**LOCAL REVIEW FOR RESEARCH OUTSIDE THE UNITED STATES**

**Background and Instruction for Investigators**

Federal regulations requiring independent review of research involving human research participants extend to research that occurs outside the United States. These regulations also indicate that the review should be conducted by (or include) individuals who are familiar with the norms of the community in which the research is being conducted. See Para. 2.3.2 in the University of Colorado at Boulder [Institutional Review Board Policies](https://www.colorado.edu/researchinnovation/sites/default/files/attached-files/irb_policies_10-28-2019.docx).

The CU Boulder IRB accepts different ways to meet this requirement. One possibility is for an investigator to have their research reviewed by an IRB, Ethical Review Committee, or the equivalent in the country in which the research is being conducted. In this case, you can provide a copy of the approval letter from this committee in lieu of the Local Review Letter described below. In most cases, the project will still need to be reviewed by the CU Boulder IRB, who will rely in part on the review by the host country’s board.

Alternatively, the requirement for local review can be met through the use of a “consultant”. It is your responsibility as PI to find a qualified person who is willing to act as a consultant to the CU Boulder IRB. A qualified person must be aware of local norms affecting your research, and have no conflicts of interest in reviewing your study (for example, the consultant must not be part of your research team, or be funding your study). Ideally, this will be a person with direct experience in overseeing or conducting human research in the proposed location. **The local reviewer will be asked to provide a CV or brief description of their background and experience in the country and type of research proposed.**

The information provided by the Consultant will be used as part of the IRB’s review process. According to the regulations, this consultant may need to be actively involved in the CU Boulder IRB discussion if the study involves higher levels of risk. According to the regulations, this consultant may need to be actively involved in the CU Boulder IRB discussion if the study involves higher levels of risk. For most studies, it would be sufficient to have the local review information provided to the committee using the attached Local Review Letter.

Provide the consultant with the attached Local Review form and instructions (**remove this guidance document**). If desired, you may complete the basic or background information on the form. The form itself should be on the letterhead of the consultant if possible, and signed by the consultant. Normally this should be submitted directly to the CU Boulder IRB office by the consultant.

**LOCAL REVIEW LETTER FOR RESEARCH OUTSIDE THE UNITED STATES**

**Instructions for Local Review Consultant**

Greetings from the University of Colorado Boulder. At our university, we have a requirement that all research that involves people must be reviewed by our Institutional Review Board (IRB). The committee is responsible for making sure the proposed research is safe for those who participate, that participation is voluntary, and that the research raises no ethical concerns.

We are asking for your help in this process. One of our researchers has proposed a study in a location that none of the committee members knows well. Because the committee is unable to evaluate the safety and appropriateness of the proposed research, we are asking for help in reviewing the study.

More specifically, we are asking that you review the researcher’s intended study Protocol and complete the attached form. Please let the committee know of any concerns you might have about the study, or any suggestions you have that might improve the study. These don’t have to be big concerns—we’d also like to know about less serious issues you may have. Please use as much room and as many pages as you like. The committee will then work with the researcher to find ways to solve any problems with the study.

If possible, we would appreciate it you could transfer the form onto your own stationery, attach a business card or something else that indicates that it was you who completed the form. Please provide information about your background and experience in conducting or overseeing research in the area where our investigator is planning to work, either in the location indicated below, or by attaching a copy of your CV.

Once you have completed the form, we would prefer that you send it back directly to the Institutional Review Board, rather than giving it to the researcher. Please send the form to us by e-mail at irbadmin@colorado.edu.

Thank you very much for your help.

 **[Local Contact or Consultant Letterhead]**

## **Local Review Letter**

**[Date]**

Institutional Review Board

563 UCB

Boulder, CO 80309

Dear Committee members:

 I have reviewed [**name of PI**]’s human research protocol, **[title of research protocol],** with regard to its conformance with local customs, research regulations, and research traditions in **[name of country].**

 I understand that [**name of PI**] proposes to **[brief description of research activities to take place in country].**

**Please check one:**

 **\_\_\_\_\_** I have no concerns about this research being conducted in **[name of country/locale]**, and agree that this protocol meets locally acceptable regulatory, ethical and cultural standards of research.

 **\_\_\_\_\_** I have the following concerns regarding how well this study conforms with local customs and research methods: **[please list concerns].**

**Please check one:**

 **\_\_\_\_\_** I have no reservations about the qualifications of the research staff (including translators, transcribers, or others) to conduct this research.

 **\_\_\_\_\_** I have the following questions regarding the qualifications of the researcher or research staff to conduct this research.  **[please list concerns].**

I understand that the researcher intends to translate consent forms and other research materials into the following languages or dialects: **[PI should include list of languages].**

**Please check one:**

 **\_\_\_\_\_** I believe that this set of languages is sufficient.

 **\_\_\_\_\_** I believe that this list of languages is not sufficient. **[please list concerns, in particular include any additional languages or dialects that should be included].**

**Please check one:**

 **\_\_\_\_\_** I have no concerns about the researcher’s plan for explaining the study to participants and for getting their voluntary consent to participate.

 **\_\_\_\_\_** I have the following concerns regarding how the researcher plans to explain the study and obtain consent for participation.  **[please list concerns].**

Do you believe that this study is risky enough that you should be personally involved (such as by telephone) in the Institutional Review Board’s discussion of this study? \_\_\_Yes \_\_\_ No

Other comments or suggestions:

**[If you have any other comments about this study that you believe would aid the Institutional Review Board in its review of this study, please add them here.]**

Sincerely,

**[name and title**

**agency/institution**

**contact information (email preferred)]**

**[Provide a brief description of your background and experience in conducting, reviewing or overseeing human research in the country where this research is proposed, OR include a copy of your CV with this letter when returning it to the IRB]**

Please return this form to the University of Colorado Boulder Institutional Review Board via email as attachment to irbadmin@colorado.edu.