TB CRG COUNTRY-LEVEL ASSESSMENT PROTOCOL TEMPLATE

(Working Document)

Version [insert version number here]
DRAFT TEMPLATE

Impact of gender, key population affiliation and the national legal environment on tuberculosis vulnerability, diagnosis and treatment in [insert country name]

Protocol

Version [insert version number]

[insert date of submission]

Principal investigators

[Insert principal investigator names]

Co-investigators

[Insert co-investigator names]

Contents

1. Investigator responsibilities and contact details

Principal Investigators	
Name and responsibility	**Position and contact details**
[Insert]	[Insert]
Co-investigators	
Name and responsibility	**Position and contact details**
[Insert]	[Insert]

1. Introduction

Tuberculosis (TB) is the world's leading infectious disease killer. International declines in incidence of 1,5% per year are lagging well behind the declines required (7-10%) if the Sustainable Development Goal of ending TB by 2030 is to be met[1]. Recognition that more needs to be done, particularly in meeting the needs of the large number of people who are not diagnosed or successfully treated (approximately 4.5 million people per annum globally) has resulted in a revitalised focus on the international TB response - not least with the convening of the first United Nations General Assembly (UNGASS) high level meeting on TB set for September 2018. Concomitantly, international bodies and National TB Programmes are scaling up their efforts to meet the aims outlined in the Global Plan to End TB (2016–2020): reach at least 90% of all people with TB, reach at least 90% of key populations (defined as the most vulnerable, underserved and at risk populations), and achieve at least 90% treatment success for all people diagnosed. In support of these ambitious targets, the StopTB Partnership (http://www.stoptb.org) is supporting an array of countries to implement national Community, Rights and Gender (CRG) assessments. These assessments are comprised of 3 components: Key Populations, Legal Environment and Gender, with the recognition that these are often neglected areas of research and implementation but play an important role in successful national TB response outcomes. Each assessment examines the respective impact of the research area on TB vulnerability, access to care and treatment outcomes in the national context.

[Insert why your country has been selected to undertake these assessments, which organization is leading the assessment and why]

The mandate underscoring this work is that it will be done in collaboration with [insert key government institutions] and the National TB Programme (NTP) through consultative processes involving a broad array of government and civil society stakeholders. In line with processes set up by the StopTB Partnership, each component of the assessment is made up

[1] Stop TB Partnership, 'The Paradigm Shift 2016 - 20120'.

of slightly different steps in an effort to develop the final report. development However, key common steps across the components include:

1. Inception planning
2. Baseline literature reviews
3. Multi-stakeholder engagement on assessment processes and selection of key populations for inclusion.
4. Rapid qualitative research to augment baseline literature reviews
5. Findings validation by multi-stakeholder group
6. Final report development

This protocol covers the qualitative research processes which will build on the baseline literature reviews and fill in research gaps for all 3 components of the [insert country] CRG assessments. The report resulting from this research will inform future international funding priorities, as well as national focus to improve TB treatment inclusion and outcomes.

2. Motivation

[Insert overview of key ways in which the assessments will assist in meeting country tuberculosis targets]

2.1. Focusing on gender

The current Global Plan to Stop TB argues that a fundamental change for a successful TB response is a shift towards a gender-based approach to TB. This is an approach which "aims at addressing the social, legal, cultural and biological issues that underpin gender inequality and contribute to poor health outcomes"[2]. The call comes in light of an international lack of focus on the ways in which gender impacts on TB vulnerability, care access and treatment outcomes. This is evident because incidence, prevalence and treatment outcome data are frequently not disaggregated, nor analyzed through a gendered perspective.

[Insert:

- A brief literature review of the available country-specific information on gender and TB in your country and what it shows
- A note on where information is lacking
- A statement about what your research will contribute to understandings of gender and TB in your country.]

2.2. Focusing on key populations

The Global Plan to Stop TB describes TB key populations as people who have increased exposure to TB due to where they live or work; people who have limited access to quality TB services; and people at increased risk because of biological or behavioural factors that compromise immune function. The Plan identifies these people as in need of differentiated

[2] Stop TB Partnership, 2016, p. 26)

services. Key populations for particular focus included in the Plan are children, healthcare workers, miners, prisoners, people affected by zoonotic TB, migrants, people who use drugs, the elderly, people with HIV and AIDS, people with diabetes, people who smoke or are exposed to smoke, and people who suffer malnutrition.

[Insert:

- information on how your country's plan (if any) on TB care for key populations relates to the Global Plan.]

The key populations included in this research have been selected through a facilitated process conducted in a multi-stakeholder meeting.

[Insert:

- How you chose the selected key populations
- What the selected key populations are for this research and how they are defined
- For each selected key population:
    - A brief literature review of the available country-specific information on the key population in your country and what it shows
    - A note on where information is lacking
    - A statement about what your research will contribute to understandings of the key population and in TB in your country]

2.3. Focusing on the legal environment

The Global Fund to Fight AIDS, TB and Malaria found that a considerable number of the factors that increase vulnerability to contracting TB or reduce access to testing, prevention, care and treatment services are associated with individuals' position or ability to realise their human rights[3]. TB has persisted throughout history because its roots are closely linked to economic and social inequalities [4]. Human rights violations or situations in which there is limited opportunity to realise human rights, create conducive economic, social and environmental conditions for the spread of TB[5]. An enabling legal framework based on human rights principles such as equality, non-discrimination, participation and equal access to quality healthcare services, to name a few, can positively contribute towards the fight against TB.

[Insert:

- A brief literature review of the available country-specific information on the legal

[3] Global Fund, 'Human Rights and the Global Fund to Fight AIDS, Tuberculosis and Malaria', 2011.
[4] Marina Smelyanskaya et al., 'Legal Environment Assessments for Tuberculosis. An Operational Guide', 2017.
[5] FXB Center for Health and Human Rights and Open Society Foundations, 'Health and Human Rights Rescource Guide', 2013.

environment and TB in your country and what it shows
- A note on where information is lacking
- A statement about what your research will contribute to understandings of the legal environment and TB in your country.]

3. Research objectives

This research aims to support an improved national TB response through:

- Providing qualitative insights into the ways that gender, belonging to certain key populations and the legal environment of a country impact on vulnerability to TB infection, access to care, and treatment outcomes.
- Providing information on how the TB response can improve to be more gender-sensitive and more responsive to key populations.
- Assessing and making recommendations for a strengthened legal and regulatory framework for improved access to TB diagnosis, treatment and care.

4. Research questions

This qualitative research will ask:

1. Gender

- How does gender identity impact on the social dynamics of TB vulnerability, care access and treatment outcomes?
- What programme delivery changes could be made to improve gender-sensitivity in the TB response?

2. Key populations

- How does belonging to one or more of the selected key populations impact on the social dynamics of TB vulnerability, care access and treatment outcomes?
- What programme delivery changes could be made to improve TB response for people belonging to the selected key populations?

3. Legal environment

- How does the current legal environment impact on access to TB-related healthcare, or increase vulnerability and create barriers to access TB-related healthcare?
- What rights-based programmatic responses - including strengthening laws, policies and regulations; reducing stigma and discrimination; increasing access to justice; and improving law and policy enforcement - could be put in place to improve the TB response?

5. Research design

5.1. Research methods

Research methods include:

- **Observations** in selected facilities or in-community with healthcare workers affiliated with the selected facilities.
- **Key informant interviews** with experts and advocates in the field
- **Interviews** with TB-affected individuals
- **Focus groups** with healthcare providers and people affected by TB. This includes focus groups with farm workers, people who use substances and healthcare workers. Issues related to vulnerability and care for TB-index patient contacts have been integrated into all methods. Therefore, a separate research tool designed for this particular group has not been provided in this research process.
- **Facilitated research activities** with people affected by TB. There are a number of methods designed, each will be used to capture a different aspect of life.

The table below provides an overview of planned participants, research topics, methods and sites. The tables are divided by research implementation location. Each method has an associated information sheet, consent document and research tool included in the appendices – the reference to these tools is included in the table. The research tools have been designed to broadly capture the dynamics and experiences of TB infection, diagnosis, care access and treatment completion from the perspectives of TB-affected individuals (patients and family members); healthcare providers; and stakeholders (including civil society advocates and government representatives). The attached tools may be adapted somewhat according to emerging data and the needs of the participants.

5.2. Research sites

[Insert which research sites you will use, and explain why you have selected these sites]

Further cities and sites are not included due to time, resourcing and capacity constraints. Key informant interviews will happen in locations suitable to the interviewee, or via phone or Skype.

Research will not start until:

- Memorandums of Understanding have been agreed upon with civil society partner organizations.
- The protocol has been approved by [insert selected ethics board]

Table 1: Research methods and participants

LOCATION:							
Method	**Participants**	Topic	# of methods per site	Tool appendix #	Info doc appendix #	Consent doc appendix #	Notes
Observations	Example: TB facility patients and staff	Example: Treatment provision process overview	1	D1	A1;A2	B1	Example: Observation (up to 8 hours) in a facility and/or in-community with facility affiliated healthcare workers.
Interviews							
Focus groups							
Facilitated activities							

5.3. Study populations

The study will include:

- Men, women and transgender people affected by TB - where "people affected by TB" refers to people ill with TB and their family members, dependents, communities and healthcare workers who may be involved in care-giving or are otherwise affected by the illness.
- People self-identifying as belonging to the following four selected key populations and affected by TB:
    - [insert selected KP and the definition of that group]
    - [insert selected KP and the definition of that group]
    - [insert selected KP and the definition of that group]
- Healthcare providers involved in the TB response
- TB response and included key population experts

5.4. Participant inclusion criteria

All participants will be required to meet the following criteria:

- Aged 18 years and older (based on self-reports)
- Provides informed consent for their data to be included in the research process

In addition, participants should meet the criteria for one or more of the following research areas:

Gender

- Affected by TB in [insert limited time period, e.g. five years]

AND/OR

- Is interested in or does work that is related to the gender-related aspects of the TB response.

Key populations

- Affected by TB in [insert limited time period, e.g. five years]

AND/OR

- Self-identifies as belonging to one of the above-described key population groups.

AND/OR

- Works with or has an interest in one of the selected key populations and the TB response.

Legal environment

- Affected by TB in [insert limited time period, e.g. five years]

AND/OR

- Works or has an interest in human rights and/or legal-environment-related aspects of the TB response.

5.5. Sampling

Participants will be purposefully sampled:

- Healthcare workers will be recruited through treatment providers, and general TB patients will be accessed through a TB treatment facility selected by the managing regional governmental institution.
- Members of selected key populations will be sampled through local advocacy and/or programme delivery organizations.
- Key Informants will be sampled through local government institutions and civil society organizations.

6. Research methods – data collection and analysis

Data will be collected by a team of trained qualitative researchers through a combination of research methods including key informant interviews, focus groups and facilitated activities.

6.1. Recruitment, eligibility assessment and consent

Stakeholders and key informant interviewees will be invited to participate by the research team based on scoping reviews and stakeholder meetings which have previously been conducted.

Healthcare providers will be invited to participate by the researchers, based on their roles in health care facilities.

Key population members will be invited to participate through civil society organizations working for the rights of the affected population. In facilities where observations are taking place, information posters will be put up (see Appendix A2.) All participants in interviews, focus groups and facilitated activities will be taken through a process of obtaining informed consent by trained team members based on the General Information Sheet (see Appendix A 1), the additional information sheets relevant to the method being used (see Appendix A 3-7) and the consent documents (see Appendix B 1- 4). Participants who are eligible and agree to take part in the research will be asked to sign 2 copies of the appropriate consent forms, one of which will be theirs to keep. In cases where key informants are interviewed by phone or Skype, signed consent documents will be collected electronically.

6.2. Data collection, security and analysis

The team is competent in conducting research in [insert researcher languages]. As far as possible, the research participant will be allowed to participate in a language of their choice. Data will be recorded through a combination of audio recordings, written notes and participant-drawn images.

Researchers will take the following precautions to maintain data security:

- Voice recorders will be securely stored
- Research notebooks and participant drawings will be securely stored while at the research sites, and will be removed from the research sites with the researchers and securely stored off-site.
- All data entered into and stored on computers will be password protected
- All data will be coded and analysed using NVivo software. Where transcriptions and translations are required, these may be done by additional staff who will also sign study-specific confidentiality agreements. Coding frameworks will be independently developed by at least 2 researchers for comparison before the coding framework is finalised.

7. Ethical concerns and processes

This study will include a variety of participants, from policy makers and people working in health access advocacy, to people affected by TB and belonging to the selected key populations. Some of the key population members [insert any very stigmatised selected key population] are subject to stigmatising responses from healthcare workers. The inclusion of these participants is critical because they are best positioned to provide insights into their own experiences, as well as insights into the barriers to care that are essential for improving healthcare processes. However, their protection requires that additional safety measures are put into place. The ethical considerations for all participants are outlined below, with special attention to these matters.

As an entirely qualitative study, this study is relatively low risk. However, there are some risks involved, including the following:

- Participants may experience negative emotions as a consequence of remembering negative events in their lives. In this case, participants will be offered professional counselling and support where needed.
- Participants attending focus groups and facilitated activities may be identified as having been affected by TB or as belonging to a key population by people who did not previously know about this. This could result in stigma and discrimination. This also requires that additional care be taken regarding the location of the research (see below).
- Group members may not respect each other's confidentiality (see below)

Participants will be warned of these risks and every effort will be made to protect privacy and confidentiality. We detail the efforts that will be put into place below.

Numerous ethical concerns are being taken into account, and processes put into place to protect research participants. These include:

Informed consent. Informed consent will be implemented as described above

Voluntary participation. Participation will always be voluntary and there will be no negative consequences for refusing to participate. People belonging to vulnerable

groups lack agency in the extent of their involvement in processes. This research therefore seeks to balance the right to participate with the right to withhold information, or withdraw from the study completely. Special attention will be paid to indications that participation is uncomfortable, such as non-responsiveness and active silences.

Privacy and confidentiality. An array of protections are being put in place to protect participants' privacy and confidentiality. These include:

- Careful management of data (see above)
- Use of pseudonyms in all data entered into [insert research analysis tool] and the removal of any other identifying features before data is made public.
- Use of private spaces for interviews and group sessions (i.e. focus groups and facilitated activities).
- Use of safe, accessible, friendly sites (not TB care facilities) for research methods with key populations. This will be done to avoid identification by healthcare providers and employers as a key population member and research participant. In so doing, the participant will be able to avoid potential future discrimination and stigma.
- The limits of the ethical principle of confidentiality will be discussed with participants. Limits would include, for example, cases where the information provided indicates that the health and lives of individuals are being placed at risk. In instances where this is the case, appropriate action will be taken and the protection of vulnerable parties will always be placed first.
- All researchers will be required to sign a study-specific confidentiality agreement (see Appendix C). Furthermore, participant privacy and confidentiality will be maintained through:

Benefits of participation. TB-affected individuals will receive remuneration [insert remuneration amount] to cover the essential costs of their participation. Stakeholders and key informant interviewees will not receive remuneration unless they have incurred travel costs coming to the interview or focus group sites, in which case travel costs up to [insert remuneration amount] will be covered. It will be made clear to all participants that they will receive no further direct benefits of participation, but that their information will have value in shaping the international and national TB response.

Disruption to healthcare services. Healthcare facilities are being selected in collaboration with Provincial Departments of Health based on their location, patient and TB burden, and the fact that they have not been over-researched. Every effort will be made to cause minimal disruption to everyday healthcare provision processes.

Language. The research team members have fluency in [list research languages], and participants will be invited to use any of these languages. Consent processes will also happen in the language that the participant is most comfortable using. The general information sheet will be available in [list languages].

Ethical approval. In addition to [insert approving ethics committee] approval, this research will not commence until ethical approval has been obtained by the required Department of Health Ethics Boards.

Infection control. Researchers and research participants will be required to follow healthcare facility infection control processes. Patients with infectious TB will not be included in group activities in other facilities unless protective masks are available for all participants.

Expert guidance. There may be times when guidance on ethical responses are not clearly provided by ethical frameworks and guidelines, or by the law. Where this is the case, expert advice will be sought.

Expectation management. Often vulnerable participants have the hope that researchers have the power to influence the care they receive. While this study is designed to have a positive systemic impact, the limited ability of the researchers to impact on individual cases will be made clear to all participants.

Negative emotions resulting from memories of unpleasant events. Participants are being asked to remember events from their history, some of which may be unpleasant. Researchers will listen with empathy, and refer participants to trained counsellors where necessary.

Ultimately, we recognise that ethical qualitative research implementation lies in negotiated, empathic engagement, in which – in addition to the implementation of core ethical principles (outlined below for this study) – the integrity, dignity and autonomy of participants are recognised. The power dynamics inherent in research relationships are also recognised, especially as they might impact on vulnerable people within health research.

8. Results dissemination

The results of the study will be integrated into the [insert country name] Community, Rights and Gender Assessment Report. The report and a short, easy to understand document outlining key research findings will be disseminated to all research sites. Policy briefs outlining the key findings for each aspect of the CRG report will be disseminated to relevant government departments, healthcare provision partners and civil society organizations. [Insert any other dissemination plans].

9. Conclusion

The planned research is designed to capture a large amount of qualitative data in a limited amount of time so as to provide lived-experience insights into the ways in which gender, specific key population membership and the [insert country name] legal environment impact on TB vulnerability, care access and treatment outcomes. The findings and recommendations will be assessed and evaluated by an expert multi-stakeholder group. The eventual report will be used as baseline information for international and national bodies working towards improved TB response outcomes.

10. Budget

The proposed research falls under the [insert country name] Community Rights and Gender Assessment budget and costs are fully covered by the StopTB Partnership. No further budget is being sought. The budget available for the immediate research implementation (outside of personnel costs) is [insert total budgeted cost].

Table 5: Research implementation direct costs

[Insert research implementation budget]

11. Conflicts of interest

There are no conflicts of interest for the proposed study.

12. Time frame

Insert timeframe details. Example:

	2018				
	August	September	October	November	December
Ethics Review					
Ethics Review - Provinces					
Research implementation site 1					
Research implementation site 2					
Data transcription and analysis					
Draft report development					
Findings validation by multi-stakeholder group					
Report finalisation					
Project close out					

13. Bibliography

[insert full bibliography here]

FXB Center for Health and Human Rights, and Open Society Foundations. 'Health and Human Rights Rescource Guide', 2013.

Global Fund. 'Human Rights and the Global Fund to Fight AIDS, Tuberculosis and Malaria', 2011.

Smelyanskaya, Marina, Colleen Daniels, Clifton Cortez, and Boyan Konstantinov. 'Legal Environment Assessments for Tuberculosis. An Operational Guide', 2017.

Stop TB Partnership. 'The Paradigm Shift 2016 - 20120'. Geneva, 2016. https://doi.org/22 August 2016.

14. Appendix A: Information Sheets

1. General Information Sheet

Researcher: _____

I am working with [insert organisation] doing research on a project for the StopTB Partnership (http://www.stoptb.org). This project is trying to understand why so many people who have TB do not get diagnosed or treated to cure. In particular, we are looking at the ways in which gender and the legal environment affect vulnerability to TB and access to care. We are also looking at how some populations [insert selected key populations] are particularly at risk of TB and what accessing care is like for these populations. This is to help inform better policy and health care provision.

We are including lots of different people in this research - from people making policy, people advocating for better treatment, to people who have been affected by TB.

We are gathering information in lots of different ways, including:

- Spending time watching the everyday ways that the facility works;
- Talking to people about their experiences of seeking, receiving and providing care;
- Conducting semi-structured individual interviews;
- Conducting focus group discussions;
- Running facilitated activities.

We may ask you if you are willing to participate in this research. This does not mean that we think that you necessarily have TB. It just means that we think you may have a valuable opinion or expertise on the subject.

It is entirely your choice whether to participate or not, and you may choose to participate in one aspect, but not another. If you *do* choose to participate in any aspect, you will be asked to sign a relevant "consent form". This form gives me permission to use the information you provide. You may change your mind later and stop participating even if you agreed earlier. If you choose *not to* participate, it won't affect you in any way.

There are no direct benefits to you for participating in the research, though we do hope that it will lead to positive change in the way TB is responded to. Some participants will receive a small remuneration for transport costs. This is detailed in the additional information sheets for the different research methods.

Any communication with any of the researchers will be completely confidential. This means that anything you say will stay private. We may discuss information amongst the researchers, but we have all signed confidentiality forms and we will only include anything you tell us in the written documents once we have removed any way for other people to know who the information comes from. The only time we might tell someone else what you said is when it puts someone in danger.

This research has been approved by [include approving ethics committee]. We also have approval from all the managers of the healthcare facilities we are working in.

If you have any questions or are uncomfortable with anything, you can speak to me or one of my colleagues at any time. You may also ask to review anything I have written that relates to you. Alternatively, you can raise any concerns you may with:

[insert details of research and ethics leads in here]

2. Facility Information Sheet

Research in Progress

To All Staff, Patients and Observers

Research is currently being done in this facility. Researchers are observing and participating in some of the operations of this facility in order to try and understand some of the things that make it easier or harder to get TB treatment.

Note that any researcher will:

- Always explain the research to you if she wants to include you in the research process;
- Always ask your permission before including you in the research;
- Always respect your treatment processes and your right not to participate;
- Never identify you personally in the research report.

Note that you:

- Have no obligation to participate;
- Can withdraw your consent to participate at any time;
- Can request that anything you say be left out of her research report.

Permission to carry out this project has been obtained from the Department of Social Anthropology and the Human Research Ethics Committee (HREC) at the University of Cape Town. If you have any concerns, please feel free to raise these concerns with [insert contacts]. You can also raise them with the management of this facility, who have also approved this research. Contact details are provided below.

[Insert contact details]

3. Interviewee Additional Information Sheet: TB-affected individuals

I am asking you to participate in a one-to-one semi-structured interview for my research because we are interested in your personal perspective, knowledge and experience on what makes people vulnerable to TB infection and what it is like getting care.

To be interviewed for this research, it is important that you understand the contents of the attached "General Information Sheet", as everything said there is relevant to interviews as well.

The interview is "semi-structured" because in addition to talking about the themes of the interview, we may also discuss additional related topics that arise. If you do not want to answer a particular question, you do not have to.

This interview will be conducted in a private space and you can decide whether you are comfortable with a voice recording or would rather that the interviewer only writes interview notes. The interview is expected to take between 20 minutes to an hour and a half, and your available time will be taken into consideration.

You will receive [insert amount] to cover the costs of your coming today.

4. Interviewee Additional Information Sheet: Key Informants

I am asking you to participate in a one-to-one semi-structured interview for my research because we are interested in your personal perspective, knowledge and experience on what makes people vulnerable to TB infection and what it is like getting care.

To be interviewed for this research, it is important that you understand the contents of the attached "General Information Sheet", as everything said there is relevant to interviews as well.

The interview is "semi-structured" because in addition to talking about the themes of the interview, we may also discuss additional related topics that arise. If you do not want to answer a particular question, you do not have to.

This interview will be conducted in a private space, and you can decide whether you are comfortable with a voice recording or would rather that the interviewer only writes interview notes. The interview is expected to take between 30 minutes to an hour and a half, and your available time will be taken into consideration.

5. Focus Groups Additional Information Sheet: TB-affected Individuals

Focus groups are small group discussions where specific questions relating to the research are asked by the focus group leader and discussed by the groups. I am asking you to participate in a focus group discussion because I think you might know something about what makes people vulnerable to TB, and what getting treatment is like for people.

To participate in a focus group discussion, it is important that you understand the contents of the "General Information Sheet" for this research, as everything said there is relevant to the focus groups as well. It is also important that you know that the focus group will be held in a private space, and everyone in the group will be asked to regard everything that is said in the group as confidential. This means that what is said in the group is not discussed outside of the group and after the event. Every participant will be asked to sign a document that agrees to this. Please note, however, that while I can guarantee that I will not identify any individual personally in my own work, I cannot promise that other people will not do so. Please be aware of this.

The focus group leader will record the discussion. Care will be taken to protect these recordings and we will ensure that these remain confidential.

You will receive [insert amount] to cover the costs of your coming today.

The discussion will take between 45 minutes to an hour and a half.

6. Focus Groups Additional Information Sheet: Healthcare Providers

Focus groups are small group discussions where specific questions relating to the research are asked by the focus group leader and discussed by the groups. I am asking you to participate in a focus group discussion because I think you might know something about what makes people vulnerable to TB, and what getting treatment is like for people.

To participate in a focus group discussion, it is important that you understand the contents of the "General Information Sheet" for this research, as everything said there is relevant to the focus groups as well. It is also important that you know that the focus group will be held in a private space, and everyone in the group will be asked to regard everything that is said in the group as confidential. This means that what is said in the group is not discussed outside of the group and after the event. Every participant will be asked to sign a document that agrees to this. Please note, however, that while I can guarantee that I will not identify any individual personally in my own work, I cannot promise that other people will not do so. Please be aware of this.

The focus group leader will record the discussion. Care will be taken to protect these recordings and we will ensure that these remain confidential. The discussion will take between 45 minutes to an hour and a half.

7. Facilitated Activities Additional Information: TB-affected individuals

Facilitated activities are activities where you are asked to take part in some creative exercises that draw on your personal knowledge and provide us with information on how you understand and experience the world you live in. In this research, we are particularly interested in what it is about your life and the lives of the people around you that creates vulnerability to TB infection and impacts on access to care.

To participate in the facilitated activities, it is important that you understand the contents of the "General Information Sheet" for this research, as everything said there is relevant to these processes as well. It is also important that you know that these processes will be held in a private space, and everyone in the group will be asked to regard everything that is said in that room as confidential. This means that what is said in the room is not discussed outside of the group and after the event. Every participant will be asked to sign a document that agrees to this. Please note, however, that while we can guarantee that we will not identify any individual personally in our own work, we cannot promise that other people will not do so. Please be aware of this. The facilitated activity will take between 30 minutes to an hour and a half.

We may also ask you to do a short, 10-minute interview with us at the end in which you summarise your thoughts on what you have done in the facilitated activity. This is not required. If you agree to this, we will ask to record the interview.

You will receive [insert amount] for your participation, whether you do the additional interview or not.

15. Appendix B: Consent Forms

For each research event, the researcher and the participant will sign 2 consent forms. One will be kept by the researcher and the other one will be given to the participant to keep, if they wish.

1. General Observation and Conversation Consent Form

I agree to participate in this research project. I am familiar with the contents of the General Information Sheet and this General Observation and Conversation Consent Sheet. I have had the opportunity to ask questions about the research and I understand what participation might entail.

In addition:

- I understand that I will not be in any way identifiable in the research
- I understand that I am not obliged to take part in this project
- I understand that I have the right to withdraw from this project at any stage
- I understand that written notes may be made of situations and conversations that I am part of in this research process.

Participant:

Signature: _____ Name: _____

Date: _____

Researcher:

Signature: _____ Name: _____

Date: _____

2. Interviewees Consent Form: All Interviewees

I agree to participate in this research project. I am familiar with the contents of the General Information Sheet, the Interview Information Sheet and this Interview Consent Form.

I have had the opportunity to ask questions about these documents, and I understand their contents. I agree to my interview responses being used for research on the condition that my privacy is respected.

In addition:

- I understand that I will not be in any way identifiable in the research
- I understand that I am not obliged to take part in this project
- I understand that I have the right to withdraw from this project at any stage
- I agree to let the interviewer take written notes/make a voice recording [delete inappropriate phrase if required] of the interview.

Participant:

Signature: _____ Name: _____

Date: _____

Researcher:

Signature: _____ Name: _____

Date: _____

3. Focus Groups Consent Form: All Focus Group Participants

I agree to participate in this research project. I am familiar with the contents of the General Information Sheet, the Focus Group Information Sheet and this Focus Group Consent Form.

I have had the opportunity to ask questions about these documents, and I understand their contents. I agree to my responses being used for research on the condition that my privacy is respected.

In addition:

- I understand that what is said in this focus group is confidential and I agree that I will maintain the privacy of other members in this group. That means that what is said in the focus group discussion is not discussed with other people later.
- I understand that I will not be in any way identifiable in the research
- I understand that I am not obliged to take part in this project
- I understand that I have the right to withdraw from this project at any stage
- I agree to let the focus group leader make a voice recording of the focus group discussion based on the understanding that this will be kept confidential.

Participant:

Signature: _____ Name: _____

Date: _____

Researcher:

Signature: _____ Name: _____

Date: _____

4. Facilitated Research Activities Consent Form: TB affected individuals

I agree to participate in this research project. I am familiar with the contents of the General Information Sheet, the Facilitated Activities Information Sheet and this Interview Consent Form. I have had the opportunity to ask questions about these documents, and I understand their contents. I agree to my interview responses being used for research on the condition that my privacy is respected.

In addition:

- I understand that I will not be in any way identifiable in the research
- I understand that I am not obliged to take part in this project
- I understand that I have the right to withdraw from this project at any stage
- I agree to let the interviewer take written notes/make a voice recording [delete inappropriate phrase if required] of the interview.

Participant:

Signature: _____ Name: _____

Date: _____

Researcher:

Signature: _____ Name: _____

Date: _____

16. Appendix C: Researcher Confidentiality Agreement

Study Title: Impact of gender, key population affiliation and the national legal environment on TB vulnerability, diagnosis and treatment in two South African provinces.

Confidentiality Agreement

I recognise that in carrying out my assigned duties as a researcher on the project [insert research title]; I may obtain access to private information about people - provided under a promise of confidentiality. I understand that I am not allowed to disclose the information collected or share any personal identifying information - either directly or indirectly - about any person that I come into contact with as part of this project. Should I be responsible for any breach of confidentiality, I understand that civil and/or criminal penalties may be brought against me. I acknowledge that my responsibility to ensure the privacy of protected health information contained in any electronic records, paper documents or verbal communications to which I may gain access shall not expire, even after my employment or affiliation with this project has terminated.

By my signature, I acknowledge that I have read, understood and agree to comply with the terms and conditions of this Confidentiality Agreement.

Name (printed): _____

Signature: _____

Date: _____

17. Appendix D: Research Tools

Example:

1. Observation Sheet

Observation Sheet

Place: Date: Researcher: Start time: End time:	Observation focus: (insert key words in here)

Insert selected, adapted and developed research tools in here