

# **PDA Ethical Review Committee**

## **GUIDANCE FOR APPLICANTS**

**2017 Draft**



*researchers. facilitators. trainers. consultants*

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## Contents

<b>1. Overview .....</b>	<b>3</b>
1.1 Purpose - why have an Ethical Review?.....	4
1.2 What we mean by Ethical Review.....	5
<b>2 Process and Time-line for Ethical Review .....</b>	<b>6</b>
2.1 Overview .....	6
2.1.1 Timelines for Ethical Review Processes .....	7
2.2. The Main Steps in the Ethical Review Process.....	8
2.2.1 Preliminary Screening .....	9
2.2.2 Expedited Review.....	9
2.2.3 Full Review .....	9
2.2.4. Decisions on Applications .....	9
2.2.5 Mode of Communication of the ERC's Decision .....	10
<b>3 Documentation Required to Complete an Application.....</b>	<b>11</b>
<b>4. Guidance Notes for Completion of the Ethical Review Application Form.....</b>	<b>12</b>
4.1 Preliminary Screening Tool: .....	12
4.2 Ethical Review Application Form: .....	12
Section 1 Details of Lead Researcher:.....	12
Section 2 Administrative Details of Research Project:.....	12
Section 3 Rationale for Proposed Research:.....	12
Section 4 Risk Assessment Checklist:.....	13
Section 5 Ethical Considerations Specific to Research Design:.....	13
Section 6 Ethical Considerations Specific to Data Management:.....	14
Section 7 Ethical Considerations Specific to Financial Aspects of Research:.....	15

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Section 8 Managing Complaints: .....	15
Section 9 Anticipating Challenges:.....	16
Section 10 Other Ethical Research Clearance / Permission:.....	16
Section 11 Declaration:.....	16
Section 12 Checklist for Supporting Documents: .....	16

## 1. Overview

Participatory Development Associates' Ethical Review Committee was set up in January 2017 to help ensure that research is carried out to the highest ethical standards. Participatory Development Associates (PDA) made this commitment to pursuing rigorous ethical review processes because it is consistent with its professed Vision, Mission and Values<sup>1</sup>. Ethical and robust research should ultimately lead to PDA's vision of: "*A world where states, communities and organisations provide an enabling environment in which all people, regardless of sex, race, ethnicity, creed, age or disability, can realise their full potential and contribute their best to the common good*".

Ethical review is aligned with our organisation's Values in the following ways:

- **Empowerment:** we believe that research should be an enlightening process for all involved, not simply an extractive exercise undertaken for the benefit of others. Paying attention to how a research process empowers and/or disempowers the people involved is of great importance to its development outcomes. In particular, PDA believes that the dignity, rights, safety and well-being of both participants and researchers is important in any research process that PDA undertakes.
- **Inclusiveness:** we believe everyone has an active role to play in realising social change and so it is important that any piece of research has carefully considered which voices are listened to, and why.
- **Innovation and creativity:** thoughtful review processes can help any group of people to think more carefully, creatively and deeply.
- **Quality:** review can help us, and others, to maintain and improve our research standards. In doing this we can also affect ethical standards in Ghana more widely
- **Efficiency:** review can identify ways in which all can make judicious use of resources, including natural resources and time.
- **Effectiveness and Impact:** a well-honed research process is more likely to leave a lasting effect.
- **Transparency and accountability:** ethical review helps to make research processes more accountable, to ourselves as researchers, to participants in the research, as well as to those who commission it.

PDA is also committed to being a learning organisation. We believe that ethical review processes should provide a framework for those involved to learn together.

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<sup>1</sup>See PDA website <http://www.pdaghana.com/index.php/about-us/what-we-stand-for.html>

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In addition to guiding and improving our own work, we believe that the ethical review process can and should help to raise the standard of research in Ghana to be consistent with best practices elsewhere.

PDA has an Ethical Review Committee made up of people who have extensive experience of social research from both an academic and field based perspective. The committee works largely independently, but is formally a committee of the PDA Board of Directors. Three members are chosen to undertake any one ethical review, and are selected on the basis of their knowledge of the area being researched, as well as their availability at the time of the application.

PDA has developed this Guidance for Applicants document to support the governance of its ethical review processes. A number of forms and templates also help streamline how the ethical review process works (see Section 3 for a list of these).

### **1.1 Purpose - why have an Ethical Review?**

A number of ethical issues have arisen in our research leading to PDA recognising the need to address these more systematically.

As a people-centred organisation engaged in human development, PDA is routinely asked to undertake research that involves highly sensitive issues, such as those related to child protection, human trafficking and the violation of the rights of excluded and marginalised groups. For such people, exposure through a research process can carry a huge risk. For them, research may not be just a brief exercise, it can cause lasting harm. In the past, we have seen for example how mere questions asked by PDA researchers have unearthed the harsh realities of child abuse, exposed cases of domestic violence and other physical and psychological abuse. For example, what starts as a few questions about school attendance can become a picture of severe parental neglect and abuse. Researchers may sometimes cause financial loss to those they interview; a study looking at disabled peoples' rights can deny the focus group participants the income they would have made while begging; a discussion in a focus group can show a person that they are the only one with a particular problem, something they hitherto assumed everyone shared.

This is the stuff of social research. It is our job is to find out more, to examine the nature of the truth, not to avoid or hide these things. But the sensitivity of this work carries immense responsibility, the responsibility to find out in such a way that information can be used to help the very situation that comes light, with as few negative impacts on the participants as possible.

An ethical review process makes us look at these things before we go head long into a situation. It makes us consider, in advance, the harm we might cause and what steps we can take to minimise this, as well as what we can do if we unearth information that requires us to act or offer a source of support after we have departed. Ethical review should make us more mindful.

## 1.2 What we mean by Ethical Review

An **ethical** review of a research proposal has a different purpose from a straightforward assessment of the adequacy of research design and methodology. Its main purpose is to assess the potential for the research to cause harm to participants or expose them to any risk that is a specific consequence of their participation. Such a risk may be to their person, or to the environment they live in and make use of in their daily lives.

As such, reviewers are looking for evidence in a proposal of the ethical principles that inform the research design and methods. These may include a commitment to objectivity, non-discrimination, partnership working (including participation of research respondents in the wider research process), sustainability, transparency and a commitment to shared learning. Relevant risks may include exposure to harm that is physical, psychological, emotional, social, economic or environmental in nature.

In addition, an ethical review brings into focus specific aspects of research and how these are managed to minimise harm and maximise benefit. These include:

- a focus on the consequences and impact of research for all participants, both immediate and in the longer term;
- a focus on ways to ensure protection of and/or support for participants in the research, should negative consequences arise from their participation in the research;
- a focus on the overall moral integrity of the research process and the benefit of research products for participants, researchers themselves and research commissioners.

Those undertaking an ethical review of research are looking for evidence that the researchers have anticipated the potential negative consequences of participation in the research for respondents and researchers, and have included in their design mechanisms to minimise these. There is therefore a balance to be struck between the requirement to obtain specific data and the exposure to risk this brings for research respondents. Reviewers check that this balance obtains the greatest benefit for the least possible harm. They check to ascertain what plans are proposed to mitigate against those risks that are necessary to the success of the research. When research involves vulnerable people, reviewers might expect to see evidence that demonstrates forethought has been given to the relationship between researcher and respondent. For example, a code of conduct for working with minors or those from disadvantaged groups<sup>2</sup>. Equally, serious thought also needs to be given to research on issues to do with the environment and fragile eco-systems, especially if there is any risk that marginalised people's access to or ownership of these will be negatively impacted by the research.

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<sup>2</sup>PDA is happy to provide examples of such codes of conduct if these would be helpful.

## 2 Process and Time-line for Ethical Review

### 2.1 Overview

All research that involves human subjects and specimens from the environment should be submitted to the ERC and will be assessed according to the timelines laid out below. Submission can be made at any time of year. All the necessary documentation to complete an application to the ERC can be found on the PDA website and downloaded for use: [\(insert link\)](#).

Researchers should first use the Preliminary Screening Tool to check whether ethical approval is required for a specific proposal and ensure that they do not submit proposals unnecessarily. Even when the Preliminary Screening Tool indicates that ethical review is not required, in order to ensure our records are complete, the research proposal and completed Preliminary Screening Tool should still be sent to the ERC Secretary.

Researchers should ensure that submission is sufficiently in advance of any planned fieldwork for the assessment process to be completed. See Table 2.1.1 below for an indication of the time taken to complete the review process. It is preferable that contact is made with the ERC at an early stage in development of any proposal, in order that ethical considerations are incorporated from the start of the research design process. As such, the ERC welcomes informal discussion and sharing of proposals in draft form whenever time-scales permit. PDA believes that integrating consideration of ethical issues into all research design and development will lead to stronger proposals and more accurate and useful results. PDA also understands that this is an evolving process for everyone and thus aims to encourage collective learning through the sharing of ideas and challenges relating to the completion of each review. Applicants should thus feel able to contact the ERC Secretary to discuss any issues that are unclear, or seek advice on any aspect of the process, while completing the documentation.

Completed applications should be submitted to the secretary to the ERC. The secretary will review the application for completeness and forward it to the chairperson and other members of the committee who are available or eligible to review the application form. The secretary will then advise whether an [expedited review](#) or [full review](#) is expected (see 2.2 for detailed descriptions of these)

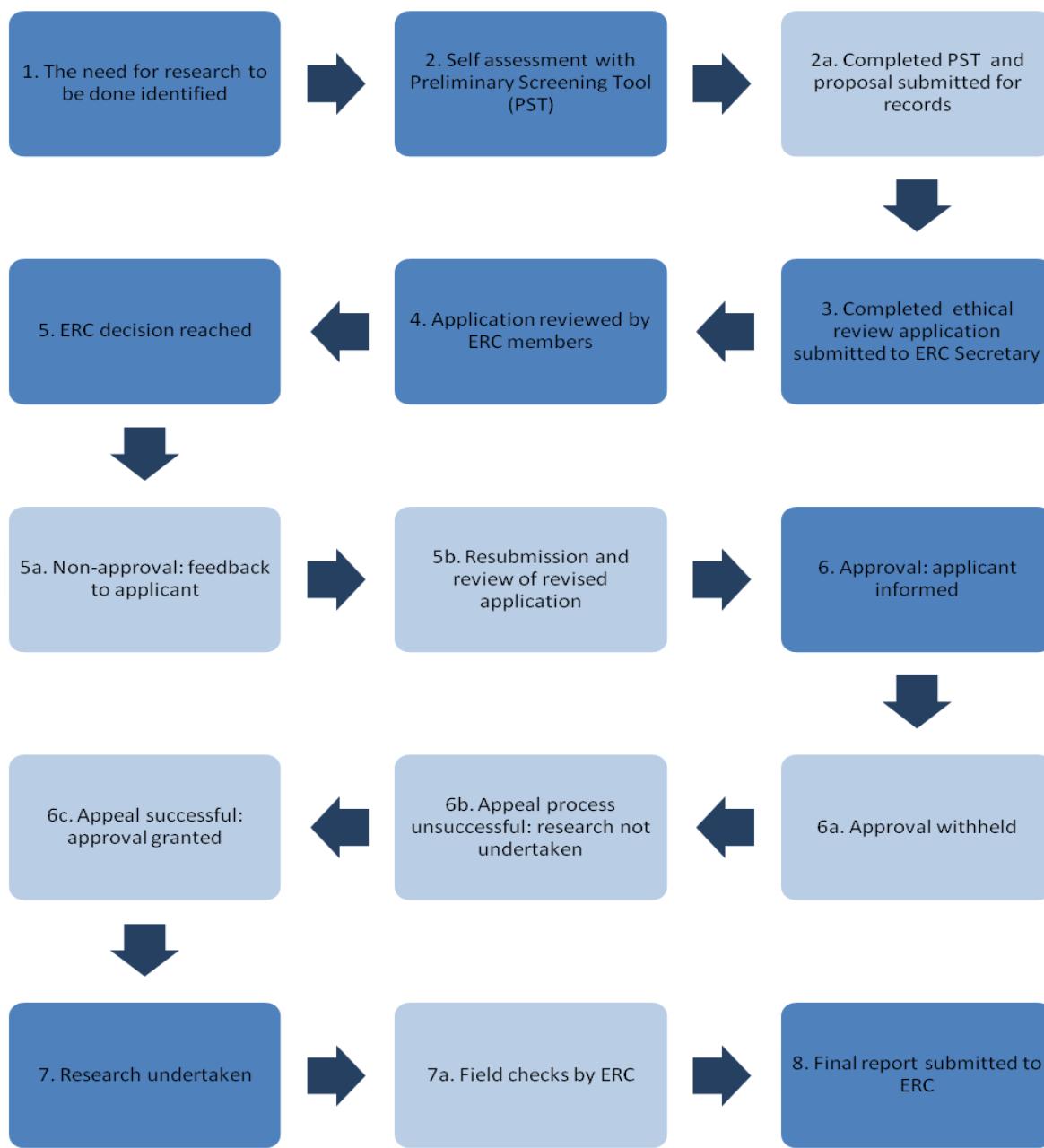


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### **2.1.1 Timelines for Ethical Review Processes**

## 2.2. The Main Steps in the Ethical Review Process

The diagram below shows the main steps in the process of obtaining ethical approval. Lighter shaded boxes indicate steps that are not always required.



The ethical review process begins as soon as the need for a specific research project is identified (Step 1).

### **2.2.1 Preliminary Screening**

Before completing a full application form, researchers are advised to use the Preliminary Screening Tool (Step 2). This provides a quick and simple mechanism to decide whether a proposal should be submitted for ethical review. Even when the screening indicates that ethical review is unnecessary, the ERC Secretary should be informed that the research is taking place so that records are complete. This can be done by submitting the completed Preliminary Screening Tool with the research proposal attached (Step 2a).

When the Preliminary Screening Tool indicates that ethical review is required, then one of two types of ethical review processes may be used by the ERC:

- i) an Expedited Review or,
- ii) a Full Review

### **2.2.2 Expedited Review**

This is appropriate for research that does not involve minors and/or vulnerable groups/populations, and that is deemed to have minimal risk or harm to researchers, participants or the natural environment. Expedited review (Steps 3 and 4) is conventionally done by the Chair of the ERC who may consult other members of the committee in determining the status of applications. Decisions taken by expedited review will be reported to the ERC. Decisions to refuse an application, or request a revision, cannot be taken by expedited review but must be referred for full review.

### **2.2.3 Full Review**

This is required if the proposed research falls into any of the categories below. A panel consisting of at least three members of the ERC is selected to conduct a full review (Steps 3 and 4).

1. Research that is intentionally conducted without the full and informed consent of respondents at the time the study is carried out or when the data are gathered
2. Research which involves or may lead to the publication of confidential information
3. Research that involves more than minimal risk of harm to participants, including:
  - research involving vulnerable groups;
  - research involving sensitive topics;
  - research involving groups where permission of a gatekeeper is normally required for initial access to members;
  - research which would induce psychological stress, anxiety or humiliation or cause more than minimal pain;
  - research where there is a possibility that marginalised people's rights to access or ownership of environmental resources could be affected as a result of the research.

### **2.2.4. Decisions on Applications**

The ERC will follow the timescale given above (Table 2.1.1) in reaching a timely decision (Step 5). The ERC will give written notification to the applicant detailing whether the application has been

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approved (Step 6), whether the application requires modification, whether the application requires further and clearer information (Step 5a) or whether an application has been denied, and provide reasons for the denial (Step 6a). Any of the following decisions could be made by reviewers:

- Approved
- Approved subject to revision
- Requires modification or additional information
- Refused

Where the Ethical Review Committee is unable to approve a research/study proposal, the researcher(s) may appeal that decision (Steps 6b and 6c).

Appeals should be made in writing to the Secretary of the ERC within seven (7) days after receipt of the Committee's decision. An application to appeal must provide all the documentation considered by the Committee and a letter setting out sufficient information to allow the grounds for appeal to be understood and demonstrating clearly the basis of the appeal. When an appeal is made, the resubmitted proposal will be reviewed by all ERC members and, if agreement cannot be reached, the matter will be referred to the PDA Board of Directors for final arbitration.

## **2.2.5 Mode of Communication of the ERC's Decision**

Once a decision is made (Steps 5 and 6), a letter shall be written to the applicant indicating whether ethical approval is granted. This letter may also be scanned and communicated as an email attachment to reduce any delays.

A letter granting ethical approval will also indicate the following:

1. Timelines for reporting back to the ERC.
2. If the duration of the research is one year or more, the timing for a brief mid-term report must be stated. The mid-term reporting should include the final data collection tools.
3. The possibility of ad hoc verification visits to the field by ERC members (Step 7). In other words, ERC members reserve the right to monitor the data collection process for compliance. This could include periodic phone calls to the lead researcher to check on compliance.
4. The date for the end of term report (Step 8).
5. The need to resubmit an application after approval, if significant change in methodology and tools occur. This may come with additional costs to the client.
6. The dates of submission of the application, of the granting of ethical approval and the expiry date for that approval.
7. The signature of the ERC chairperson or designated representative.
8. The stamp of the ERC.
9. The name and contact address of the Lead Researcher.

### **3 Documentation Required to Complete an Application**

The ERC uses a number of templates for the various stages of the ethical review process. These have been developed by the committee to aid transparency and efficiency. It is expected that these may be continually refined on the basis of user feedback and ERC member's own evaluation of the reviews undertaken.

The following documents must be submitted to the ERC during both expedited and full review processes:

- 1.) Preliminary screening tool
- 2.) Application documents:
  - i. completed ethical review application form
  - ii. research proposal summary sheet
  - iii. information sheet and consent form
  - iv. questionnaire/ question guide/ interview guide
  - v. other documents or information relevant to the research
  - vi. relevant codes of conduct for researchers

In carrying out the review, ERC members use standardised criteria in research and ethical considerations. Examples of these are available to view on the website [\(insert address\)](#) as they may help you in completing the application form.

Reviewers use an assessment form based on the information provided in the application and an overall risk level scoring matrix. Following their separate reviews, the reviewers 'assessments are synthesised into one document which is shared with the applicant to provide detailed feedback.

If the ERC decides not to approve a research proposal, even after revisions and discussion, then the proposers may appeal that decision using the [Appeal Form \(needs developing\)](#) provided. This requires the applicants to provide justification for seeking the appeal. Additional documents addressing concerns raised by the initial ERC review may also be requested.

## 4. Guidance Notes for Completion of the Ethical Review Application Form

Within the following sections, detailed guidance is provided to enable applicants to successfully complete the application form and ensure that all the necessary supporting documents are included with the submission.

As explained above, PDA believes that integrating consideration of ethical issues into all research design and development will lead to stronger proposals and more accurate and useful results. Applicants are encouraged to contact the ERC Secretary to discuss any issues that are unclear or seek advice on any aspect of the process.

### 4.1 Preliminary Screening Tool:

Question c) - please consider whether your research is likely to disrupt or negatively impact upon social relationships for the participants, either during or after the research.

Question d) - please consider whether there will be short- or longer-term damage to the physical environment. In particular, also consider whether access to or ownership of environmental resources by marginalised people will be affected in any way.

### 4.2 Ethical Review Application Form:

#### Section 1 Details of Lead Researcher:

Insert the details requested for the Lead Researcher. This is the person with whom all communications about the submission will be made.

#### Section 2 Administrative Details of Research Project:

Completion of these details will assist in the timely assessment of your proposal and in identifying any potential conflicts of interest that may arise in relation to the sponsorship of the research.

#### Section 3 Rationale for Proposed Research:

The information provided here will provide justification for the research overall and explain why it is necessary and beneficial. It will give an overview of the aims and objectives of the research and the selected methodology and research tools that will be applied.

You should explain how the decisions you have made on these issues ensure that the research will achieve the greatest benefit for the least possible risk or harm for participants. For example:

- How does your choice of data collection tools impact on the way that participants understand the research or on their ability to engage in analysis and dissemination of research findings?
- How will attainment of your research objectives bring benefit to the participants in the research (as well as the commissioners/funders of the research)?

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- How do you justify the need to explore sensitive topics that could be difficult for participants and what are you doing to minimise this through your research design?
- How are you identifying potential conflicts of interest and what will you do if these arise?

#### Section 4 Risk Assessment Checklist:

This allows you to come to a conclusion about the level of risk that is entailed in this research project. The checklist questions highlight areas of particular ethical concern. For each area, use the scoring matrix provided to consider the nature of any harm or risk and how likely it is to occur during or after the research. This will enable you to reach a conclusion on the overall risk level (4a).

#### Matrix Scoring Example:

*You are researching children's experience as child soldiers. It is likely that a child may suffer post-traumatic stress as a result of recalling their experience. On the scoring matrix, this equates to a 'moderate/major' consequence being 'possible/likely' to occur, resulting in a risk score of 9-16 and making the research 'high risk'.*

Some research is inherently risky but it is also worthwhile, so do not expect to eliminate all risk. Take the opportunity as you complete the application form to consider what the risks might be and what can be done to protect participants as much as possible. The aim is not that all research should be 'low risk' but that when we have to undertake 'high risk' research we give serious consideration to the ethical implications of what we intend to do and the potential consequences for those involved. For 'high risk' research it is vital that we plan ahead to minimise any negative impact.

#### Section 5 Ethical Considerations Specific to Research Design:

**Informed consent** is fundamental to the ethics of research. However, in some cases it may not be possible to ensure this, for example, in covert observation, or when **deception** is integral to the research design. If this is the case for the research you propose, provide justification for this decision. Will it be possible to fully explain and debrief participants on conclusion of the research?

Consent should be given freely, but again, in some cases there may be subtle pressures or psychological coercion on people to take part/withdraw from research especially when this focuses on sensitive issues involving cultural practices or power relationships. How will you manage these?

Participants should also consent to any future use of the data they provide. However, you may not yet know exactly when and how the information you collect will be used or by whom. What steps are you taking to be sure that any consent given also applies to future uses of the information?

Selection of the **target populations and sampling** can fundamentally affect the quality of any research and the validity of its findings. Consider who you have included/excluded, why you have done this and what the consequences are. How might the **process of recruitment** into your research affect people's willingness to participate or the nature of the information you are able to collect? What can you do about this? Why may some people be reluctant to participate, and if they are important to your research, how can you encourage them to take part?

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The ways in which people participate in research are varied and their **level of participation** in different elements of the overall process has an ethical dimension. The most basic level of participation is by simply providing information. However, you may choose to ask people to participate in other elements of the research process. If you do so, you need to consider the ethical implications of this and ensure that you have anticipated any issues that may arise. For example, have participants been involved in deciding that the research should take place; in selecting the overall approach or the specific tools to be used? Will they provide access to additional participants (snowball sampling) or perhaps collect information themselves? Will you ask participants to analyse the data or help you to reach your conclusions and/or recommendations? Will they be involved in the validation or dissemination of the research and if so, to which specific audiences? For each of these aspects there may be a risk of harm, and you should consider and explain how you will minimise this. Finally, you should explain how you will manage if a participant **withdraws** from the research before the project is complete.

You may also want to explain if you plan for very little active participation and justify the 'extractive' nature of your research. If your target population is one that is 'over-researched' you should justify why this specific research is needed and how you will manage any apathy or cynicism predicted among participants.

## **Section 6 Ethical Considerations Specific to Data Management:**

This section encourages you to explain how you will ensure the security and integrity of all the data you collect, both during the life of the research project and in the future. These issues are particularly important when the data you plan to collect is sensitive in nature. This includes personally identifiable data as well as data on topics such as abuse or illegal activity, and any data that might be misused by others to gain advantage over that individual or in general.

**Confidentiality** is fundamental and it should be ensured that any personal or sensitive information provided by a participant cannot be traced back to that individual. The simplest way to ensure this is anonymisation. However, sometimes research takes place in small, close-knit communities or in locations that are easily identifiable. If this is the case for your research, explain how you will ensure that your research participants cannot be identified in any dissemination of findings.

If participants are involved in data analysis, drawing conclusions and dissemination of findings, how will you ensure confidentiality is respected by everyone?

If your research is into a subject where there may be legal implications from what people tell you, such as child abuse or trafficking, then your capacity to respect confidentiality may be limited. How will you manage this 'duty of care' or the legal requirement to inform others of what has been shared? For some participants, it may be possible to offer them the choice to go 'on the record' and be clearly identified in any dissemination process.

**Storage** of research data must be secure at all times. How will you ensure this during the field research, the period of analysis and in the long term? Will data be destroyed once your research is completed and report submitted? Who might be granted access to information in the future if it is

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stored? What format will data be stored in (physical, electronic, audio-visual)? There may also be legal data protection standards that you must comply with.

The process of data **analysis** can enhance or undermine the integrity and validity of your research. How will you ensure it is the former and that any conclusions or recommendations are fully justified? What sort of statistical test or quality check will you apply during analysis? Have you looked for contradictory data that might support different conclusions and is this clear in your report?

Sometimes data may be confusing in its nature. For example, an interview transcript may look straightforward as text:

*"They won't believe the change it makes - I wouldn't have thought it would make a difference but it has."*

but have been said in an uncertain tone of voice that implies something quite different.

If you involve participants in data analysis, they must be able to understand and assess the data.

**Dissemination** of findings is the final goal of most research. It is through dissemination via the relevant channels that the wider benefits of any research can accrue, but it is also a point at which risk for participants may be severe if they are exposed in any way as a result. How do your choices about dissemination enhance the usefulness of the research? What steps can you take at this stage to protect participants from any risk or harm?

### **Section 7 Ethical Considerations Specific to Financial Aspects of Research:**

Sometimes it may be necessary to incentivise participants with a financial payment. If you plan to do this, justify why you are doing so. Explain how you will minimise any negative impact on the validity or integrity of the research.

If you plan to compensate participants financially for their time or any expenses incurred, again explain why this is necessary and how it will be managed. How will you inform participants of the availability of compensation?

### **Section 8 Managing Complaints:**

What plans do you have in place to deal with any complaints about the research that may arise? Do you have a protocol for managing complaints? If a participant feels they have been negatively affected by their experiences during the research process, how will you ensure their concerns are treated seriously? What support might you offer to them?

How will you ensure that you learn from any difficulties and challenges experienced? How might you enable others to benefit from your experience and avoid similar mishaps?

### **Section 9 Anticipating Challenges:**

It is always possible for things to go wrong, despite our best intentions and well-laid plans. Considering your research proposal overall, and in the light of any issues raised in this application form, can you foresee any specific ethical challenges that are likely to arise? What can you do in advance to mitigate any risks these represent for the research or its participants?

Have you identified any conflicts of interest that are relevant to this research? How will you ensure that these do not impact on the project?

### **Section 10 Other Ethical Research Clearance / Permission:**

If you are required to seek ethical approval from any other body or organisation for this research, state this here. The intention is to avoid duplication of effort.

### **Section 11 Declaration:**

When you are satisfied that you have completed all the sections and provided all the requested information, this declaration indicates that you will abide by the information provided and communicate any changes to the ERC.

Inclusion of the Supervisor's Signature is intended to show that there is organisational support for and knowledge of the research proposed. The Supervisor should therefore be an individual with appropriate seniority and authority.

### **Section 12 Checklist for Supporting Documents:**

There are a number of supporting documents that are required by the ERC to assess your submission. The nature of each of these is described below.

#### **Research Proposal**

Please include the full research proposal in order that the ERC members can understand the nature of the project and make a fully informed decision. A summary may also be included.

#### **Information Sheet**

The information sheet must contain the full name and contact details of the lead researcher(s) for the research project. It must be addressed to the study participants, stating the reasons for the study, his/her roles, any potential risks and benefits to them, who else is involved in the study (not specific names or persons) and the duration of the study. It must be clearly stated in the information sheet that the participant(s) are free to withdraw from the study at any point in time until the final report is written; and that they are free to contact the research organisation or lead researcher(s) if they feel that the study has had negative impact on them in any way.<sup>3</sup>

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<sup>3</sup> If any such report or feedback comes to the attention of the Lead Researcher, the ERC should be notified in writing as soon as possible. This information could also be part of the mid-term or end-term reporting.

### **Consent Form**

The consent form could be part of the information sheet. It involves obtaining confirmation from the participants that they understand what the study is about, and that they are willingly participating in it without any pressure or financial inducement. If there will be financial compensation for travelling or other expenses, this should be stated here. In a study that involves collection of very sensitive information, this must be signed by both the participant(s) and data collector(s). Where there is the possibility that the data collected shall be shared beyond the team undertaking the study, this must be included in the consent form, and must be well understood by the participant(s). The nature of dissemination of findings from the research should be explained and the possibility of others accessing data in the future if this is the case.

### **Questionnaire/ question guide/ interview guide**

This must be the draft or finished tool that is expected to be used for data collection. Please make clear which it is.

**NB:** *If only draft tools are available at the time of submission, please ensure you have provided as much detail as possible in response to Sections 5 and 6 above. This will enable the ERC members to understand your intentions and make an adequate evaluation of your plan, even if the actual data collection tools have not been finalized*

### **Codes of Conduct**

Researchers must give detailed information regarding the standards and behaviours expected of researchers while undertaking the research project. A ‘code of conduct’ indicates relevant steps and procedures that the researchers and the research organisation will follow to handle all matters pertaining to the research before, during and after the study. It should explain clearly how researchers must conduct themselves at each stage of the study process, such as relations with respondents, data collection, and data storage and information dissemination. The code of conduct sheet must also include rules or best practices relating to how field researchers should deal with ethical, moral, legal or cultural sensitivities. This is especially important for research that involves minors or other particularly vulnerable groups. PDA is happy to provide examples of such codes of conduct if these would be helpful.

### **Other Relevant Documents**

These may include other research tools that will be used or protocols that will be followed.