name of an appropriate local ethics committee or a tribal council within the country for the study site(s) in question. The protocol could be reviewed by the committee/council, and the information so provided used to assist the IRB in its review.

Click or tap here to enter text.

- (f) It is highly recommended that you indicate circumstances where it would not be appropriate for local ethics committees, tribal councils, or certain individuals to review the research in question, either to protect human subjects, or to preserve the integrity of the research.

Click or tap here to enter text.

- (g) The following means may be used as necessary to identify appropriate consultants, local ethics committee or tribal councils:

Click or tap here to enter text.

- a. Refer to [The International Compilation of Human Subject Research Protections](#) . See also <http://www.hhs.gov/ohrp/international/>.
- b. An organization or department within Rutgers or another academic or research institution.

- (h) It is not acceptable for the consultant to be one of the following:

- a. A friend of the investigator(s).
- b. A collaborator on protocols or grants of the investigator(s).
- c. Anyone who has personal/professional ties with the protocol investigator(s) that precludes him or her (in the opinion of the IRB) from speaking independently and objectively about the research project.
- d. Anyone who in the estimation of the IRB is not qualified to conduct the review.