Art by Sudarshan Shaw

ETHICS AND SAFEGUARDS

FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

WCS INDIA

Ethics and Safeguards for Research Involving Human Participants

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01

INTRODUCTION

WCS-I envisions a world where wildlife is valued by societies that embrace and benefit from the diversity and integrity of life on earth and therefore enable biodiversity conservation in healthy lands and seas. Empathy, respect, accountability and transparency, innovation, diversity and inclusion, collaboration and integrity are values that we consider to be at the heart of our organization. It is therefore of great importance to us that every research project that we carry out is true to the core values that we uphold as an organization. A part of this is the process of reflecting upon ethical considerations of the impact and repercussions that our projects have on people and finding ways of reducing the negative impacts and the risk of negative impact.

Since the publication of the Belmont Report in 1979, researchers across various disciplines and geographies have articulated the relevant ethical concerns associated with conducting research with human participants. This report as well as later reports such as the Declaration of Helsinki, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (ICMR), Guidelines for Ethical Considerations in Social Research & Evaluation in India (CMS-IRB) provide a framework upon which organizations such as ours can build our own processes and guidelines for evaluating ethics.

01: INTRODUCTION

All studies that involve human subjects in the conservation and ecological sciences must follow a strict set of guidelines that are aimed at ensuring that the study follows the principles of social justice and dignity, maintains personal privacy and autonomy, and that no physical or psychological harm comes to study participants.

The *WCS-India Ethics and Safeguards* document is an amalgamation of pertinent points from several important existing documents that discuss ethical concerns regarding working with human participants; especially in the context of India and the field of wildlife conservation research. Centrally, this document builds on the pre-existing WCS-India Ethics and Safeguards (2020) document and the Wildlife Conservation Society Institutional Review Board Procedures (2020) document. Though both of these documents are already strong and discuss several important ethical considerations, this document aims at making the Human Ethics IRB process at WCS-India more robust and nuanced in its consideration. The Ethics and Safeguards documents of other conservation organizations such as the Nature Conservation Foundation, Dakshin and Ashoka Trust For Research In Ecology And The Environment have been used while creating this document. Furthermore, this document also relies on the Constitution of India as well as other laws and policies such as the Prevention of Atrocities Act, 1989 and Forest Rights Act 2006 which articulate the rights afforded to the people of our country.

02

PROCEDURES

A) WCS-India IRB Committee

The WCS-India Institutional Review Board (IRB) is set up to review and decide whether each research project proposed to be carried out by people at WCS-India is sound according to the ethics and safeguard parameters of our institution.

The IRB committee will consist of two internal members from within the organization as well as four external members. The internal as well as the external members of the IRB will be instituted by the board members of WCS-India in consultation with the country director and the academic committee. Significant work experience in the field of social science research, prior social science peer reviewed publications and academic qualification in a social science subject are important criteria to consider when identifying IRB members. If an IRB member is part of the research project that needs IRB approval or works under the PI that has applied for an ethics approval, the IRB member can recuse themselves from evaluating that application. IRB members are appointed on a rotational basis for a term of 2 years, after which the academic committee will identify and appoint new IRB members.

External IRB members conduct ethics reviews without the expectation of monetary benefit. It is therefore extremely important for us to recognize their generosity and respect the time and effort they are contributing for the betterment of our projects. In order to ensure that we do not overburden the external IRB members, four external IRB members will be identified, out of whom two members will be approached by the internal IRB members for each project application on a rotational basis. The academic committee is requested to choose members with complementary social science expertise between the four external IRB members, so as to ensure sufficient diversity and competence within the internal review board.

PRESENT IRB COMMITTEE

Internal IRB members:

- Saloni Bhatia
- Gargi Sharma

External IRB members:

- Hita Unnikrishnan
- Siddhartha Krishnan
- Meera Ooman
- Sahil Nijhawan
- Manish Chandi
- Ovee Thorat

The application forms (Annex I) have to be submitted to the two internal IRB committee members. The internal IRB committee members will then do a preliminary evaluation to determine whether the application is suitable for exemption or whether the application is complete and suitable to send to external reviewers (Table 1-A). The internal committee members will then forward the application to two of the four external committee members according to expertise and availability. The IRB committee will then conduct a review of the application and decide whether the application is rejected, accepted or needs revision (Table1-B). The IRB members can use the guidelines provided in the next section and Annex II to determine whether the application must be accepted or rejected. If the IRB committee sees that an application cannot be accepted in its current state but has the potential to be accepted with a few suggested changes, the IRB committee can choose to ask the applicant for a revised application.

Once the applicant re-submits the revised application to the internal IRB members, the IRB committee will do a final review of the application and determine approval or rejection of the application. If the application is rejected, the internal IRB members will send the applicants an email which will include an explanation of the reasons why the application was rejected. If the application is accepted the committee will send a formal IRB approval letter which will include the approval number. It is recommended that researchers should plan to submit their research proposal for review **at least one month prior** to the start of field work, so as to allow sufficient time for the IRB process.

TABLE 1: TIMEFRAMES FOR REVIEW PROCESS

	PROCESS	TIMELINE
A	Determining IRB exemption	3 working days
B	Initial review	15 working days *(3 weeks)*
C	Final review	5 working days *(1 weeks)*
D	Changes to the project	5 working days *(1 weeks)*

An IRB approval letter is valid to conduct the project for a period of 3 years from the date of approval. Long term projects that are conducted for more than three years have to periodically (every 3 years) undergo IRB re-evaluation. For re-evaluation, 'Human Research Ethics Re-evaluation Form' (Annex 1C) should be submitted to the IRB committee. Using this, the internal IRB committee will ascertain whether the project or the IRB process has changed significantly over the last three years to warrant a resubmission of the IRB form or

minor enough (ref to subsection C) to directly provide IRB approval for 3 more years. It is the responsibility of the PI to keep note of the time period for which IRB clearance has been provided and apply for re-evaluation before validity of IRB clearance expires. IRB should receive a copy of any publication (eg. academic papers, reports, popular media publication, presentations) that is produced through the projects that have gained ethics clearance. It is the responsibility of the PI to ensure that a copy of the publication is sent to the IRB committee. The IRB members can use the publications to cross-check if the ethical measures detailed in the IRB form have been implemented during the study.

B) IRB exemption

All WCS-India projects that propose to carry out research that involve human participants have to send an application to the WCS-India IRB human ethics board. However, if the proposed research falls within the criteria for exemption (as listed below) from IRB scrutiny, the researcher/conservationist can file an IRB Exemption Form (Annex 1A) with the IRB instead of the Human Ethics form. The IRB committee rather than the PI of the project will determine whether or not a project requires IRB clearance.

The internal IRB committee will determine whether the project can be sanctioned as an exemption from the IRB review. The IRB committee can use the exemption criteria provided below to determine the sanctioning of exemption. For convenience, researchers as well as IRB members may also use the WCS IRB decision tree provided in Annex II.

The criteria for exemption for projects involving human subjects are as follows:

i) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

ii) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement). Eg. post workshop assessment of knowledge gained.

iii) Research involving the gathering of behavioral, structural and procedural information from non-interactive observation of human subjects in public spaces. Eg. observational market surveys (however there is a separate risk assessment process for market surveys).

iv) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(a) Public benefit or service programs

(b) Procedures for obtaining benefits or services under those programs

(c) Possible changes in or alternatives to those programs or procedures

(d) Possible changes in methods or levels of payment for benefits or services under those programs

However, there are several factors that have to be considered before exempting any research project from an IRB review. Any research project, **including the kinds of projects listed above**, cannot be exempt from IRB if:

i) Any project where the information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and any disclosure of the human subjects' responses outside the research could rea sonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation cannot be exempt from IRB.

ii) Research that includes individuals from vulnerable populations is not exempt from IRB review, even if the project falls within one of the exemption categories. Definition of vulnerable populations include children, pregnant or nursing women, physically hand capped persons, mentally disabled or cognitively impaired persons, certain indigenous groups, elderly and aged persons, economically or educationally disadvantaged persons, students or employees of the researcher or his/her employer, traumatized persons, and

persons otherwise at risk for unjust persecution or having diminished capacity for consent. Under this definition, marginalized communities in India including commun ties notified as Scheduled Caste, Scheduled Tribe and Other Forest Dwelling Commun ties are also considered as vulnerable populations. For further description of vulnerable populations refer to subsection (D) in the 'Ethics and Safeguards for Research' section of this document. Please note that if the research methodology does not exclude children or vulnerable populations from participation, the project will not be eligible for exemption.

iii) Any project where even a part of the project is conducted in a region notified under the V Schedule or VI Schedule cannot be exempted from IRB review.

iv) Any project that involves people working within WCS-India or people working within the forest department as participants for the research project/conservation initiative cannot be exempted from IRB review.

v) Any project that contributes to generalizable knowledge in the form of research papers, publications, reports or any other publicly available documents cannot be eligible for exemption. Any research that informs or aims to inform future conserva tion interventions would be considered as contributing towards generalizable knowledge and therefore cannot be exempt from IRB review.

The following forms are made available on the WCS-India Website:

- IRB Exemption Form
- Human Ethics Form for Research
- Changes and Continuing Review form

C) Changes to the project

Through the course of a research project, modifications are sometimes made to the study design in response to unforeseen circumstances, or improved understanding. All modifications to human subjects' research must be reviewed and approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subjects. There is a separate 'Human Ethics Re-evaluation Form' made available for informing the ethics committee about the changes made to a project (Annex 1C). This form must be sent to the IRB internal committee members. The internal IRB members will determine whether the changes made to the study are Major, warranting a re-evaluation by the IRB board; or Minor such that the internal members can issue an approval. The same 'Human Ethics Re-evaluation Form' and criteria should also be used for the re-issue of IRB approval beyond 3 years of a project. The criteria provided below can be used to help determine whether the project has to undergo re-evaluation.

Minor modifications include those that do not alter the risk–benefit assessment for the research. Examples include changes in the investigators; minor changes in the consent form(s), recruiting materials, measures, or procedures; minor changes in compensation, time of participation, or subject recruitment or the use of a new site that is not materially different from a previously approved site. Minor modifications may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experience with the protocol.

Major modifications include significant protocol changes that would cause subjects to engage in activities not previously approved; or that involve an increased level of risk to the physical, emotional, or psychological well-being of participants (including the loss of confidentiality); that involve a decreased benefit; or that otherwise result in alteration of the risk–benefit assessment for the research. For example, adding a new subject population, adding new measures that significantly differ from those currently approved, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality are all potentially major modifications.

D) Multi-Institutional Collaborative Research

With respect to research involving multiple institutions, the WCS IRB acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations.

While each institution may elect to provide concurrent review of the research activities pursuant to its own IRB policies and procedures (e.g., where the research takes place at multiple sites and each site's IRB will review the protocol for research to be conducted at its respective site), in many instances concurrent review is not warranted. In such a situation, WCS-India may enter into a signed "reliance agreement" (also known as an authorization agreement) with the other institution(s), pursuant to which WCS-India agrees to rely upon the review of another qualified IRB or the other institution(s) agree to rely upon the review of the WCS-India IRB. The WCS-India IRB committee will help determine the need for and nature of the reliance agreement.

03

GUIDELINES FOR RESEARCH WITH HUMAN PARTICIPANTS

A) Informed Consent

The principle of 'Free, Prior and Informed' consent expresses the belief in the need for truthful, ethical and respectful exchange between researchers and the individuals and communities that they study. A participant cannot be involved in research unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative. Investigators should ensure that they seek consent only under circumstances that provide the prospective participant sufficient opportunity to consider participation without coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

Presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice. Investigators are responsible for ascertaining that the subject has comprehended the information.

It is to everybody's benefit that ambiguity over research questions and answers are not lost in translation and semantics to participants as well as in representing our understanding of cross-cultural settings and experiences. We need to be aware of possibilities in objective or subjective ambiguity that can result through our often short term engagements (due to temporal and financial constraints) with local communities. Every effort should be taken through research design in subjective, qualitative, quantitative and objective research methods to ensure that misrepresentation does not take place through our field research. Researchers must particularly ensure that the field staff hired to carry out the research are sufficiently trained to appropriately implement the gaining of free, prior, standardized informed consent. We should recognize our obligations to provide unambiguous information to the community (participating) we interact with, the research community we share our findings with, managers and decision makers who may make use of our research results as well as information to the lay public. Informed consent should not include exculpatory language i.e. language that makes it seem like the participant has waived legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

It is important to think about gaining free prior informed consent not only from the individual participants but also from the community with whom the research is conducted. Though this might not be relevant in an urban or semi-urban landscape, it is relevant to consider community consent from the gram panchayath and village elders in rural areas, and mandatory for conducting research with Schedule Tribes in Schedule V and Schedule VI regions to gain community consent from the gram panchayat or village council respectively (Articles 244(2) and 275(1) of the Indian Constitution, 1950). This is in recognition of the customary rights that indigenous communities have to protect traditional knowledge, and self determine as a

community whether or not they want to share traditional knowledge (Article 29 and Article 350 of the Indian Constitution, 1950, UNDRIP, 2008) In such cases, applicants should specify a two-part process: first for obtaining Free, Prior and Informed Consent or a collective agreement to conduct research in a specific community, and then obtaining consent from specific individuals participating in research.

Below is a list of the kinds of information that should be communicated to the participants and community representatives in order to meaningfully gain informed consent.

i) The purpose of the study

ii) Expected duration of the subject's participation, a cursory description of the methods employed

iii) The anticipated consequences of the research

iv) The anticipated uses of the data

v) Possible benefits of the study

vi) Potential risks of participating in the study, and possible harm or discomfort that might affect participants

vii) The degree of anonymity and confidentiality which may be afforded to informants and subjects

viii) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject

ix) The forms of publication in which the data given by the participant will be shared with the public/or other specific stakeholder

x) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

xi) Any potential conflicts of interest

xii) When technical data-gathering devices such as audio/visual-recorders and photo

graphic records are being used, those studied should be made aware of the capacities of such devices and be free to reject their use.

The persons studied must have the legal capacity to give consent. In this context, please note that there are strict laws when minors (individuals less than 18 years old) are involved in a study. Where this is the case, permissions must be obtained from parental authorities (or legal guardians) for the minors to participate in the project, and these permissions must be clearly documented for the records in oral or written format. The principle of informed consent, as noted above, will here apply to both the parental permissions and the agreements by minors to participate in the study.

Where subjects are legally compelled (e.g., by their employer or government) to participate in a piece of research, consent cannot be said to have been meaningfully given by subjects. In such cases it has to be ensured that informed consent is gained from each participant outside the pressures of the governing bodies. Special care has to be taken to communicate that no individual is compelled to participate in the study and have the right to refuse participation.

DOCUMENTATION OF INFORMED CONSENT

Ideally informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. It has to be ensured that the written consent form is in the language that the participant can read and comprehend completely.

In cases where it is not possible or deemed inappropriate to gain signed written consent, audio documentation of oral consent can be used. The use of audio recorded oral consent is particularly considered appropriate in several parts of rural India where a portion of the population might be illiterate. However, investigators have to ensure that their study design includes the audio recording of informed oral consent.

It is important to document not only the individual consent gained from the participants but also any collective consent gained from the communities where the research is taking place. While it is prefered that the community consent is also documented in writing, researchers can use their discretion to decide to document consent through the minutes of a meeting and photographs of a meeting held with the community. The researcher can also propose any other culturally appropriate way of documenting consent, which will be evaluated by the IRB committee.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

i) That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

B) Confidentiality and Anonymity

What researchers consider as data is often private and confidential information for respondents. Researchers must respect every individual's right to be free from unauthorized or unreasonable intrusion, including control over the extent, timing and circumstances of obtaining personal information from or about them. It is important for researchers to recognize the confidence, trust and understanding based on which participants share their private information for the sake of research.

Private information includes any information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (medical history, finances, home address or GPS coordinates) as well as behavior that occurs in a context where

an individual would reasonably expect no observation or recording is taking place. Affording confidentiality involves the collection of only the minimal necessary information and taking steps to anonymize the data, to ensure that information can't be traced back to participants of the study.

Particular care should be taken to protect sensitive information such as personal behavior (sexual preferences, drug use etc.) illegal conduct and information which if released could result in damage to the participant in terms of financial well-being, employability, or reputation. It is the responsibility of the researcher to ensure that the participant does not suffer from any form of hardship, discrimination or stigmatization as a consequence of having participated in the research or experiment. It is important to ensure that all persons involved in the research project (including researchers, volunteers, interns, translators and locally hired field staff) maintain anonymity of the participants and the confidentiality of the information shared by the participants. Names and any other individual identifier information must be stored separately from the electronic devices, paper, audio or video recordings that serve to document the research. Photographs, audio and video recordings often have metadata associated with them, which jeopardies anonymity. Researchers must take measures to ensure that the metadata is removed from all electronic files before it is stored or shared. What this means to the participant is that her/his family, friends, community or government will never know the answers that they provide to us.

Researchers often use transcribers and translators external to the project team to process social science research data. In order to maintain confidentiality, the PI has to ensure that the raw data is anonymised before the data is given to the transcriber or translator. This may involve processes such as deleting certain sections of the audio recording, changing names to codes in transcripts and blurring of faces in photographs and videos. Though this might be a time and effort intensive process, it is extremely important to ensure that we as researchers do not breach confidentiality.

Representing information from the field through academic publication or other means and media has to consider the sensitivity of the local communities through such representation. The representation of information provided by the participant has to come from a place of trust and understanding between the participant and investigator.

During the process of gaining informed consent, the PI should ensure to explicitly communicate the degree of anonymity and confidentiality which may be afforded to the participant. If the PI believes in an obligation to report, or plan on reporting, any information associated with illegal activities, or any specific information that they deem relevant for conservation, to enforcement agencies or other stakeholders, this must be stated explicitly to the participant as part of gaining prior informed consent.

PIs should also ensure that they follow all the norms and requirements articulated in the Non-Disclosure and Confidentiality Agreement of WCS-India, especially when planning how to protect and share the data procured through their research.

C) Risks and Benefits

Participation in research can pose several types of risks to the potential participants involved in the research including physical risk, psychological risk, legal risk, economical risk or social risk. It is the responsibility of the PI to determine all the potential risks that their research might pose to the participants and analyze the probability and magnitude of each envisioned harm. Researchers must strive to minimize the risks posed to the participants as much as possible, ensuring that this has been given due consideration when designing the research methodology. Though the IRB committee understands that some risks might be inevitable and unavoidable, it is important to distinguish between cases that simply inconvenience the investigator and those that invalidate the research.

As part of the process of gaining prior informed consent, the researchers must inform all the participants of the potential risks of participating in the research (question 14 of Human

Ethics Form for Research, Annex 1 can be used in formulating this). This will assist the participants to determine whether or not to participate in the study. While there is always an obligation to ensure that information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research.

There is potential for a research project to negatively impact not only the participants but also the local field staff hired for carrying out the project. While researchers, who are often not from the landscape, rarely continue to reside in the area beyond the project duration, for the locally hired staff our study area is their home. Conducting the proposed research can pose physical, psychological, legal, economic or social risks to the locally hired staff due to their history and future in the landscape. It is important for researchers to recognize these potential risks and factor in ways to reduce these risks in their study design.

It is important for researchers to recognize that they are not entitled to participants. It is out of a willingness rather than a compulsion that participants engage with the study or share information. The Belmont Report discusses beneficence, the obligation of a researcher and research itself to do good and be beneficial. Rather than thinking of research as a purely extractive process, researchers must reflect upon the ways in which their proposed research is beneficial; to the participants involved, to the communities they represent and to society at large. Similar to there being different kinds of risk, there are different kinds of benefits that researchers can anticipate from their work, such as; physical benefits, psychological benefits, economic benefits, livelihood benefits, social benefits and legal benefits.

The anticipated benefits of a study can be utilized towards the justification of the risks endured by the participants due to the research. However, in this context it is important to take notice of who potentially faces risk and who potentially benefits from the research conducted and ensure equality in this process. The importance of sharing benefits equitably is also highlighted by the National Biodiversity Authority in the Biodiversity Act, 2002. Researchers must

therefore conduct a systematic, non-arbitrary analysis of potential risks and anticipated benefits of their study. Members of the IRB can utilize this to analyze whether the risks outweigh the benefits or the benefits outweigh the risks and determine whether or not to approve the proposed research.

D) Vulnerable Populations and Marginalized Communities

It is important to recognize that participants identified as belonging to vulnerable populations might by privy to additional ethical concerns especially due to; limitations in decision making capacity, situational circumstances, risk of exploitation (NBCA 2001). In such circumstances, it is the responsibility of the researcher to take additional effort to address these vulnerabilities in the conceptualization of the research methodology and its implementation. It is of particular importance to the IRB that vulnerable populations are given due consideration in the process of i) gaining free, prior, informed consent without undue influence ii) anonymity of the participants and confidentiality of the information provided during research iii) evaluation of risks and benefits of the research project.

Vulnerable populations include persons with a limited or compromised autonomy, such as children, pregnant or nursing women, physically handicapped persons, mentally disabled or cognitively impaired persons, certain indigenous groups, refugees, ethinc minorities, elderly and aged persons, economically or educationally disadvantaged persons, students or employees of the researcher or his/her employer, traumatized persons, and persons otherwise at risk for unjust persecution or having diminished capacity for consent. Researchers must strive to understand vulnerabilities not only in terms of vulnerable populations as a whole but also in terms of intersectionalities where individual participants may be impacted by layers of multi-category vulnerabilities (CIOMS 2016).

Economically disadvantaged individuals are those who are under-resourced to provide for themselves or their families, and experience particular hardships due to disparities and

inequalities in the society in which they live. These situational factors can affect or limit the subject's voluntariness to participate in research. For example, the prospect of getting monetary compensation for participation in research could significantly affect the willingness to participate, influencing the subject to accept greater risks of harm than they would otherwise accept. Socially marginalized individuals are those who lack influence in society or standing for a socially constructed reason (such as caste, race, religion, or disease state). Individuals who are socially marginalized often lack adequate access to social organizations such as the legal system. The potential for undue influence or manipulation is higher for these subjects.

INCLUSION/EXCLUSION OF VULNERABLE POPULATIONS

In some types of research, a vulnerable group may be the primary group on which the research is conducted because the investigation is focused on the source of vulnerability. This means that the research burden is heaviest on the group based solely on the presence of their vulnerability. This also could mean that those who experience this vulnerability may be the primary beneficiaries of the research results. According to the concept of justice in the Belmont Report, research with a vulnerable group may be acceptable.

Some individuals or groups who are vulnerable may become the study focus merely for ease or convenience of access, or because risks of harm or burdens to them are trivialized, as the group is undervalued. This is a significant issue and should be monitored carefully. There are historical cases of prisoners or wards of the state being studied because of convenience when there were more appropriate study groups to enroll. This was the case for both the Jewish Chronic Disease case and the Willowbrook case. In these instances, researchers enrolled populations that were both undervalued by society and convenient for them to study.

Designing studies to exclude individuals or vulnerable groups from the research because of the complications and additional requirements for studying them is problematic (either real or perceived). In this case, the lack of inclusion hurts the ability to advance understanding and the underlying science and denies the group the potential benefit of research.

(Extract from the CITI training program module on Ethics)

The Scheduled Castes and the Scheduled Tribes (Prevention of Atrocities) Act, 1989 provides additional protection for people belonging to castes and communities termed as Scheduled Castes (SC) and the Scheduled Tribes (ST) according to article 366 of the Indian Constitution. The Forest Rights Act, 2006 discusses the right of access for SC/ST and Other Forest Dwelling Communities to biodiversity and community rights, to intellectual property and traditional knowledge related to biodiversity and cultural diversity. As WCS-India seeks to afford the highest standards of protection to its research participants, communities that have been recognized as an indigenous community in any one state of India will be considered as an indigenous community, regardless of state variations. All researchers conducting studies that may include participants belonging to communities notified as SC/ST and Other Forest Dwelling Communities must ensure that they have read the aforementioned acts, be cognizant of all the laws and rights they articulate and must abide by them.

The Provisions of the Panchayats (Extension to the Scheduled Areas) Act 1996 recognizes the importance of safeguarding and preserving the traditions and customs of the people, their cultural identity, community resources and the customary mode of dispute resolution. This act also grants the Gram Sabhas in the Schedule V regions a degree of self governance as well as the responsibility of safeguarding the traditions and customs of the Scheduled tribes in the region. The VI Schedule (Articles 244(2) and 275(1) of the Indian Constitution) , grants similar autonomy for self governance and responsibility towards cultural heritage and traditions to the District Councils and Regional Councils in the Tribal Areas of Assam, Meghalaya, Tripura and Mizoram. It is mandatory for all the research projects with study areas falling under Schedule V or Schedule VI to gain informed consent from the local governing bodies of the region (Gram Sabha/Regional Council). However, WCS-India encourages researchers to, as much as possible, gain informed consent from not only the individual participants but from the community elders/ local governing bodies whenever relevant.

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04

ANNEX 1

The following forms are attached below:

A) Exemption form

B) Human Research Ethics Form

C) Human Research Ethics Re-evaluation Form

05

ANNEX 2

Does your study require an IRB review?

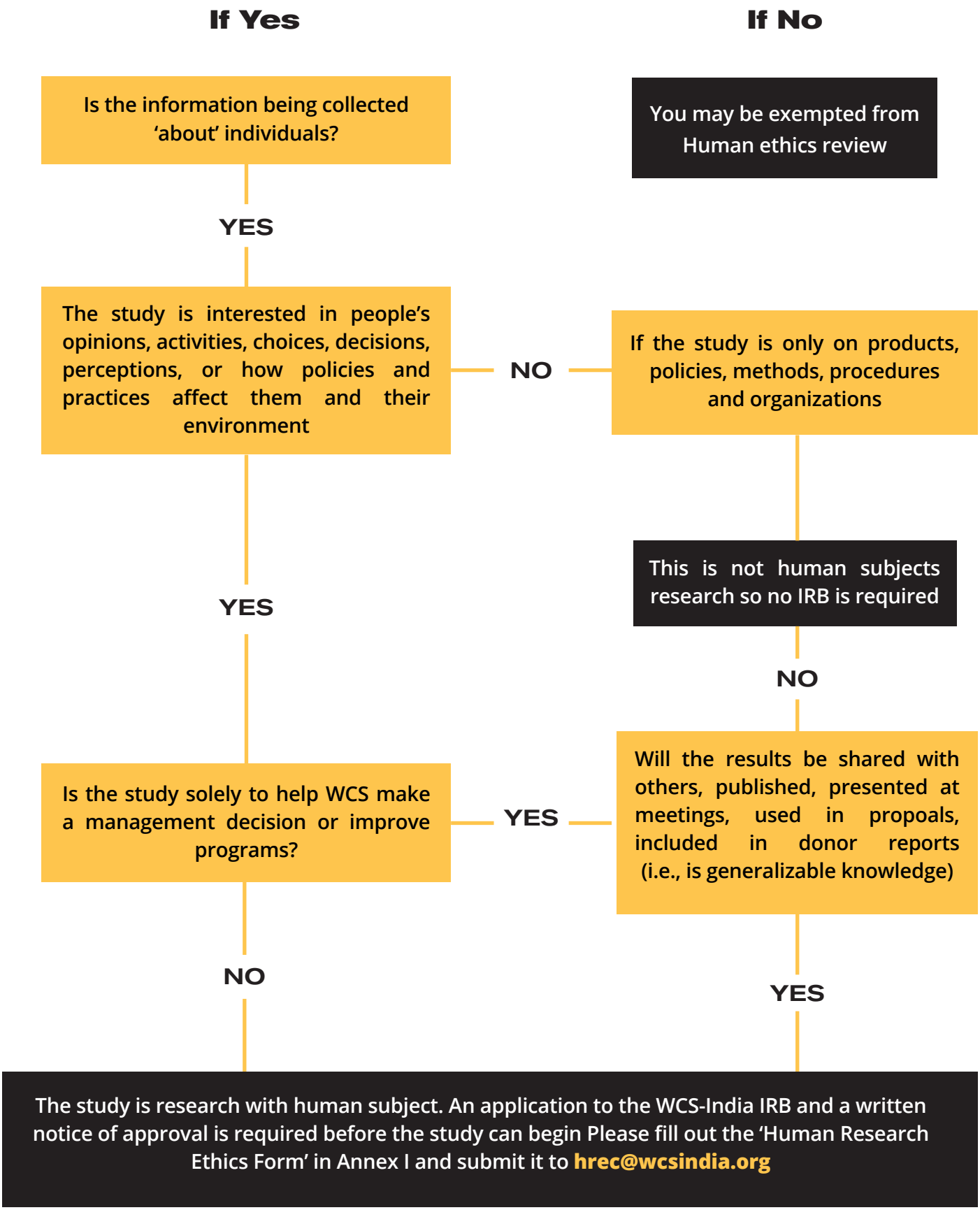
DECISION TREE 1

WILL YOU, A MEMBER OF YOUR RESEARCH TEAM OR A COLLABORATOR OBSERVE, INTERACT WITH, OR INTERVENE WITH INDIVIDUALS TO GATHER INFORMATION THAT WILL BE USED FOR RESEARCH?

For example:

- Surveys, questionnaires, focus groups, interviews
- Games, experiments in physical or in electronic environments
- Physical or biomedical procedures – imaging, scanning, blood collection, anthropomorphic procedures
- Diet, nutrition studies, taste tests
- Studies examining effectiveness of educational or conservation tools or curricula
- Use of instruments or devices, including phones or GPS co-ordinates, to collect data or monitor or influence behavior
- Passive observation of public behavior (in physical or online environments, including social media) Studies examining individuals' responses to manipulation of their physical or online environment
- Another activity that involves observation of, or interaction with, individuals to gather information for research

05: ANNEX 2


If Yes
If No
Is the information being collected 'about' individuals?
You may be exempted from Human ethics review
YES
The study is interested in people's opinions, activities, choices, decisions, perceptions, or how policies and practices affect them and their environment
NO
If the study is only on products, policies, methods, procedures and organizations
This is not human subjects research so no IRB is required
YES
NO
Is the study solely to help WCS make a management decision or improve programs?
YES
Will the results be shared with others, published, presented at meetings, used in propoals, included in donor reports (i.e., is generalizable knowledge)
NO
YES
The study is research with human subject. An application to the WCS-India IRB and a written notice of approval is required before the study can begin Please fill out the 'Human Research Ethics Form' in Annex I and submit it to hrec@wcsindia.org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