INTRAC Policy

Code of Research Ethics

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1. Introduction

In keeping with its vision and values, INTRAC is committed to maintaining the highest standards of ethical conduct. This Code of Research Ethics details INTRAC's expectations of employees, external consultants, and volunteers undertaking research on behalf of our organisation. This could refer to research as part of delivery (i.e. data collection and analysis for a client), research as part of a collaborative research project (i.e. with a research partner), research designed and delivered by INTRAC with external grant funding, or in-house research funded from INTRAC's own resources and related to INTRAC's strategic objectives and learning agenda.

This document should be read in conjunction with INTRAC's Code of Ethics, INTRAC's Code of Conduct for employees and consultants, as well as our Safeguarding Policy.

2. Fundamental Ethical Principles

The set of ethical principles outlined in this document align to the Fundamental Ethical Principles that INTRAC upholds in all its work:

- Beneficiaries first
- Integrity
- Openness
- Right to be safe

As a provider of professional services, we furthermore uphold the following principles:

- Objectivity
- Professional competence and due care
- Confidentiality
- Professional Behaviour
- Environmental Protection

A more detailed description of INTRAC's fundamental ethical principles is available in our general Code of Ethics.

3. Ethical Principles for Research

Following the above principles, INTRAC upholds a set of specific principles related to undertaking research. These principles have been developed to ensure that we maintain the highest standards of ethical behaviour, and to promote core objectives of research such as generating verifiable data, contributing to knowledge, as well as avoiding error and subjectivity. INTRAC's ethical principles for research furthermore promote values that are essential for collaboration in research, ensure that researchers can be held accountable for their work, and contribute towards public support for research.[1]

These principles apply to any form of primary or secondary data collection undertaken by INTRAC, and should be applied to the entire research and evaluation cycle: commissioning, planning and design of research (1), data collection, management and analysis (2), reporting and dissemination (3) and monitoring and/or follow up (4). It therefore encompasses activities undertaken across INTRAC's research, consultancies, training and programme work. Where INTRAC is contracted to deliver research, in the event that clients or partners do not have similar procedures in place, we will default to these procedures.

Building on our fundamental ethical principles, INTRAC's ethical principles for research include:

- Safeguarding in research ('do no harm' principle)
- Protection of data and intellectual property
- Scientific objectivity (objectivity in research)
- Honesty and integrity
- Accuracy
- Openness and accountability in research
- Responsible reporting and publication

3.1 Safeguarding in research

Our first and foremost ethical principle for research is to protect the physical, social and psychological well-being of all research participants – also referred to as 'do no harm'. Adhering to the principles of declarations on international human rights[2] and international rights of research participants[3], we will ensure to uphold the participants' rights to:

- Protection from physical, mental and emotional harm and exploitation
- Human dignity
- Informed consent
- Voluntary participation
- Withdraw from a study
- Privacy, confidentiality and anonymity

[1] David B Resnik (2015). *What is Ethics in Research & Why is it Important?* Accessed on 28 November 2019, via: https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm

[2] United Nations General Assembly (1948). *Universal Declaration of Human Rights (UDHR).* https://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf

[3] 18th World Medical Association General Assembly (1964). *WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.* https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

- Autonomy[4]
- Access to information regarding research

When conducting research with and/or on human subjects, INTRAC will always seek to minimize harms and risks and maximize benefits of the research activities, and shall strive to distribute the benefits and burdens of research fairly.

We will take special precautions with vulnerable populations, including but not limited to children, refugees, people living with a disability, people in ill-health (this includes both physical and mental health), and people from discriminated and/or marginalized communities. INTRAC undertakes research activities in a wide range of geographical, cultural, and legislative contexts, and acknowledges that vulnerability is highly dependent on the context. The vulnerability of research participants and related risks should be assessed on a case-by-case basis.

The 'do no harm' principle goes beyond the research participants we directly work with and will also be considered for the wider community where we undertake research as well as researchers and other staff involved. We thereby adhere to the UK Collaborative on Development Research (UKCDR) definition of safeguarding as *"preventing and addressing any sexual exploitation, abuse or harassment of research participants, communities and research staff, plus any broader forms of violence, exploitation and abuse such as bullying, psychological abuse and physical violence."*[5]

In order to avoid unintended harm to the wider community and other third parties, we are committed to undertaking a risk assessment of the research activities prior to data collection.

INTRAC's polices relating to protecting staff from harm are set out in INTRAC's Code of Conduct, and documented in INTRAC's Employee Handbook. Specific consideration should go to women, junior researchers and local fieldworkers who are more likely to be at risk of harassment by fellow researchers and/or risks posed by challenging or high-risk research contexts, topics, and relationships.

Our safeguarding in research principle outlined in this section, goes hand in hand with INTRAC's fundamental principle of 'Beneficiaries First' as well as principles described in our Safeguarding Policy.

3.1 Protection of data and intellectual property

INTRAC will seek to uphold participants' contractual and/or legal, interests and rights in data, recordings and publications in line with our Data Protection Policy. We will only hold data that is needed for a specific organisational purpose (see section 2.1. of the Data Protection Policy for further specification), and we will not retain data longer than is necessary to achieve that purpose. Our procedures are compliant with the European Union General Data Protection Regulation[6] (see section 1.6 of the Data Protection Policy).

In terms of research, this means that all research data gathered will be carefully collected, processed, stored and ultimately deleted. We strive to mitigate the ethical concerns arising from the use of personal data by anonymising our data samples as much as possible. We furthermore aim to minimise our data risks by only collecting the data that we need in order to meet our research objectives, and by placing restrictions on accessibility and sharing of data that we hold.

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[4] Autonomy (or respect for people) demands that the ability of competent subjects to make their own decisions be recognized and respected, while also protecting the autonomy of the vulnerable by preventing the imposition of unwanted decisions (Owonikoko 2013, Oncologist, 18(3): 242-244).

[5] UKCDR (2020) Guidance on Safeguarding in International Development Research.

[6] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679

We furthermore uphold data retention arrangements and regulations, and are committed to removing all personal data 6-months after completion of the study (defined as payment of the final invoice), or to anonymise personal information within 6 months of completion of the study where we are contractually obliged to retain research data for a longer period of time.

Distinction should be made between contractual research work undertaken by INTRAC (i.e. INTRAC operates as Data Processor) and internal research (i.e. INTRAC is the Data Controller).[7] For contractual work, we will inform clients of our commitment to protect data and intellectual property and enquire about their data protection policies. We will ensure that these commitments are reflected in the contract.

In terms of general intellectual property rights, INTRAC will abide with patents, copyrights, and other forms of intellectual property of individuals and organisations. We will not use or share unpublished data, methods, or results without permission, and shall always seek to provide acknowledgement or credit for all contributions to our work by means of suitable referencing.

3.2 Scientific objectivity

The principle of scientific objectivity aligns to our fundamental principle of objectivity. INTRAC will not allow bias, conflict of interest or the undue influence of others to compromise our professional or business judgement. For research, this specifically refers to avoiding bias in the design of methodologies, in undertaking data analysis and data interpretation, and in reporting and communication of research findings. Where appropriate, an additional consultant/researcher will be assigned to provide quality assurance on these aspects. INTRAC will ensure to disclose all personal, organisational and financial interests that may affect our research.

3.3 Honesty and integrity

Building on INTRAC's fundamental ethical principle of integrity, we strive for honesty in all our communications. Research undertaken by INTRAC shall clearly and honestly report on methods and procedures, data and results, including a critical reflection on limitations of methods and gaps in evidence. We will ensure that data is not fabricated, falsified, misrepresented or purposefully misinterpreted. We strive to deliver information that will not deceive colleagues, clients, partners, donors, nor the public.

3.4 Accuracy

At INTRAC we always aim for accuracy, supported through robust methodologies, avoidance of careless errors and negligence. We will seek to carefully and critically examine our own work and that of our colleagues (staff and non-staff). It is our goal to keep clear and consistent records of all research activities, including research proposals, data, reports, and correspondence with collaborators.

3.5 Openness and accountability in research

Openness is one of INTRAC's Fundamental Ethical Principles. With regards to research this additionally means that – within the limits of any contractual obligations to clients or partners - we are willing to share data, results, ideas, tools and resources as much as possible[8]. INTRAC is dedicated to sharing research results with participants and other stakeholders as much as possible to encourage openness and to contribute to accountability and feedback mechanisms. We furthermore aim to be open to collaboration, critique, and new ideas related to our research

7 Data Controller is the legal person who decides how data is collected, held and processed, a Data Processor is engaged by a data controller to process data as instructed.

8 Thereby considering protection of our commercial interests as an organisation delivering consultancy services and training.

activities. We therefore commit to always negotiating with clients and partners the parameters for openness in research.

3.6 Responsible reporting and publication

In line with INTRAC's mission, we strive to advance knowledge on strengthening civil society and shifting power to the global south. Within the limits of contractual obligations, reports and publications will be used to inform our own work, the work of clients, or the general public. We will strive to avoid unnecessary and duplicative reports and publications merely aimed to advance our own organisation or individual careers of the people who undertake research on our behalf.

When INTRAC is involved in preparation and review of scientific publications, we will seek objectivity in processes of peer review and author contributions.

4. Research Ethics in Practice

The Ethical Principles for Research as outlined in the previous section have practical implications for all research activities undertaken by INTRAC staff, volunteers, contracted consultants and research partners. This includes the implementation of safeguarding and whistleblowing procedures, procedure for obtaining informed consent prior to data collection, as well as procedures and policies for data storage. These procedures will apply to all research developed and delivered by INTRAC.

4.1 Safeguarding in research in practice

Researchers and principal consultants who are leading primary data collection should ensure that all staff (including support staff such as data collectors and translators) who operate in the field and are in direct contact with research participants and communities:

- Have been provided, read and understood this Code of Research Ethics
- Have read and understood INTRAC's Whistleblowing Policy, and Complaint or Concern Procedures.
- Have contact details of the Principal Researcher leading this study, as well as INTRAC's designated Safeguarding Officer.

Refer to Annex A for handout templates on safeguarding in research. For more information, please refer to the Safeguarding Policy.

4.2 Informed consent

INTRAC researchers will always obtain informed consent prior to data collection. This means that each research participant and individual consulted in relation to the delivery of our work will be provided with information on the research and will be informed of their rights related to research participation. This process can be completed in writing or verbally, and includes two components (1) provision of information, (2) obtaining consent for participation in the research.

The information provided must include the following elements:

- Introduction of research and researchers
    - Purpose of study
    - Type of research and methodology
    - Participant selection
- Statement related to voluntary participation on the part of the individual
- Procedures
- Duration
- Risks

- Benefits to the individual or the community
- Reimbursements that the participant may be entitled to
- Confidentiality
- Sharing the results
- Right to refuse or withdraw
- Contact details

Following the provision of information, we will obtain consent. This is preferably done in writing but can be done orally, which may be more appropriate in contexts where written consent is not standard practice or where the participant has concerns about written consent. It can also be practical in the case of audio-recorded conversations. INTRAC will amend the informed consent procedure for those who require additional assistance; this includes an amended informed consent process for minors and their parents/guardians, for people living with a disability and for people who are illiterate.

Refer to Annex B for a practical example of the informed consent procedure and INTRAC templates for informed consent.

4.3 Data protection in practice

Researchers and principal consultants who are leading primary data collection are the assigned data owner. The data owner is the person responsible for defining the rules for holding, processing, retention and security of that type of data. In practical terms this means that the data owner needs to ensure that:

- He/she is familiar with INTRAC's Data Protection Policy.
- Data is stored in an appropriate manner on the secure shared drive of INTRAC as soon as possible.
- All staff working on the research project is aware of data storage and data protection policies (i.e. share and adhere to Annex C)
- Data protection is reflected in contracts with external consultants who are involved with data collection.
- INTRAC adheres to our commitment to remove all personal data 6-months after completion of a research project and/or closure of a consultancies contract, or to anonymise personal information within 6 months of completion of the study where we are contractually obliged to retain research data for a longer period of time.
- In case of contractual work, agreements on data retention and sharing of data are reflected in the contract.

Refer to Annex C for a more practical protocol on data management.

5. Reference Documents

In addition to the references provided in the footnotes, INTRAC's Code of Research Ethics is broadly based on the following sources:

- Civil Service - Government Social Research Unit. GSR Professional Guidance: Ethical Assurance for Social Research in Government
- DFID (2019) DFID ethical guidance for research, evaluation and monitoring activities*
- European Union (2018). Ethics in Social Science and Humanities.
- Shamoo A and Resnik D. 2015. Responsible Conduct of Research, 3rd ed. (New York: Oxford University Press).

- UKCDR (2020) Guidance on Safeguarding in International Development Research.*
- Various international declarations and codes:
    - The Belmont Report
    - The Declaration of Helsinki
    - The Foundation for the Ethical Conduct of Clinical Research
    - The Nuremberg Code
    - UN Declaration for HR

*Especially the sources by DFID and UKCDR contain practical information and a series of questions to be considered when developing research proposals.

ANNEXES

A. Template Safeguarding Handout for INTRAC Researchers and Support Staff

[Name of Project]
[Name of Principal Consultant]
[Name of Organisations involved with project]
[Name of Client and/or Donor, Funder]

As INTRAC we have a duty of care towards the people we work with. This includes research participants, communities and other stakeholders as well as our own staff, consultants and volunteers. It is therefore important that you read and understand this safeguarding handout prior to undertaking work on behalf of INTRAC.

What is safeguarding?

Safeguarding is the responsibility of organisations to make sure their staff, operations, and programmes do no harm to the people they work with. It focuses on preventing and addressing any sexual exploitation, abuse or harassment of research participants, communities and research staff, plus any broader forms of violence, exploitation and abuse such as bullying, psychological abuse and physical violence.

Special consideration should go to vulnerable populations who are more at risk of being harmed, this includes but is not limited to children, refugees, people living with a disability, people in ill-health (both physical and mental health), and people from discriminated and/or marginalized communities.

How does safeguarding fit in with Research Ethics?

INTRAC's first and foremost principle in research is the 'do no harm principle' (i.e. safeguarding in research). However, there are additional ethical principles that apply to undertaking research with INTRAC. These include:

- Protection of data and intellectual property
- Scientific objectivity (objectivity in research)
- Honesty and integrity
- Accuracy
- Openness and accountability in research
- Responsible reporting and publication

What are the rights of research participants?

All research participants have the right to:

- Protection from physical, mental and emotional harm and exploitation
- Human dignity
- Informed consent
- Voluntary participation
- Withdraw from a study
- Privacy, confidentiality and anonymity
- Autonomy (i.e. making your own decisions)[9]
- Access to information regarding research

What are the rights of other stakeholders and the wider community?

Community members and other stakeholders who do not directly participate in research may still be affected by our research, and have the same right to be protected from physical, mental and emotional harm and exploitation.

What are my rights as a researcher?

As a researcher you also enjoy the right to be protected from physical, mental and emotional harm and exploitation. This means that your safety is more important than the work you undertake. In practical terms this, for example, means that you are always allowed to refuse to go to a location for data collection or speak

[9] Autonomy (or respect for people) demands that the ability of competent subjects to make their own decisions be recognized and respected, while also protecting the autonomy of the vulnerable by preventing the imposition of unwanted decisions.

to speak to specific people. You also have the right to leave if you feel unsafe/uncomfortable. It furthermore means that INTRAC is obliged to assess the risk related to you working in a certain region or with a specific group of people, and that we should provide you with sufficient information on our safety protocols. Lastly it is very important that we explain to you what you should do if you have a concern or a complaint. This process is commonly referred to as 'whistleblowing'. Please refer to the next section for more information.

Who should I contact when I have a safeguarding concern? (whistleblowing)

If you have any safeguarding complaint or concern it is important that you raise this as soon as possible with the principal consultant of this project: INSERT NAME, EMAIL ADDRESS & PHONE NUMBER (KEEP THIS SECTION ORANGE). If this is deemed inappropriate (for instance because it is about him or her), you can also raise your concern directly with INTRAC's designated Safeguarding Officer: Ms Karen Saxl at ksaxl@intrac.org or via +44 (0)1865 263 047, or send an email to whilstleblowing@intrac.org.

Concerns or complaints should ideally consist of the following details:

- detailed facts (when, where, what, who is involved);
- documented evidence, if any;
- your name, contact details and availability, so investigators can follow up with you as needed. However, you can submit an anonymous complaint if you prefer and we will to investigate this with equal rigour (subject to any legal constraint).

Your complaint or concern, will be referred within 24 hours to INTRAC's Safeguarding Officer. Within 72 hours of receiving a complaint or concern, INTRAC's Safeguarding Officer must convene a case conference.

It is important that you:

- Always ensure your own safety first.
- Act swiftly upon any disclosure and suspicion, especially if someone is in imminent danger of abuse.
- Raise any suspicion that you have. This means that you do not need to have evidence or be 100% sure. It is the responsibility of INTRAC to look further into the case.
- Understand that there will be no negative repercussions to you if you raise a concern that turns out to be untrue or no issue (unless you have intentionally raised a false accusation).
- Keep calm and act normally; do not say or show that you are shocked.
- Do not investigate or question the person at risk or in a vulnerable situation. You should only ask questions to get enough information to understand the complaint (e.g. 'who, what, where, when' questions, but not 'why' questions) so that you can raise the concern with INTRAC.
- Never agree to keep a secret. If a person is in danger you will have to inform others.
- Do not directly challenge the alleged abuser or parent/carers/others around the person at risk about your concerns. We first need to further investigate the case and this might put you at risk yourself.
- Record all the details that support your suspicion and report this in line with internal reporting procedures.

Where can I find more information about safeguarding and research ethics?

Safeguarding is a very important responsibility, so you are always welcome to contact the principal consultant of this project if you have more questions. For more information you can also read INTRAC's Safeguarding Policy, Whistleblowing Policy, and Complaint or Concern Procedures.

As mentioned before, safeguarding is only one element of our research ethics. For more information on the other ethical principles related to undertaking research we recommend that you read and understand INTRAC's full Code of Research Ethics.

B. Informed Consent

This Annex includes an example of a very detailed information sheet and consent form for providing information to research participants (B.1), and a simplified set of informed consent templates that should be used by researchers who collect data on behalf of INTRAC (B.2).

B.1 Guided example of informed consent procedure

This section is based on an informed consent template that has been adapted from the World Health Organization[10]. It can be used as a guided example of the procedure to take informed consent and as reference for the elements that should be included in an information sheet and consent form. The example is applicable to research that uses questionnaires, in-depth interviews, focus group discussions or other participatory methods.

Title information

The heading of an informed consent form should include:

- Name of Principal Consultant or Principal Researcher
- Name of Organisation
- Name of Client and/or Donor, Funder
- Name of Project

Also name the group of individuals for whom this consent is written in the header. Because research for a single project is often carried out with a number of different groups of individuals representing a variety of stakeholders - for example community members, clients of services, donors - it is important that you identify which group this particular consent is for.

Example: This informed consent form is for social service providers in community X and who we are inviting to participate in research Y, titled "The Community Response to Malaria Project".

Introduction

Briefly state who you are and that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at any time.

Example: I am X, working for the Y organisation. I am doing research on the disease malaria which is very common in this country and in this region. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

[10] https://www.who.int/ethics/review-committee/informed_consent/en/

Purpose of the research

Explain the research question in lay terms which will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. You should also keep in mind your participant sample, and possibly update your informed consent for certain vulnerable groups such as children. Researchers however need to be careful not to mislead participants, by suggesting research interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out about how the practitioners are advertising themselves. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee.

Example: Malaria is making many people sick in your community. We want to find ways to stop this from happening. We believe that you can help us by telling us what you know both about malaria and about local health practices in general. We want to learn what people who live or work here know about the causes of malaria and why some people get it. We want to learn about the different ways that people try to stop malaria before someone gets it or before it comes to the community, and how people know when someone has it. We also want to know more about local health practices because this knowledge might help us to learn how to better control malaria in this community.

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire.

Example: This research will involve your participation in a group discussion that will take about one and a half hours, and a one-hour interview.

Participant Selection

Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

Example: You are being invited to take part in this research because we feel that your experience as a social worker (or as a mother, or as a responsible citizen) can contribute much to our understanding and knowledge of local health practices.

➢ ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group

discussion has already taken place, the person cannot 'stop participation' but can request that the information provided by them is not used in the research study.

Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, all the services you receive at this Centre will continue and nothing will change.

OR

The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.

➢ ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Procedures

A. Provide a brief introduction to the format of the research study.

Example: We are asking you to help us learn more about malaria in your community. We are inviting you to take part in this research project. If you accept, you will be asked to….

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

Example for focus group discussions: … take part in a discussion with [number of] other persons with similar experiences. This discussion will be guided by [name of moderator/guider] or myself. The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about malaria and give you time to share your knowledge. The questions will be about malaria in your community, how is it recognized, what people do to stop it from spreading to other people, who people go to for help and what happens when people become sick with it.

We will also talk about community practices more generally because this will give us a chance to understand more about malaria but in a different way. These are the types of questions we will ask [insert example]. We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing. The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be audio-recorded, but no-one will be identified by name on this recording. The recordings will be kept [explain how this will be stored]. The information recorded is confidential, and no one else except the researchers working on this project [name of person(s)] will have access to the recordings. The recordings will be destroyed after [number of days/weeks/months].

Example for interviews: … participate in an interview with [name of interviewer] or myself. During the interview, I or another interviewer will sit down with you in a comfortable place. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to

be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be audio-recorded, but no-one will be identified by name on this recording. The recordings will be kept [explain how this will be stored]. The information recorded is confidential, and no one else except the researchers working on this project [name of person(s)] will have access to the recordings. The recordings will be destroyed after [number of days/weeks/months].

Example 3 for questionnaire surveys: … fill out a survey which will be provided by [name of distributor of blank surveys or explanation of online platform] and collected by [name of collector of completed surveys]. You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want the researcher to write down. If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a randomly assigned identification-number will identify you, and no one other than the researchers working on this project [name of person(s)] will have access to your survey.

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

Example: The research takes place over [number of days/weeks/months] in total. During that time, we will visit you [number of times] for interviewing you at one-month intervals and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hours.

➢ ***Examples of question to elucidate understanding:*** *If you decide to take part in the study, do you know how much time the interview will take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time the discussion with other people will take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Do you have any more questions?*

Risks

Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of research methodologies, and should be, as usual, tailored to the specific issue and situation. During this section it is important to highlight all potential risks related to participation, and should stress that the research has been designed to minimize harms and risks of the research activities, and to distribute the burdens of research fairly.

If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits, etc. then an example of text could be something like "We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview."

OR

If, for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen.

You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.

Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. The research should also emphasize that the research has been designed to maximize benefits of the research activities, and to distribute the benefits of research fairly.

Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and treat malaria in your community.

Reimbursements

State clearly what you will provide the participants with as a result of their participation. In general, INTRAC does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research or refreshments. These may include, for example, travel costs and reimbursement for time lost, or provision of refreshments. The amount should be determined within the context where research will take place.

Example: You will not be provided with any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expenses (if applicable).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions that you will take to ensure safety and anonymity.

Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will protect that information either by securing it in a safe data space or physically with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, your clinician, etc.].

<u>The following applies to focus groups:</u>

Focus groups provide a particular challenge to confidentiality because once something is said in the

group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.

Example: We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.

➢ ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you understand that the we cannot guarantee complete confidentiality of information that you share with us in a group discussion? Do you have any more questions?*

Sharing the Results

Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

Example: Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name unless you have given us your permissions to do so. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the community and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a community social worker. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

Example: You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected. I will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted. This element always needs to be provided in writing.

Example: If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]
This proposal has been reviewed to make sure that research participants are protected from harm. If you wish to find out more about the research you can contact [name].

➢ ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to. Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study?*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Elements of Certificate of Consent

This section is mandatory and must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate could also be asked to include their thumb print.

A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

Example: I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

OR

I have witnessed the accurate reading of the consent form to the potential participant, and the individual [insert full name] has had the opportunity to ask questions. I confirm that the individual has given consent freely.

The Certificate of Consent should be amended for minors; this means that the informed consent form has to be provided in language and writing that is understandable to their age group. The informed consent form should also be accompanied with an informed consent form for the parent or guardian of the minor. The parent/guardian will subsequently sign on behalf of the child. Please note that the legal age to give consent differs per country.

Example: I have read the foregoing information, or it has been read to me and my child. We have had the opportunity to ask questions about it and any questions we have been asked have been answered to our satisfaction. My child consents voluntarily to be a participant in this study, and I agree that my child/person [insert full name of child/person] for whom I am a guardian may take part in the above research project.

B.2 INTRAC's templates for informed consent

Informed Consent Form for [participant group/sample]

[Name of Project]
[Name of Principal Consultant and Local Researcher(s)]
[Name of Organisations involved with project]
[Name of Client and/or Donor, Funder]

What is this study about?

- This research is carried out by INTRAC and *[insert other groups or client]*, it is about *[insert research objective in concise lay terms]*.
- You have been invited to take part in this study because you can help us understand *[insert reason for consultation of this stakeholder group/research sample*].
- By doing this research we hope to *[list benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question].*

What will I be asked to do?

- If you do decide to take part in this study, we ask you to *[insert short explanation of methods*]. This will for example include a discussion/questions on *[give a couple of relevant topics, especially if this is anticipated to be sensitive]*.
- Your participation will take roughly *[insert time]* of your time *[insert period or spread of events if applicable]*.
- You will not be provided with any incentive to take part in the research. But, we will give you *[provide a figure, if money is involved]* for your time, and travel expense *(if applicable).)*
- It is important that you know that taking part in this study means that *[clearly highlight all potential risks]*. Being part of the study may draw attention and if you participate you may be asked questions by other people in the community.

What are my rights?

- Before we start it is important for you to know that you are free to decide whether you would like to participate in this study or not. Your participation is entirely voluntary.
- You can ask questions about this information sheet, and take your time to decide whether you would like to participate in this study.
- If you do decide to participate in this study, we will ask you to sign a form. But it is important for you to know that you can always change your mind. You have the right to stop your participation at any given time without having to give a reason for it.
- You also have the right to ask us to change or delete the information that your provided to us. This will have no negative implications to you or your relatives.

What will happen to the information that I provide?

- For individual methods (please remove bullet point if not applicable): The information that we obtain through this research will be kept confidential. This means that:
    - We will not share information about you to anyone outside of the research team. The information that we collect from this research project will be kept private.
    - Any information about you will be anonymous, as it will have a number on it instead of your name, unless you give us permission to use your name or image (for instance a quote or a short story). Only the researchers will know what your number is and we will protect that information.
- For group methods (please remove bullet point if not applicable): We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. But you should know that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.
- The information you provide to us will inform *[mention research outputs].* This will be shared *[insert with whom, where and when, mention whether this will be online or not]*.
- If we directly use any of your data (such as a quote or provided answer) in our reports or presentations, we will make sure that your information is anonymised unless you give us permission. This means that we will not include any of your personal details such as your name, family name or where you come from.
- Your personal data will be stored under the United Kingdom General Data Protection Regulation (GDPR) guidelines. This is a set of guidelines to make sure that all your information, especially digital information, is kept safe. Any personal information that you provide us with will be removed and destroyed from our protected online system 6 months after the research project has ended, unless we are contractually obliged to keep it for longer in which case we will ensure that it is anonymized.
- You will have full access to the information that you provide to us and will be able to withdraw the information at any time by asking us.
- Once the study has been completed, we will share the results of this study with you.

What if I have questions?

If you wish to know more about the research before you decide to take part and/or during the study you can also always contact *[insert contact details of someone who is involved, informed and accessible - a local person who can actually be contacted].*

I would like to take part in this study

If you are happy to proceed, please tick the following boxes and sign the form below:

1. I have read the Information Sheet, or it has been read to me.	
2. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction.	

3. I understand that my participation is voluntary and that I am free to withdraw from this study at any time without giving a reason.	
4. I understand that personal data will be stored and accessed by the research team working on the project.	
5. I agree to the use of anonymised data in publications.	
6. I am willing to be contacted in the future to clarify any questions arising from the information that I have provided.	
7. I agree voluntarily to take part in the study.	

Name of Participant:

Signature of Participant:

Date (day/month/year):

Name of Researcher taking consent:

Signature of Researcher taking consent:

I would like to take part in this study (if illiterate[11])

If you are happy to proceed, please select a person who could provide consent on your behalf

Statement by witness

I have witnessed that (please tick the following boxes):

1. The Information Sheet has been accurately read to the potential participant.	
2. The potential participant has had the opportunity to ask questions about it and any questions asked have been answered to their satisfaction.	
3. The potential participant understands that participation is voluntary and that (s)he is free to withdraw from this study at any time without giving a reason.	
4. The potential participant understands that personal data will be stored and accessed by the research team working on the project.	
5. The potential participant agrees to the use of anonymised data in publications.	
6. The potential participant is willing to be contacted in the future to clarify any questions arising from the information that (s)he has provided.	
7. The potential participant agrees to voluntarily take part in the study.	

Name of Witness:

Thumb print of participant:

[11] A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

Signature of Witness:

Date (day/month/year):

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the research procedures. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher taking consent:

Signature of Researcher taking consent:

My child would like to take part in this study[12]

If your child and you are happy to proceed, please tick the following boxes and sign the form below:

1. The Information Sheet has been accurately read to myself and my child/the person for whom I am a guardian.	
2. We have had the opportunity to ask questions about it and any questions asked have been answered to our satisfaction.	
3. We understand that his/her participation is voluntary and that (s)he is free to withdraw from this study at any time without giving a reason.	
4. We understand that personal data will be stored and accessed by the research team working on the project.	
5. We agree to the use of anonymised data in publications.	
6. We are willing to be contacted in the future to clarify any questions arising from the information that (s)he has provided.	
7. My child/the person for whom I am a guardian agrees to voluntarily take part in the study.	
8. I agree that my child/the person for whom I am a guardian may take part in the above research project.	

Name of Parent/Guardian: Name of Child:

Signature of Parent/Guardian: Signature of Child (if possible):

Date (day/month/year):

[12] Please ensure that entire information sheet is appropriate to be read out and explained to a child. Avoid jargon, use examples, reduce text and include images.

Name of Researcher taking consent:

Signature of Researcher taking consent:

C. Data Management Protocol

All INTRAC staff who are involved with primary data collection and analysis of such data should read, understand and adhere to this data management protocol. In addition to reading and understanding this data management protocol, we recommend that you refer to our general Data Protection Policy.

Contracting

In case of data collection as part of contractual work, it is important that:

- Agreements on data retention and sharing of data are reflected in the contract or agreement with the client or lead partner on a programme, making clear:
    - They are the data controller
    - INTRAC will only process the data as instructed by them, operating as the data processor
    - The data controller is responsible for ensuring that the individuals concerned are aware of the data being collected and how it is being used.
- Data protection is reflected in contracts with external consultants who are involved with data collection. ensuring that:
    - It is clear how and where data should be stored
    - All data should be saved on a central secured drive as soon as possible (even during field work if internet allows).
    - All data must be submitted to INTRAC upon completion of the contract
    - All data must be removed from personal computers and laptops upon completion of the contract

Ensuring data protection in the design of your study

When designing research tools, it is important to ensure the following:

- Minimise our data risks by only collecting the data that we need in order to meet the research objectives
- Do not obtain any personal data if not considered critical
- Anonymise data samples as much as possible
- Develop data collection templates, especially when different people are collecting similar data (i.e. various local consultants in different countries) – this will not only benefit data management processes but also general data analysis and reporting. Templates must include:
    - A specified section for personal data at start of document
    - Subsequent referral to personal data should be anonymized (e.g. do not repeat a name listed at top of document further down in a transcript but simply use initials, which will become untraceable once personal data has been removed)
    - Project number
    - Principal consultant
    - Name of data collector
    - Date of data collection

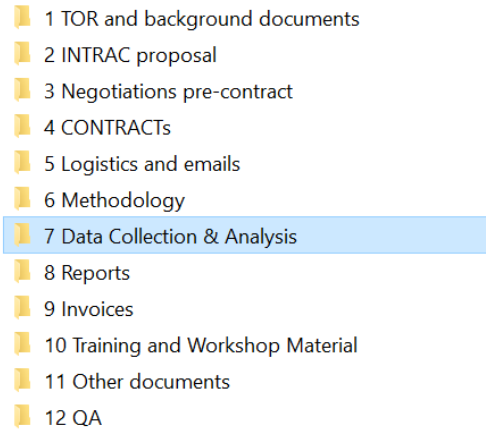
Safe data storage during data collection

All primary and secondary data should be safely and securely stored on INTRAC's encrypted shared drive and **should not be kept on personal computers and laptops** of staff members nor external consultants (as reflected in their contracts) any longer than necessary.[13]

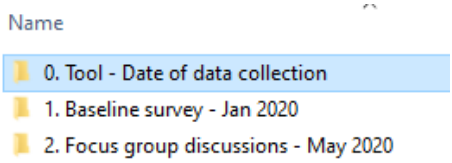
When working with associates and local consultant it is thus important that as a job manager (and/or project coordinator) you remind them of this contractual obligation, and ask to share all data upon completion of data collection and data analysis. This also means that if you decide to make use of another data storage platform (such as Dropbox or Google Drive), then data on this platform is frequently moved to INTRAC's shared drive and cleared from the temporary platform upon completion of the project.

To ensure adherence to data protection policies, it is critical that **all data related to a project is stored in one place and not in various folders**.

The standard job folder template has therefore been adjusted to:



All data collected by INTRAC as part of the research project must be stored in folder 7 'Data Collection & Analysis', subsequent folders should be set up per research tool including the date of data collection.



Data removal

INTRAC is committed to follow GDPR commitments and to remove personal data 6-months after completion of a research project and/or closure of a consultancy contract (defined as payment of the final invoice), or to anonymise personal information within 6 months of completion of the study where we are contractually obliged to retain research data for a longer period of time.

A notification has been embedded into Salesforce to ensure that the job manager and consultancies team receive an automated email reminder 6-months after completion of a project.

The consultancies assistant will subsequently remind (and could possibly assist the job manager) to:

- Reach out to the client to notify them that we will be deleting the data
- Delete all data in the job folder, or at least delete all personal non-anonymised data
- Record in Salesforce that data management and GDPR rules have been adhered to

[13] Limited access to internet while undertaking fieldwork might cause a delay in ensuring safe storage, however, all consultants are requested to complete storage on the encrypted shared drive as soon as possible upon return to the office and/or securing a stable connectivity.