



## **Research Ethics Review (RER) Policy and Toolkit**

25 December 2015

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**CIFOR Research Ethics Review (RER) Process  
Checklist and Cover Sheet**

**I. IN PREPARATION**

- Review [CIFOR Principles of Ethical Research](#) and the CIFOR Research Ethics Review Policy and Process
- Complete online Collaborative Institutional Training Initiative (CITI) [Human Subjects Research \(HSR\) Training](#) (if you haven't done so in the past 3 years). The institution name under which to register is Center for International Forestry Research (unabbreviated). Completion of all required modules and the elective "international research" module of the HSR course, as well as the Responsible Conduct of Research (RCR) course, is required. A minimum score of 80% is required. The Completion Reports are to be sent to HR (Peni Kartika: w.kartika@cgiar.org). Retain CITI Completion Reports to use in this and future RER applications as Document 6 (D6)
- Complete [Research Risk Assessment Summary](#) as Document 2 (D2)

\*\*\*\*\*

**II. APPLYING FOR REVIEW**

*If requesting Exempt Status:*

- Complete [Request for Exempt Status](#) as Document 3a (D3a)
- OR

*If requesting Minimal Risk Review OR Low or Greater than Low Risk Review:*

- Complete [Application for Ethics Committee Review as Document 3b](#) (D3b)
- OR

*Upon expiry of approval period, if requesting Continuation, Modification or Closure:*

- Complete [Request for Continuation, Modification or Closure as Document D3c](#) (D3c)
- AND

- Complete Informed Consent Form OR Informed Consent Letter as Document 4 (D4) (See [Guidance – Informed Consent Forms and Letters](#))

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**III. SUBMISSION**

- Prepare Research Protocol for attachment to application package (including for Requests for Exempt Status) as Document 5 (D5) (There is no format for this. A detailed description of methods to be used is sufficient.)
- Order documents according to their number for submission if submitting on paper.

In case of digital submission, each filename should start with the document number (D1 – D6) followed by "RER APP" followed by the Principal Investigator's last name, followed by the date (sample file name = D2 RER APP Asher 23-3-2015.pdf)

- Attach this Cover Sheet to the application as Document 1 (D1)
- Submit this form with all attachments to:  
CIFOR Ethics Review Committee  
Attn: Lucya Yamin  
CIFOR HQ, Bogor  
E-mail: l.yamin@cgiar.org

**Principal Investigator (or CIFOR Lead Contact) Name:** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

[◀ RETURN TO CHECKLIST AND COVERSHEET](#)

## ***CIFOR's Principles of Ethical Research<sup>1</sup>***

1. Researchers should endeavor to ensure that research is commissioned and conducted with respect for all groups of society, regardless of race, ethnicity, religion and culture.
2. Researchers should ensure that research participants/human subjects are protected from undue intrusion, distress, indignity, physical discomfort, personal embarrassment, or psychological or other harm.
3. Researchers should endeavor to ensure that research is commissioned and conducted with respect for under-represented social groups and that attempts are made to avoid their marginalization or exclusion.
4. Researchers should endeavor to ensure that research is commissioned and conducted with respect for, and awareness of, gender differences.
5. Researchers should endeavor to ensure that the concerns of relevant stakeholders are addressed.
6. Researchers should endeavor to ensure that an appropriate research method is selected on the basis of informed professional expertise.
7. Researchers should endeavor to ensure that the research team has the necessary professional expertise and support.
8. Researchers should endeavor to ensure that the research process does not involve any unwarranted material gain or loss for any participants and/or human subjects.
9. Researchers should ensure factual accuracy and avoid falsification, fabrication, suppression or misinterpretation of data.
10. Researchers should reflect on the consequences of research engagement for all participants and/or human subjects, and attempt to alleviate potential disadvantages to participation for any individual or category of person.
11. Researchers should ensure that reporting and dissemination are carried out in a responsible manner.
12. Researchers should ensure that methodology and findings are open for discussion and peer review.
13. Researchers should ensure that any debts to previous research as a source of knowledge, data, concepts and methodology should be fully acknowledged in all outputs.
14. Researchers should ensure that participation in research should be voluntary.
15. Researchers should ensure that decisions about participation in research are made from an informed position.
16. Researchers should ensure that all data are treated with appropriate confidentiality and anonymity.
17. Researchers should at all times respect applicable national laws, customary rules and norms and international laws when conducting research.
18. CIFOR's research results are International Public Goods and CIFOR staff members should endeavor to assume the public responsibility that such results entail, as well as protect the interest of CIFOR in the dissemination of such results.

[◀ RETURN TO CHECKLIST AND COVERSHEET](#)

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<sup>1</sup> Adapted from Respect Project, professional and ethical codes for socio-economic research in the information society ([www.respectproject.org](http://www.respectproject.org)). Updated: BB/LP 17/4/15

# **Center for International Forestry Research Research Ethics Review (RER) Policy and Process**

## **1. Purpose**

The purpose of this policy is to ensure the ethical conduct of research by CIFOR staff and partners. “Ethical conduct” is that which is consistent with international norms and principles<sup>2</sup>, as articulated by the *CIFOR Principles of Ethical Research*, and recognized through CIFORs Research Ethics Review (RER) Process.

## **2. Implementation**

This policy has been in place since 21 April 2015, and will be enforced strictly as from 1 January 2016.

## **3. Policy**

All CIFOR field research must be approved prior to implementation by the designated RER Committee following the RER application process. All CIFOR Scientists are required to review the [CIFOR Principles of Ethical Research](#). In addition they are required to complete the online Collaborative Institutional Training Initiative (CITI) [Human Subjects Research Training](#) every three years. A minimum score of 80% is required.

## **4. Ethics Review Committee**

The Committee comprises a Chair, qualified representatives of at least two research portfolios, and at least one member external to CIFOR, with an appropriate balance of gender and research interests.

The current committee (April 2015) comprises: Christine Padoch (Chair, Dir LIV), Robert Nasi (Deputy Chair, DDG), Bimbika Basnett (Scientist, GOV & Gender team), Ujjwal Pradhan (Regional Coordinator, ICRAF SEA) and Louis Putzel (Senior Scientist, ENV). The committee will normally meet bi-monthly. A schedule of meetings & deadlines will be posted on myCIFOR.

The Chair will recuse him/herself from approval of applications originating in his/her own research division, with authority for approval automatically delegated to the Deputy Chair.

## **5. The RER application process**

The RER application process must be completed prior to the implementation of field research. The process consists in applying for review following the process outlined in the CIFOR Research Ethics Review Process Checklist. The Checklist describes the step-by-step process and provides links to all necessary documents.

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<sup>2</sup> Relevant international norms and principles include: The *Singapore Statement on Research Integrity* ([www.singaporestatement.org](http://www.singaporestatement.org)); The *Australian National Statement of Ethical Conduct in Human Research 2007 (updated 2013)* ([www.arc.gov.au/general/research\\_integrity.htm](http://www.arc.gov.au/general/research_integrity.htm)); and the *Canadian Tri-Council Policy Statement – Ethical Conduct of Research Involving Humans 2010* ([www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS\\_2\\_FINAL\\_Web.pdf](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf)).

The main elements of the process include:

- Submission of project research protocol
- Provision of evidence of completion of the Collaborative Institutional Training Initiative (CITI) Human Subjects Research Training with the past three years with a minimum score of 80%. Completion of all required modules and the elective “international research” module of the HSR course, as well as the Responsible Conduct of Research (RCR) course, is required. A minimum score of 80% is required.
- Submission of Research Risk Assessment Summary

*If requesting exemption from the review process:*

- Submitting Request for Exempt Status as Document

*If requesting Minimal Risk Review OR Low or Greater than Low Risk Review:*

- Completing Application for Ethics Committee Review

OR

*Upon expiry of approval period, if requesting Continuation, Modification or Closure:*

- Completing Request for Continuation, Modification or Closure

AND

- Completing Informed Consent Form OR Informed Consent Letter

## **6. Determination by the Committee of the level of risk, and assessment of the proposed research in that context**

The Committee will firstly make its own judgment of the level of risk. It may delegate the assessment of risk of nominated minimal risk proposals to the Chair, who must consult with the committee in any case of uncertainty. Based on the Committee’s assessment, it will assess the proposal according to the level of risk assigned, as summarized in Table 1.

Research involving vulnerable and/or marginalized groups, such as children or Indigenous peoples, will normally elevate the level of risk above ‘negligible’.

## **7. Timing benchmarks for application; Expected timeframes for approval**

The project manager is responsible for completing the RER application process prior to accessing project funds and launching a project. In order to ensure that projects start on time, the process can be initiated at any time; it is recommended, however, that applications be submitted as soon as there is an indication that a proposal or concept note will be successful, and at the latest upon notification from a donor that a project is funded.

For projects above US\$300,000, the project manager may receive automated reminders to launch the process through the CIFOR system, and project budgets will not be released until the RER is approved. For project below US\$300,000, the project manager is bound to follow the same schedule, but may not receive automated reminders.

The Committee will provide written advice to the proponent of its decision (approval, rejection or request for revision) in each case.

The expected timeframes for approval of applications are as follows (from date of submission):

Request for Exempt Status: 1 week

Request for Minimal Risk Review: 2 weeks

Request for Low or Greater than Low Risk Review: 1 month

Request for Continuation, Modification or Closure: 1 week

### **8. Reporting back to the Committee by the researcher according to a specified schedule**

Researchers will be required to advise the Committee of their compliance with the approved research protocol by completing the Request for Continuation, Modification or Closure. This form is required at the end of the conduct of the research involving human participants, or annually, whichever is the lesser period.

### **9. Research Partnerships and Compliance to RER**

In research projects conducted by CIFOR researchers in collaboration with partners, the following provisions apply:

- If CIFOR is the lead partner (i.e. the primary grant recipient) CIFOR's RER policy must be followed.
- If a partner institution is the lead partner, either CIFOR's RER policy or the partner institution's RER policy will be followed. If the partner institution does not have an adequate RER policy, CIFOR's RER policy must be followed.

### **10. Compliance to RER policy**

Compliance to CIFOR's RER policy is mandatory. Any researcher conducting field research without RER approval will be exposing him/herself to disciplinary action.

### **11. Revision of RER policy**

CIFOR's RER policy and processes will be revised from time to time as necessary.

### **12. Records**

The Committee will keep records of its decisions, and approved and completed protocols.

**Table 1. Definitions of risk relevant to assessment of proposals**

Term	Definition	CIFOR Ethics Committee action
Risk	<p>“Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or to third parties. A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk.”</p> <p><i>Canadian National Statement, p22.</i></p>	na
Negligible or minimal risk	<p>“Research is ‘negligible risk’ where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.”</p> <p><i>Australian National Statement, 2.1.7</i></p> <p>““Minimal risk” research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.”</p> <p><i>Canadian National Statement, p23</i></p>	Likely to be exempt from review; subject to expedited consideration (i.e., may be delegated to Chair or their nominee)
Low risk	<p>Research is ‘low risk’ where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.</p> <p><i>Australian National Statement, 2.1.6</i></p>	Review by committee; may be expedited, depending on case.
Greater than low risk	Any risk greater than negligible or low risk.	Review by committee; cannot be expedited.
Risk to researchers	<p>“Risks in research are not limited to participants. In their conduct of research, researchers themselves may be exposed to risks that may take many forms (e.g., injury, incarceration). Risks to researchers may become a safety concern, especially for student researchers who are at a learning stage regarding the conduct of research, and who may be subject to pressures from supervisors to conduct research in unsafe situations.”</p> <p><i>Canadian National Statement, p25</i></p>	Consideration in review process

PK, 22.04.14; BB, UP, LP 10.04.15/17.04.15, LP 12.08.15

[◀ RETURN TO CHECKLIST AND COVERSHEET](#)



***CIFOR Research Ethics Review (RER)  
Research Risk Assessment Summary***

Please complete this Risk Assessment Summary<sup>3</sup>, referring as necessary to the CIFOR Research Risk Assessment Guidance (appended as Note 1) and Risk Assessment Checklist (appended as Note 1a). Please note the guidance on categories of risk in Notes 1, 1a, 2 and 3, and please refer to the source documents footnoted for additional guidance.

**1. Vulnerability and Consent**

	Yes	No	Not certain
Does the study involve human subjects who are in any way vulnerable or may have any difficulty giving informed consent?			
Will it be necessary for human subjects to take part in the study without their knowledge and consent at the time? (e.g. covert observation of people in public places).			
Does the study involve research on activities or behaviors that do not comply with national or local laws, potentially increasing the vulnerability of human subjects?			

**2. Research Design/Methodology**

	Yes	No	Not certain
Does the research methodology use deception?			
Does the design of the research project raise any of the risk factors listed in the Risk Assessments Checklist, or any other concerns?			
Does the project involve the handling of any sensitive information?			

**3. Financial Incentives/Sponsorship**

	Yes	No	Not certain
Will the independence of the research be affected, or might it be seen to be affected, by the source of the funding?			
Are there payments to researchers/human subjects that may have an impact on the objectivity of the research?			
Will financial inducements be offered to human subjects?			

<sup>3</sup> Adapted from London School of Economics, Research Ethics Review Checklist.  
This version – April 2014/Revised 17/4/15 BB & LP

**4. Research Subjects**

	Yes	No	Not certain
Is pain or more than mild discomfort likely to result from the study?			
Could the study induce unacceptable social or psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?			
Are drugs, placebos or other substances to be administered to the study human subjects or will the study involve invasive, intrusive or potentially harmful procedures of any kind?			

**5. Risk to Researchers**

	Yes	No	Not certain
Do you have any doubts or concerns regarding your (or your colleagues') physical or psychological wellbeing during the research period?			

**6. Confidentiality**

	Yes	No	Not certain
Are there any concerns regarding confidentiality, privacy or data protection?			

**7. Dissemination**

	Yes	No	Not certain
Are there any particular groups who are likely to be harmed by dissemination of the results of this project?			

**Overall risk assessment**

Guidance

- If all answers to the questions in the two checklists are 'no', your proposal may be exempt from ethics review.
- If some of the answers to the questions in the two checklists are 'yes', your application may or may not fall within the 'minimal risk' category (see Notes below for definitions and guidance, and supporting documents for further guidance).
- If many of the answers to the questions in the two checklists are 'yes', your application is likely to fall in the 'low risk' or 'greater than low risk' categories (see Notes below for definitions and guidance, and supporting documents for further guidance).
- In all cases, you need to make a judgment based on your assessment.

Researcher's Assessment

On the basis of the assessment factors above, and taking into account the definitions and guidance in the Notes below, my assessment of the risk status of the proposed research is:

- Exempt from review
- Minimal Risk
- Low Risk
- Greater than Low Risk

-----  
Signature & name

-----  
Date

**Note 1.**

**CIFOR ETHICS REVIEW COMMITTEE  
Research Risk Assessment Guidance**

Definitions of risk relevant to self- and Committee- assessment of proposals<sup>4</sup>

<b>Term</b>	<b>Definition</b>	<b>CIFOR Ethics Review Committee action</b>
Risk	“Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to human subjects or to third parties. A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk.” <i>Canadian National Statement, p22.</i>	na
Negligible or minimal risk <sup>5</sup>	“Research is ‘negligible risk’ where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.” <i>Australian National Statement, 2.1.7</i> ““Minimal risk” research is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by human subjects in those aspects of their everyday life that relate to the research.” <i>Canadian National Statement, p23<sup>6</sup></i>	Likely to be exempt from review; subject to expedited consideration (i.e., may be delegated to Chair or their nominee)
Low risk	Research is ‘low risk’ where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk. <i>Australian National Statement, 2.1.6</i>	Review by committee; may be expedited, depending on case.
Greater than low risk	Any risk greater than low risk.	Review by committee; cannot be expedited.
Risk to researchers	“Risks in research are not limited to human subjects. In their conduct of research, researchers themselves may be exposed to risks that may take many forms (e.g., injury, incarceration). Risks to researchers may become a safety concern, especially for student researchers who are at a learning stage regarding the conduct of research, and who may be subject to pressures from supervisors to conduct research in unsafe situations.” <i>Canadian National Statement, p25</i>	Consideration in review process

<sup>4</sup> Taken from - For Australia: *National Statement of Ethical Conduct in Human Research 2007 (updated 2013)*, [www.arc.gov.au/general/research\\_integrity.htm](http://www.arc.gov.au/general/research_integrity.htm); for Canada: *Tri-Council Policy Statement – Ethical Conduct of Research Involving Humans 2010*, [www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS\\_2\\_FINAL\\_Web.pdf](http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf)

<sup>5</sup> Note the terms ‘negligible’ and ‘minimal’ are used synonymously in different countries

<sup>6</sup> Note that this is essentially the same definition as that used by IFPRI: “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.” *IFPRI Institutional Review Board, Form 2*

**Note 1a.****CIFOR RESEARCH ETHICS REVIEW (RER)  
Risk Assessment Checklist<sup>7</sup>**

Please consider whether your research involves any of the following risk groups or categories<sup>i</sup>.

**1. Research involving vulnerable groups:**

- minors (without parental or guardian consent)
- members of a socially identifiable group with special cultural or religious needs or political vulnerabilities (e.g. indigenous peoples, ethnic minorities, low castes or status)
- people suffering from psychological disorder
- people dependent on medical care
- people whose ability to give consent is impaired because of disability
- people unable to give free informed consent because of difficulties in understanding information statement (language difficulties)
- those in dependent relationship with researchers (lecturer/student, professional/client)
- participants able to be identified in any report when specific consent for this has not been given.
- people involved in livelihood activities that are or may be deemed as being 'illicit'

**2. Research involving sensitive topics:**

- exploration of grief, death or serious/traumatic loss
- depression, mood states, anxiety
- gambling
- eating disorders
- illicit trade
- substance abuse
- self reporting of behavior that may be deemed as being 'criminal'
- any psychological disorder
- suicide
- gender identity
- sexuality
- disease or health problem
- fertility
- termination of pregnancy
- sensitive cultural issues such as female infanticide, genital mutilation, etc.
- related to conflicts such as civil conflicts/war, physical violence, domestic violence, etc.

**3. Research undertaken in a politically unstable area****4. Research involving groups where permission of a gatekeeper is normally required for initial access to the members.****5. Research in countries where criticism of government, institutions and/or influential individuals might put pa**

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<sup>7</sup> Adapted from London School of Economics, Research Ethics Risk Assessment Checklist.

**6. Research involving deception or which is conducted without participants' full and informed consent at the time the study is carried out, including:**

- concealing the purposes of the research
- covert observation
- audio or visual recording without consent

**7. Research involving access to records of confidential information such as the use of personal data obtained from government agencies or NGOs; use of medical records where participants can be identified or linked**

**8. Research which would induce unacceptable psychological stress, anxiety or humiliation or cause more concern than minimal pain.**

**9. Research involving intrusive interventions:**

- invasive physical procedures
- infliction of pain
- administration of ionizing radiation
- tissue sampling or blood taking
- collecting body fluid
- genetic testing/DNA extraction
- drug trials or other clinical trials
- administration of drugs or placebos
- withholding from one group specific interventions or information, from which they may benefit (economically, socially etc.)
- disregard of personal property, tenure arrangements etc.

**10. Research where a real or perceived conflict of interest may arise which could comprise the integrity and/or independence of the research, due to:**

- the nature of the funding
- the nature of relationship between researchers and research participants

**Note 2.*****ADDITIONAL GUIDANCE - EXEMPTION<sup>8</sup>***

At least one of the following must apply to qualify a protocol as EXEMPT. If none of the following apply, the proposal is subject to review in a higher risk category.

Research involving the collection or study of existing:

- Data
- Documents
- Records
- Pathological, diagnostic specimens

IF THESE SOURCES ARE:

Publicly available

OR

If the information is recorded by the investigator in such a manner that human subjects cannot be identified by anyone, directly or through identifiers linked to the human subjects.

NOTE: If human subjects are identifiable, directly or through identifiers linked to the human subjects, this activity is not exempt. Research involving vulnerable groups, including children, is not exempt, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

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<sup>8</sup> Adapted with permission from IFPRI IRB Ethics Review Form 3

**Note 3.*****ADDITIONAL GUIDANCE - MINIMAL RISK REVIEW<sup>9</sup>*****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.**

Research activities must present no more than minimal risk to humans AND involve only procedures listed in one or more of the following categories in order to be eligible for minimal risk review. If NONE of the following apply, the application requires full review. The categories in the list apply regardless of the age of subjects, except as noted. Inclusion on the list does not mean that an activity is automatically defined as minimal risk, but rather that the activity is eligible for review through the minimal risk review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The minimal risk review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks relate to invasion of privacy and breach of confidentiality are no greater than minimal.

*NOTE: The requirement for informed consent applies regardless of the risk category.*

***Research Categories Eligible for Minimal Risk Review***

- Research employing survey, interview, oral history, focus group methods
- Research on individual or group characteristics or behavior (such as research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour)
- Collection of data from voice, video, digital, or image recordings made for research purposes
- Research involving materials (data, documents, records or specimens) that have been collected previously by CIFOR or other research institutions
- Research involving measurements of body composition (weight, height, skinfold thicknesses or other non-invasive methods)
- Research involving collection of biological specimens (urine, stools, saliva) for research purposes by noninvasive means
- Research involving collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:
  - Healthy, non-pregnant adults who weigh at least 110 pounds, from whom amounts drawn will not exceed 550 ml in an 8-week period, collected no more frequently than 2 times per week
  - Other adults and children, considering the age, weight, and health of the subjects, the collection of procedure, the amount of blood to be collected, and the frequency with which it will be collected. The amount drawn will not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, collected no more frequently than 2 times per week.

[◀ RETURN TO CHECKLIST AND COVERSHEET](#)

<sup>9</sup> Adapted with permission from IFPRI IRB Ethics Review Form 2



***CIFOR Research Ethics Review (RER)  
Request for Exempt Status<sup>10</sup>***

***Section One: Application Information***

**Team:** \_\_\_\_\_

**Title of Proposal:** \_\_\_\_\_

**Principal Investigator or CIFOR contact:** \_\_\_\_\_

**Collaborating Institution(s):** \_\_\_\_\_

**Study Duration:** From \_\_\_\_\_ To \_\_\_\_\_

**Study Location:** Country \_\_\_\_\_ Region \_\_\_\_\_

**Funding Status:**

\_\_\_\_\_ Award Pending

\_\_\_\_\_ Award Pending but funding approved (written confirmation received)

\_\_\_\_\_ Funded Start Date: \_\_\_\_\_ End Date: \_\_\_\_\_

**Name of Funding Agency:** \_\_\_\_\_

**Project Number (if applicable) :** \_\_\_\_\_

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<sup>10</sup> Revised: 19/4/15 BB & LP

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**Section Two: Information for Research Ethics Review (RER) Committee**

1. Please indicate whether or not the project involves human subjects.

Yes

No

2. If you have answered NO to question 1, please provide a short statement of why that is the case. The remainder of the form can be left blank. The research protocol should still be attached.

3. Please indicate whether or not the project has undergone ethical review by a partner organization as grounds for exemption from CIFOR's RER process.

Yes

No

4. If you have answered YES to question 3, please append all relevant documentation including the application for research ethics review and the official document demonstrating approval of the partner organization. Note: CIFOR's RER committee is not required to endorse the review of another organization.

If you have responded YES to question 1 and NO to question 3, please answer each specific question below and use additional sheets as needed. A response of "See attached project description or grant application" is not sufficient.

5. Study objectives:

**6. Human subjects involved in the research:**

a. Describe population of human subjects

b. Does this research involve minors? (*Note: the exemption for interviews/surveys/focus groups does not apply to research involving minors*)

c. How will human subjects be identified and contacted?

d. Are the human subjects involved in the study engaged in activities or behaviors that do not comply with national laws?

- e. How does the research protocol address the requirement for informed consent?

**7. Study Procedures:**

- f. List briefly the main study procedures followed in this activity/protocol

- g. Summarize nature and amount of risk (including side effects), or substantial stress or discomfort involved

- h. What is the source of data, records, or specimens used in this study?

- i. Have the data, records, or specimens to be used in this study already been collected? (*Note: the “existing data” exemption applies only to data, records, or specimens existing at the time of this review.*)

- j. If yes, describe the circumstances under which the data, records, or specimens were collected. Please also provide evidence of approval to access data from the source of the records or specimens

- k. Will your study use records or specimens from human subjects who can be identified directly, or through codes linked to the human subjects?

If yes, please note this activity is **NOT CONSIDERED EXEMPT.**

Eligibility for exemption

Explain how this activity meets the criteria for exemption

***Investigator's Certification Statement  
Request for Exempt Status***

As principal investigator, I acknowledge that this research is being conducted in compliance with CIFOR's Research Ethics Review Policy, and that CIFOR's Research Ethics Review Committee was provided all the information on this research project necessary for this review.

I am responsible for reporting any emergent problems or serious adverse effects or reactions that might occur in the conduct of the research. I understand that a significant change in the scope of work of this research may require that I submit a new application for CIFOR's Research Ethics Review Committee review. This research project will not be put into effect until Committee approval is received.

---

Principal Investigator  
(Signature and name)

---

Date

### Application Status (For RER Committee Use Only)

\_\_\_ Approved    Date: \_\_\_\_\_    Approval Expires: \_\_\_\_\_

\_\_\_ Denied    Date: \_\_\_\_\_

\_\_\_ Referred for further review    Date: \_\_\_\_\_    Minimal Risk \_\_\_ Full \_\_\_

Comments:

\_\_\_\_\_  
**RER Committee Chair or Delegate**  
(Signature over printed name)

\_\_\_\_\_  
**Date**

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***CIFOR Research Ethics Review (RER) Process***

***Application for RER Review: Minimal, Low or Greater than Low Risk***

***Section One: Application Information***

Principal Investigator or CIFOR lead	
CIFOR Team	
Title of Proposal	
Collaborating Institution(s)	
Study Duration	
Study Locations	
Funding Status	<ul style="list-style-type: none"> <li>• Pending</li> <li>• Funding approved but not formalized</li> <li>• Funded – specify dates</li> </ul>
Funding agency	
Project number or identifier (where applicable)	

For administrator use

CIFOR Ethics Review Proposal Number	
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***Section Two: Information for Ethics Committee Review***

Please answer each specific question, attaching additional sheets as needed. A response of “See attached project description or grant application” is not sufficient.

**1. Objectives of Research: (Summary)**

**2. Selection of Study Subjects**

- 1. Approximate number of subjects: \_\_\_\_\_
- 2. Age range of subjects \_\_\_\_\_

3. Do you anticipate including any members of vulnerable groups?

(Refer to checklist, Note 1a appended to CIFOR RER Document D2 Research Risk Assessment Summary) if so, which?

4. Do you anticipate covering any sensitive topics?  
(see checklist, Note 1a appended to CIFOR RER Document D2 Research Risk Assessment Summary) if so, which?

5. What are your selection (inclusion) criteria?

6. What exclusion criteria apply? Explain the rationale for these criteria.

7. What are the primary languages of the human subjects?

**3. Recruitment and Compensation**

a. How will potential human subjects be identified?

b. Will human subjects be paid? If yes, how much? What is the basis for payment and for deciding the amount of payment?

c. Will non-monetary inducements or incentives be offered to human subjects? If yes, describe.

- 
- d. Will other services, compensations be offered to individuals, households or communities?  
If yes, describe.

**4. Research Procedures and Data collection**

- a. Does the research involve an intervention? Yes \_\_\_\_\_ No \_\_\_\_\_

- i. If so, what is the unit of intervention (individual, household, community?)

- ii. What is the method of allocation of the intervention to individuals, households or communities (e.g., random, self-selection, other)?

- b. List the different component of the research procedures, e.g. what activities, measurements will be done to the human subjects and how much time will be required of the human subjects for each activity?

c. What other expectations, requirements are there from human subjects?

d. Will you access existing stored records, data, or specimens for secondary research use? If yes, specify the source.

e. Will your activity involve collection and analysis of biological specimens for research purposes? If so, which types of specimens? Describe training/qualifications required for staff who will collect specimens and/or protocols to ensure safety of staff and subjects.

f. Will your activity involve collection/storage of specimens for future research analysis? If yes, how does your informed consent document address this issue?

**5. Risk vs. Benefit Analysis**

*Risks to human subjects may include physical risks, emotional or psychological risks such as stress, discomfort, or invasion of privacy; and social risks, such as jeopardy to insurability, employability, or social status. Sources of risk may include drugs, venipuncture, biopsy or other*

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*invasive procedures, over-treatment if treatment is based on symptomatic diagnosis; sources of risk may also include questionnaires on sensitive topics, recordings (audio, video or photography), or risk associated with failure to maintain confidentiality.*

- a. Summarize the nature and amount of risk (including social, emotional, psychological, or physical) or substantial stress or discomfort involved in participation in research.

- b. Are there any anticipated adverse effects? If yes, indicate section of proposal where these are described.

- c. Summarize planned provisions for monitoring for possible adverse effects during and after data collection.

- d. Summarize planned provisions for addressing acute health or other problems when identified through data collection (such as severely malnourished children, identification of severe micronutrient malnutrition, domestic violence which may be associated with the intervention, etc.)

- e. Will there be extra costs to the subject or families related to their participation in the study (e.g. transport). If yes describe.

- f. Summarize the nature of the benefits for the human subjects, their community or for humanity. Explain how the benefits outweigh the risks.

**6. Confidentiality**

- a. Describe the steps taken to assure that participation by study subjects will be kept confidential. Be specific.

- b. What safeguards are used to protect against identifying directly or indirectly, any human subject in the research project?



- c. Describe provisions for control over access to documents and data. What safeguards are used to protect information from disclosure to others not involved with this research project?

- d. Describe procedures to remove or destroy at the earliest possible opportunity, consistent with the purposes of the study, information that would enable a human subject to be identified.

**7. Informed Consent**

*Informed consent is required for all research involving human subjects. All applicable items on the attached list of required elements (p. 7 of this form) must be included in the informed consent document. **Documentation of informed consent is required for all research projects unless a waiver of documentation of consent is obtained (section 8).***

- a. What type of consent will be used?

- \_\_\_\_\_ Written consent signed by human subject or human subject’s legal guardian
- \_\_\_\_\_ Oral consent with documented signature by the human subject or human subject’s legal guardian (i.e. human subject or legal guardian gives oral consent in front of witness who documents consent for each human subject/legal guardian)
- \_\_\_\_\_ Oral consent statement or written study overview not requiring documented signature (waiver of documentation of consent) *If choosing this option, complete section 8 below.*

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b. Describe the consent process: What and when will the consent process occur?

c. Who will obtain consent?

d. Will a witness be present? If yes, who will serve as witness?

e. Describe any measures other than the consent form used to confirm the human subject's understanding of the research. Attached copies of written materials used for this purpose.

**8. Request for waiver of documentation of consent**

CIFOR's Ethics Committee may waive the requirements for documentation of consent if the investigator confirms that:

- a) The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.

OR

- b) The research presents no more than minimal risk of harm to subjects (as determined by the Ethics Committee) and involves no procedures for which written consent is normally required outside the research context.

If requesting a waiver of the requirement for documentation of consent, explain how this research meets the criteria for waiver, per the above conditions a) or b):

9. **Local ethical review**

- a. Has this research activity undergone ethical review by a local institution (collaborator or other if collaborator does not have an institutional review board), or is such a review planned?

Yes \_\_\_\_\_ No \_\_\_\_\_

If No, please explain why no local ethical review is planned.

If Yes, what institution is responsible for this review?

**10. Use and benefits of research findings to study human subjects**

- a. How will your research results benefit the subjects/informants of the research?

- b. What plans do you have for feeding back research findings to informants and/or other stakeholders in the research setting?

Revision: BB/LP 12.07.15

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***CIFOR Research Ethics Review (RER) Process***

***Investigator’s Certification Statement***

***Minimal, Low, or Greater-than-low Risk Review***

I hereby certify that:

- all procedures performed under this study will be conducted by individuals legally and responsibly entitled to do so;
- the study will not be initiated until CIFOR’s Research Ethics Review Committee’s Approval is granted;
- the consent form used in the study will bear a statement indicating CIFOR’s Research Ethics Review Committee’s approval;
- any modification to the study protocol, e.g. change in principal investigator, research methodology, subject recruitment procedures, etc., will be submitted to CIFOR’s Research Ethics Review Committee for its approval prior to implementation (except where necessary to eliminate apparent immediate hazards to subjects, in which case CIFOR’s Research Ethics Review Committee will be notified immediately after implementation)
- any adverse reactions experienced by subjects involved in the research will be immediately reported to CIFOR’s Research Ethics Review Committee
- all CIFOR’s Research Ethics Review Committee decisions, conditions and requirements will be complied with; and
- all research will conform to legal and other requirements governing human research in the country in which it is conducted.

Principal Investigator’s (or CIFOR’s lead contact) signature

\_\_\_\_\_ Name (type or print)

\_\_\_\_\_ Date

*Note that Ethics Committee approval needs to be renewed every year during the full duration of the research project. A “Request for Continuing Review” (Form ) needs to be submitted to CIFOR’s Research Ethics Review Committee no later than 30 days prior to expiration of the current approval (i.e. 11 months from today)*

<p><b><i>FOR USE BY Ethics Committee ONLY:</i></b>  <i>Date for receiving “Request for Continuing Review”</i> _____</p>
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### Application Status (For Ethics Committee Use Only)

Approved: \_\_\_\_\_ Date: \_\_\_\_\_ Approval Expires: \_\_\_\_\_

Denied: \_\_\_\_\_ Date: \_\_\_\_\_

Referred for further review: Date: \_\_\_\_\_ Minimal Risk Review \_\_\_\_\_ Full Review \_\_\_\_\_

Comments:

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<hr/> <p><b>Signature over printed name</b> <b>Ethics Committee Chair or Delegate</b></p>	<hr/> <p><b>Date</b></p>
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**CIFOR Research Ethics Review (RER) Process****Request for Continuation, Modification or Closure<sup>11</sup>**

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**NOTE:** For continuation or modification, please submit this form together with an Application Cover Sheet (Form 2) and a copy of the original approved application (Form 3).

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**Section One: Application Information**

Division: \_\_\_\_\_

Title of Proposal: \_\_\_\_\_

Principal Investigator or IFPRI contact: \_\_\_\_\_

Collaborating Institution(s): \_\_\_\_\_

Study Duration: From \_\_\_\_\_ to \_\_\_\_\_

Study Location: Country \_\_\_\_\_ Region \_\_\_\_\_

**Funding Status:**

\_\_\_\_\_ Award Pending

\_\_\_\_\_ Award Pending but funding approved (written confirmation received)

\_\_\_\_\_ Funded Start Date: \_\_\_\_\_ End Date: \_\_\_\_\_

Name of Funding Agency: \_\_\_\_\_

Project Number (if applicable) : \_\_\_\_\_

Date of original RERC approval for this project: \_\_\_\_\_

(see page 15 of "Application for RERC review" (Form 3))

Date of last approved "Request for Continuing Review": \_\_\_\_\_

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<sup>11</sup> Revised: 17/4/15 BB & LP



**Section Two: Information for Review Committee**

Please answer each specific question and use additional sheets as needed. A response of "See attached project description or grant application" is not sufficient.

## 1. For continuation or modification

1. What is the date of the current approved Informed Consent Form \_\_\_\_\_
2. Please submit a copy of your most current approved Informed Consent Form (if applicable)
3. Total number of subjects studied:
  - a. This past year \_\_\_\_\_
  - b. Combined total \_\_\_\_\_
4. Do you have a signed informed consent form for each subject involved?
  - a. Yes \_\_\_\_\_
  - b. No \_\_\_\_\_ (provide reason)
5. Has there been a change in the research protocol? (If yes, please attach a sheet addressing the changes)
  - a. Yes \_\_\_\_\_
  - b. No \_\_\_\_\_
6. Are there any problems with human subjects to report? (If yes, please attach a sheet to explain)
  - a. Yes \_\_\_\_\_
  - b. No \_\_\_\_\_
7. Is this study closed to further human subject involvement?
  - a. Yes \_\_\_\_\_
  - b. No \_\_\_\_\_

## 2. For closure:

Date of completion \_\_\_\_\_

\_\_\_\_\_  
(Signature over printed name)  
Principal Investigator (or CIFOR contact)

Date

**Application Status (For IRB Use Only)**

Approved for \_\_\_\_\_ months.                      Date: \_\_\_\_\_

Denied: \_\_\_\_\_    Date: \_\_\_\_\_

Comments:

\_\_\_\_\_  
**(Signature over printed name)**  
**IRB Chair or Member**

\_\_\_\_\_  
**Date**

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***CIFOR Research Ethics Review (RER) Process  
Guidance – Informed Consent Forms or Letters<sup>12</sup>***

**Note:** There is no form for RER Document 4 (D4). Please append the Consent Form/Letter to this document and submit as D4.

***Elements of Informed Consent Forms/Letters***

The informed consent of human subjects must be obtained and documented prior to their participation in research conducted by CIFOR scientists and their teams and collaborators. The standard informed consent process includes provision of information about the research project (as described below) and receipt of a signed consent form documenting each subject's consent to participate. In contexts where asking human subjects to sign forms is not feasible or inappropriate, oral consent may be sufficient.

1. **Purpose of research:** Provide a clear, concise explanation of the research including the name of the study and its main objectives.
2. **Methods, procedures:** Describe methods, procedures of the study. Explain what will be happening to the subject during the study, and indicate the time commitment of each component and other expectations from human subjects. If study involves an experimental design and/or random allocation of subjects to different intervention groups, explain procedures in language that subjects can understand.
3. **Risks:** Describe the frequent and/or important risks, side effects or discomforts of the study procedures.
4. **Benefits:** Describe any benefit from participating.
5. **Voluntary participation:** State that the subject's participation is voluntary, that the subject may refuse to participate before the study begins, discontinue at any time, or skip any questions that may make him/her feel uncomfortable, with no affect or penalty or loss of benefits to him/her.
6. **Request for information:** state that the subject is allowed to ask questions concerning the study, both before agreeing to be involved and during the course of the study (see required contact information in #11 below).
7. **Confidentiality:** describe how subject's confidentiality will be protected
8. **Use of the information:** describe how the data will be used when the study is completed.
9. **Use of recording devices** (where applicable): describe how audio or video equipment will be used and what will be done with the tapes upon completion of the study (destroyed, erased, archived, etc.) and after which period of time (number of years). Provide a separate signature line on the consent form for the subject to agree to be video/audio taped or photographed.
10. **Copy of the signed and dated consent form:** indicate that the subject will receive a copy of the signed and dated consent form;

**OR**

**Documentation of oral consent** either on the questionnaire being used for the research or on a separate roster maintained for that purpose.

11. **Contact information:** provide the name(s) of the investigator(s) and contact information.

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<sup>12</sup> Adapted with permission from IFPRI IRB Ethics Review Form 2

12. **Additional contact information:** indicate that the subject may contact the Ethics Committee Chair at CIFOR with any concerns or complaints. Include email address, phone number and website
13. **Approval:** Indicate at the bottom of the form: “Consent form approved by CIFOR Ethics Review Committee on [date]”.

**Note: If subject is under the legal age of consent, parental consent is required.**

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<sup>i</sup> Adapted from London School of Economics, Research Ethics Risk Assessment Checklist.  
This version – March 2014

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