**Adhering to HIV treatment during adolescence: a multi-method qualitative study in Uganda**

**Information sheets and consent forms for the BREATHER QUALITATIVE STUDY**

(Interviews and audio/written diaries)

INFORMATION SHEETS

1. Parents/ carers
2. Young adults (18-24 years old)
3. Young adults (16-17 years old)
4. Young people (approx 12-15 years old)
5. Children (approx 10-11 years old)
6. Carer interviews

CONSENT FORMS

1. Parents/ carers
2. Young adults (18-24 years old)
3. Young adults (16-17 years old)
4. Carer interviews

ASSENT FORMS

1. Anyone participating under 16 years old

**Focus groups- Information sheets and consent forms -BREATHER QUALITATIVE STUDY**

Focus groups- INFORMATION SHEETS

1. Parents/ carers
2. Young adults (16-24 years old)
3. Young people and children

Focus groups- CONSENT FORMS

1. Parents/ carers
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Focus groups- ASSENT FORM

1. Anyone participating under 16 years old.
2. **BREATHER Qualitative study- Young people and HIV treatment adherence**

**AN INFORMATION SHEET FOR PARENTS/ CARERS**

As part of the BREATHER trial, we are carrying out a qualitative interview study to hear from children and young people (aged 10-24 years) about their experiences of HIV treatment. At least 40 children and young people from the PENTA trial will take part in this study.

Before you decide whether you would like your child to participate it is important that you understand why the research is being done and what it involves. Please read this information sheet carefully and ask any questions you may have. You can also ask one for of the study researchers to telephone you should you like to discuss the study in more detail before deciding.

***Thank you for taking the time to read this information.***

**What is the purpose of the study?**

The study aims to gain a better understanding of what the day-to-day experience of HIV treatment is like for children and young people. There is little research asking children and young people themselves of their experiences, and this is why we are doing the study. We are especially interested in how they manage taking their treatment day-to-day and any difficulties they have with this. We are also interested in how they experience being involved in the study. By listening to what children and young people tell us, we hope to suggest ways to improve the experience of treatment including supporting long term adherence to taking HIV treatment.

**Who is carrying out the study?**

This research is part of the BREATHER study. It is therefore organised by the Paediatric European Network for the Treatment of AIDS (PENTA). This qualitative study is being run by [researcher names] at the London School of Hygiene and Tropical Medicine.

**What is involved?**

This is a ‘qualitative’ study. The approach assumes that the best way to learn about the experiences of children and young people is to listen carefully to what they have to say. We would therefore like to talk to your child about what their experience of HIV treatment is like, and whether they experience difficulties in maintaining adherence to their prescribed medications. We would also like to learn about their experience of this study, either through ‘short-cycle therapy’ or continuous therapy.

Children and young people in the study will participate in three interviews and if they would like to, in keeping an audio diary.

**Interviews**

The first interview will take place in the early stages of the trial. The second interview will be towards the end of their participation in the trial. There may be a third interview, which will take place 3-6 months after the study has ended. All interviews will take place at a place and time convenient to you and your child. It will be conducted by one of the qualitative researchers and will last about an hour. We ask that we record the interview unless your child does not want this. Your child does not have to talk about things that he or she does not want to talk about, and they can end the interview at any time and without explaining why.

***Audio diaries***

In addition to the interviews, we would like to invite your child to keep an audio diary, which is like a spoken diary. We will provide your child with a Dictaphone and ask him/ her to record an audio diary over two fortnightly periods. This will be in the early stages of the study and the second period will be around 36 weeks.

***Written Diaries***

If your child happens to be keeping a written diary relating to their HIV and treatment and would like to share this with the research team, this could also be used as part of the research to better understand their experience.

Both audio and written diaries are options. If preferred, your child can participate in the study interviews only.

**Is the research confidential?**

**Yes**. Any information that your child shares with us will only be seen by members of the research team. This means that whenever we write or talk about anything we have been told we never use your child’s real name. All information about your child will be stored securely.

The only information that we may have to pass on is information about children and young people who are at risk of serious harm, such as physical harm or neglect.

**How will the research be used?**

The findings of this study will be reported to a wide range of people, including those who provide treatment, care and support for children and young people living with HIV. The findings will be used to guide the future implementation of HIV treatment, short-cycle therapy, and HIV treatment studies involving children and young people.

**What are the benefits and risks of taking part?**

Your child will be part of a study that aims to help young people maintain long term adherence. Your child may see the opportunity to talk about their HIV treatment as an entirely positive experience. For some, however, this is a sensitive topic which may be difficult to talk about. Your child will not need to answer any questions that they do not want to. They are free to withdraw from the interview and/or study at any time. Great care is given to asking questions as sensitively as possible. The content of the interviews is also led by the child (as well as the researcher) and what they wish to talk about. Support is also available to participants through their clinic, including immediately after the interview.

**Does my child** **have to take part?**

**No**, your child does not have to take part in the study. Your child’s participation in the BREATHER study will not be affected in anyway if you prefer for your child not to take part. It will not affect any of the services your child receives.

**Will my child** **receive anything from taking part?**

Yes, all children and young people who take part will receive a £15 gift-voucher for the first interview and £20 for the second and third interview.

Travel expenses to attend interviews will be reimbursed. *[Country specific, delete if not applicable]*

**Can I have some more information before I decide?**

If you would like some more information, the staff at your clinic can arrange for you to speak to the research team about the study and answer any further questions you may have.

**Ok, I’m happy for my child to take part. Now what?**

Please sign the consent form and give it to the staff at your clinic. We will not be inviting everyone to take part who is participating in the study. Instead we will invite a representative group of young people to take part in this qualitative study. If your child is selected [researcher names] will contact you on the phone number that you have given the clinic to arrange the first interview.

**Thank you for reading this!**

**If you do decide to participate your help will be very valuable to us.**

1. **BREATHER QUALITATIVE STUDY- YOUNG PEOPLE AND HIV TREATMENT ADHERENCE**

**AN INFORMATION SHEET FOR YOUNG ADULTS (18+)**

As part of the BREATHER study, we are doing a qualitative interview study to hear from children and young people (aged 10-24 years) about their experiences of HIV treatment. At least 40 children and young people from the PENTA study will take part in this study.

Before you decide whether you want to participate it is important that you understand why the research is being done and what it involves. Please read this information sheet carefully and ask any questions you may have. You can also ask for one of the study researchers to telephone you should you like to discuss the study in more detail before deciding.

***Thank you for taking the time to read this information****.*

**What is the purpose of the study?**

The study aims to gain a better understanding of what the day-to-day experience of HIV treatment is like for children and young people. There is little research asking young people themselves of their experiences, and this is why we are doing the study. We are especially interested in how they manage taking their treatment day-to-day and any difficulties they have with this. We are also interested in how you find being involved in the study. By listening to what you and other young people tell us, we hope to suggest ways to improve the experience of treatment including long term adherence to taking medications.

**Who is carrying out the study?**

This research is part of the BREATHER study. It is therefore organised by the Paediatric European Network for the Treatment of AIDS (PENTA). This qualitative study is being run by [researcher names] at the London School of Hygiene and Tropical Medicine.

**What is involved?**

This is a ‘qualitative’ study. The approach assumes that the best way to learn about the experiences of young people is to listen carefully to what they have to say. We would therefore like to talk to you about what your experience of HIV treatment is like, and whether you experience any difficulties in maintaining adherence to their prescribed medications. We would also like to learn about your experience of this study, either through ‘short-cycle therapy’ or continuous therapy.

If you choose to take part the study will involve participating in three interviews and if you would like to, in keeping an audio diary.

**Interviews**

The first interview will take place in the early stages of the trial. The second interview will be towards the end of your participation in the trial. There may be a third interview, which will take place 3-6 months after the study has ended. All interviews will take place at a place and time convenient to you. It will be conducted by one of the researchers and will last about an hour. We ask that we record the interview unless you do not want this. You do not have to talk about things that you do not want to talk about. You can end the interview at any time, without explaining why.

**Diaries**

***Audio diaries***

In addition to the interviews, we would like to invite you to keep an audio diary, which is like a spoken diary. We will provide you with a Dictaphone and ask you to record an audio diary over two fortnightly periods. This will be in the early stages of the trial and the second period will be around 36 weeks.

***Written Diaries***

If you happen to be keeping a written diary relating to your HIV and treatment and would like to share this with the research team, this could be used as part of the research to better understand your experience.

Both audio and written diaries are options. If you prefer, you can participate in the study interviews only.

**Is the research confidential?**

Yes. Any information that you share with us will only be seen by members of the research team. This means that whenever we write or talk about anything we have been told we never use your real name. All information about you will be stored securely.

**How will the research be used?**

The findings of this study will be reported to a wide range of people, including those who provide treatment, care and support for children and young people living with HIV. The findings will be used to guide the future implementation of HIV treatment, short-cycle therapy and HIV treatment studies involving children and young people.

**What are the benefits and risks of taking part?**

You will be part of a study that aims to help young people maintain long term adherence. You may see the opportunity to talk about your HIV treatment as an entirely positive experience. However as this is a sensitive issue it may be difficult to talk about. Great care is given to asking questions as sensitively as possible. The content of the interviews is also led by you (as well as the researcher) and what you wish to talk about. Support is also available to you through your clinic, including immediately after the interview.

**Do I have to take part?**

No, you do not have to take part in the study. Your participation in the BREATHER study will not be affected in anyway if you prefer not to take part. It will not affect any of the services you currently receive.

**Will I receive anything for taking part?**

Yes, you will receive a £15 gift-voucher for the first interview and £20 for the second and third interview. Travel expenses to attend interviews will be reimbursed.[Country specific, delete if not applicable]

**Can I have some more information before I decide?**

If you would like some more information, the staff at your clinic can arrange for you to speak to the research team about the study and answer any further questions you may have.

**Ok, I’m happy for to take part. Now what?**

Please sign the consent form and give it to the staff at your clinic. We will not be inviting everyone to take part who is participating in the study. Instead we will invite a representative group of young people to take part in this qualitative study. If you are selected [researcher names] will contact you on the phone number that you have given the clinic to arrange the first interview.

**Thank you for reading this!**

**If you do decide to participate your help will be very valuable to us.**

1. **BREATHER Qualitative study- Young people and HIV treatment adherence**

**AN INFORMATION SHEET FOR YOUNG ADULTS (16-17 YEARS OLD)**

As part of the BREATHER study, we are doing a qualitative interview study to hear from children and young people (aged 10-24 years) about their experiences of HIV treatment. At least 40 children and young people from the PENTA study will take part in this study.

Before you decide whether you want to participate it is important that you understand why the research is being done and what it involves. Please read this information sheet carefully and ask any questions you may have. You can also ask for one of the study researchers to telephone you should you like to discuss the study in more detail before deciding.

***Thank you for taking the time to read this information.***

**What is the purpose of the study?**

The study aims to gain a better understanding of what the day-to-day experience of HIV treatment is like for children and young people. There is little research asking young people themselves of their experiences, and this is why we are doing the study. We are especially interested in how they manage taking their treatment day-to-day and any difficulties they have with this. We are also interested in how you find being involved in the study. By listening to what you and other young people tell us, we hope to suggest ways to improve the experience of treatment including long term adherence to taking medications.

**Who is carrying out the study?**

This research is part of the BREATHER study. It is therefore organised by the Paediatric European Network for the Treatment of AIDS (PENTA). This qualitative study is being run by [researcher names] at the London School of Hygiene and Tropical Medicine.

**What is involved?**

This is a ‘qualitative’ study. The approach assumes that the best way to learn about the experiences of young people is to listen carefully to what they have to say. We would therefore like to talk to you about what your experience of HIV treatment is like, and whether you experience any difficulties in maintaining adherence to their prescribed medications. We would also like to learn about your experience of this study, either through ‘short-cycle therapy’ or continuous therapy.

If you choose to take part the study will involve participating in three interviews and if you would like to, in keeping an audio diary.

**Interviews**

The first interview will take place in the early stages of the trial. The second interview will be towards the end of your participation in the trial. There may be a third interview, which will take place 3-6 months after the study has ended. All interviews will take place at a place and time convenient to you. It will be conducted by one of the researchers and will last about an hour. We ask that we record the interview unless you do not want this. You do not have to talk about things that you do not want to talk about. You can end the interview at any time, without explaining why.

**Diaries**

***Audio diaries***

In addition to the interviews, we would like to invite you to keep an audio diary, which is like a spoken diary. We will provide you with a Dictaphone and ask you to record an audio diary over two fortnightly periods. This will be in the early stages of the study and the second period will be around 36 weeks.

***Written Diaries***

If you happen to be keeping a written diary relating to your HIV and treatment and would like to share this with the research team, this could be used as part of the research to better understand your experience.

Both audio and written diaries are options. If you prefer, you can participate in the study interviews only.

**Is the research confidential?**

Yes. Any information that you share with us will only be seen by members of the research team. This means that whenever we write or talk about anything we have been told we never use your real name. All information about you will be stored securely.

The only information that we may have to pass on is information about young people who are at risk of serious harm, such as physical harm or neglect.

**How will the research be used?**

The findings of this study will be reported to a wide range of people, including those who provide treatment, care and support for children and young people living with HIV. The findings will be used to guide the future implementation of HIV treatment, short-cycle therapy and HIV treatment studies involving children and young people.

**What are the benefits and risks of taking part?**

You will be part of a study that aims to help young people maintain long term adherence. You may see the opportunity to talk about your HIV treatment as an entirely positive experience. However as this is a sensitive issue it may be difficult to talk about. Great care is given to asking questions as sensitively as possible. The content of the interviews is also led by you (as well as the researcher) and what you wish to talk about. Support is also available to you through your clinic, including immediately after the interview.

**Do I have to take part?**

No, you do not have to take part in the study. Your participation in the BREATHER study will not be affected in anyway if you prefer not to take part. It will not affect any of the services you currently receive.

**Will I receive anything for taking part?**

Yes, you will receive a £15 gift-voucher for the first interview and £20 for the second and third interview. Travel expenses to attend interviews will be covered. [Country specific, delete if not applicable]

**Can I have some more information before I decide?**

If you would like some more information, the staff at your clinic can arrange for you to speak to the research team about the study and answer any further questions you may have.

Ok, I’m happy for to take part. Now what?

Please sign the consent form and give it to the staff at your clinic. We will not be inviting everyone to take part who is participating in the study. Instead we will invite a representative group of young people to take part in this qualitative study. If you are selected [researcher names] will contact you on the phone number that you have given the clinic to arrange the first interview.

**Thank you for reading this!**

**If you do decide to participate your help will be very valuable to us.**

1. **BREATHER Qualitative study- Young people and HIV treatment adherence**

**An information sheet for young people**

As part of the BREATHER study, we are doing a study to hear from children and young people (aged 10-24 years) about their experiences of HIV treatment. At least 40 children and young people from the PENTA study will take part in this study. We would like you to join our study.

Before you decide if you want to take part please read this information sheet carefully and ask any questions you may have.

**What is the purpose of the study?**

This is a study to find out about what it is like for young people to take HIV treatment. This will be done by talking with young people, like you, about their experiences of HIV treatment. This is because we think that the best way to learn about the experiences of young people is to listen carefully to what they have to say.

**Why is the study being done?**

Until now there hasn’t been much research done which asks young people themselves about their experiences of taking HIV treatment. This is why we are doing the study. By listening to what young people tell us we hope to make some suggestions about how to help young people maintain long term adherence to taking their HIV treatment medicines

**Who is doing the study?**

This is study is part of the BREATHER study and is organised by the same group. It is being conducted by [researcher names] from the London School of Hygiene and Tropical Medicine.

**What would I be asked to do?**

**Interviews**

If you do take part in the study you would meet the research team for an interview two times during the study. The first interview would be in the early stages of the study. The second interview will be towards the end of the study. There may be a third interview, which will take place 3-6 months after the study has ended. These interviews are like conversations and will each last for about an hour. There are no wrong or right answers. You do not have to answer any questions that you do not want to. You can stop the interview at any time, without having to explain why.

We would like to audio record these interviews, if this is ok with you. The interviews will take place somewhere that you feel comfortable.

**Diaries**

***Audio diaries***

In addition to the two interviews we would also like you to keep an audio diary. This is like a spoken diary. We would provide you with a Dictaphone and give guidance to what topics we would like you to talk about. We would want you to record your audio diary for two weeks near the start of the study and again for two weeks around the 36th week of the study.

***Written diaries***

If you are already keeping a diary in which you talk about taking HIV treatment and would like to share it with the research team, then we could use this to better understand your experiences.

However, both the audio and written diaries are options. If you want to take part in the interviews only then that is absolutely okay.

**Is the research confidential?**

**Yes**. Any information that you share with us will only be seen by members of the research team. This means that whenever we write or talk about anything you have told us we never use your real name. All information about you will be stored securely.

The only exception to this is if you tell us something that makes us worried about you or another young person’s safety, such as physical harm or neglect. If we have to tell someone else, we will talk to you about it first.

**How will the research be used?**

The findings of this study will be reported to a wide range of people who are involved in providing treatment, care and support for children and young people living with HIV. The findings will be used to guide future interventions to support young people to take their HIV treatment effectively for a long time. It will also be used to help people who are conducting other HIV treatment studies with young people.

**What are the benefits and risks of taking part?**

You will be part of a study that aims to help young people maintain long term adherence. Some young people may find the opportunity to talk about their HIV treatment to be a really good thing. Some young people though might find it difficult to talk about. The research team have done research with young people and will take care to ask questions sensitively. It is up to you what you want to tell us. Also if you want, there can be someone available from your clinic to talk to, including after the interview.

**Do I have to take part?**

**No**, you do not have to take part in the study. Your participation in the BREATHER study will not be affected in anyway if you decide not to take part. It will not affect any of the services you currently receive.

**Will I receive anything for taking part?**

Yes, you will receive a £15 gift-voucher for the first interview and £20 for the second and third interview. Travel expenses to attend interviews will be covered. *[Country specific, delete if not applicable]*

**Can I have some more information before I decide?**

If you would like to find out more before deciding the staff at your clinic can arrange for you to speak to the research team more about it.

**Ok, I’m happy to take part. Now what?**

About half of the young people in the study can take part in this study. We will be inviting a representative group from amongst the participants in the study. If you are selected [researcher names] will contact you and your parents/ carer to arrange the first interview.

**Thank you for reading this!**

**If you do decide to take part your help will be very helpful to us.**

1. **BREATHER Qualitative study- Young people and HIV treatment adherence**

**An information sheet for children**

We would like you to join our study. Please read this information sheet carefully. You can ask any questions you may have.

**What is the study?**

This is a research study to find out about what it is like for children to take anti-HIV medicines. This will be done by talking with children, like you, about their experiences. This is because we think that the best way to learn about the experiences of children is to listen to what they have to say.

**Why is this study being done?**

Until now there hasn’t been much research done which asks children themselves about what it is like to take anti-HIV medicines. This is why we are doing the study. By listening carefully to what children tell us we hope to make some suggestions about how to make it easier for children to take anti-HIV medicines.

**Who is doing the study?**

This study is part of the BREATHER study and is organised by the same group. It is being conducted by [researcher names] from the London School of Hygiene and Tropical Medicine.

**Do I have to take part?**

No. You can say no and this is perfectly fine. If you do not want to take part you will still be part of the PENTA study. Your doctor will still look after you as they do now. So, please don’t feel you have to take part if you don’t want to.

**What would I be asked to do?**

**Interviews**

If you do take part in the study you would meet the research team for an interview two times. The first interview would be near to the start of the study. The second interview will be near the end of the study. There may be a third interview 3-6 months after the study has ended. These interviews are like conversations and will each last for about an hour. There are no wrong or right answers.

We would like to audio record these interviews, if this is ok with you. The interviews will take place somewhere that you feel comfortable.

**Diaries**

***Audio diaries:***If you wanted to we would like you to keep a spoken diary for some of the time that you are doing the study. This is called an audio diary. We would provide you with a tape recorder for you to speak into about what it’s like taking your anti-HIV medicines. We would like you to keep this diary for two weeks near to the beginning of the study and for two weeks towards the end (at 36 weeks).

***Written diaries****:* If you keep a diary about your anti-medicines and would like to show it to us then we can use this as well to help us understand more about your experiences.

If you want to take part in the interviews but not do the diaries, then that is absolutely okay.

**Will people know what I’ve said?**

Only the study team will listen to what you have said. If we tell people what you tell us we will never use your real name, so no one will know that it is you. You can choose the name we use if you like.

Your interviews and diaries will be kept locked away safely. The only time that we may have to share what you have told us with someone else is if we are worried about you or another child’s safety.

**Are there any risks?**

Some children might find it hard to talk about taking their anti-HIV medicines. It is up to you what you want to tell us. You do not have to answer any questions that you do not want to. You can stop the interview or being part of the study at any time. You won’t have to say why. If you want to you can talk to someone from the clinic after the interview.

**Will I be given anything for taking part?**

Yes, you will be given a £15 gift-voucher for the first interview and £20 for the second and third interview. Your travel to come to interviews will be paid for. *[Country specific, delete if not applicable]*

**Can I have some more information before I decide?**

If you would like to find out more, the staff at your clinic can arrange for you to speak to the research team about it.

**Ok, I’m happy to take part. Now what?**

About half of the children in the study can take part in this study. If you are selected [researcher names] will contact you and your parents/ carer to arrange the first interview.

**Thank you for reading this!**

**If you do decide to take part your help will be very helpful to us.**

# PENTA Breather Qualitative study- Young people and HIV treatment adherence

# Uganda - An information sheet for carers

## Carers interviews

As part of the PENTA Breather trial, we are doing a qualitative interview study to hear from children and young people (aged 10-24years) and their carers about their experiences of HIV treatment. We are inviting 15 carers, who look after children who have taken part in the PENTA Breather trial, to participate in an interview after the trial has ended.

Before you decide whether you would like to participate it is important that you understand why the research is being done and what it involves. Please read this information sheet carefully and ask any questions you may have. You can also ask for one of the study researchers to telephone you should you like to discuss the study in more detail before deciding.

***Thank you for taking the time to read this information.***

**What is the purpose of the study?**

The study aims to gain a better understanding of what the day-to-day experience of HIV treatment and participating in a trial is like for young people and their carers. There is little research asking young people and their carers about their experiences, and this is why we are doing the study. We are especially interested in how carers are involved in how young people manage their treatment day-to-day and how this may change over time. We are also interested in carers’ experiences of a child they look after participating in the trial. By listening to what carers’ say we hope to suggest ways to improve the experience of participating in trials and managing HIV treatment, including supporting long term adherence.

**Who is carrying out the study?**

This research is part of the PENTA Breather study. It is therefore organised by the Paediatric European Network for the Treatment of AIDS (PENTA). This qualitative study is being run by a small team of researchers at the JCRC. Their names are XXXX.

**What is involved?**

This is a ‘qualitative’ study. The approach assumes that the best way to learn about the experiences of carers is to listen carefully to what they have to say. We would therefore like to talk to you about what your experience of caring for a child on HIV treatment is like and whether you experience difficulties in supporting them to maintain their adherence to their prescribed medications. We would also like to learn about your’ and the child you care for’s experience of this trial, either through ‘short-cycle therapy’ or continuous therapy.

The interview will take place after the trial has finished. It will take place at a place and time convenient to you. It will be conducted by one of the qualitative researchers, XXX or XXXX, and will last about an hour. We ask that we record the interview unless you do not want this. You do not have to talk about things that you do not want to talk about, and you can end the interview at any time and without explaining why.

**Is the research confidential?**

**Yes**. Any information that you share with us will only be seen by members of the research team. This means that whenever we write or talk about anything we have been told we never use you or the child that you care for’s real name. All information about you and the child you care for will be stored securely.

The only information that we may have to pass on is information about children who are at risk of serious harm, such as physical harm or neglect.

**How will the research be used?**

The findings of this study will be reported to a wide range of people, including those who provide treatment, care and support for children and young people living with HIV. The findings will be used to guide the future implementation of HIV treatment, short-cycle therapy, and HIV treatment trials involving children and young people.

**What are the benefits and risks of taking part?**

You will be part of a study that aims to help young people maintain long term adherence. You may see the opportunity to talk about their HIV treatment as an entirely positive experience. For some, however, this is a sensitive topic which may be difficult to talk about. You will not need to answer any questions that they do not want to. You are free to withdraw from the interview and/or study at any time. Great care is given to asking questions as sensitively as possible. The content of the interviews is also led by you (as well as the researcher) and what you wish to talk about.

**Do I have to take part?**

**No**, you do not have to take part in the study. Your child’s participation in the PENTA Breather trial will not be affected in anyway if you prefer not to take part. It will not affect any of the services your child receives.

**Will I receive anything from taking part?**

Yes, your travel expenses for the interview will be covered.

**Can I have some more information before I decide?**

If you would like some more information, the staff at the clinic can arrange for you to speak to either XXX or XXX about the study and answer any further questions you may have.

**Ok, I’m happy to take part. Now what?**

Please sign the consent form and give it to the staff at your clinic. We will not be inviting everyone who is caring for a child participating in the PENTA Breather trial to take part. Instead we will invite a representative group of carers to take part in this qualitative study. If you are selected XXX or XXX will contact you on the phone number that you have given the clinic to arrange the first interview.

**Thank you for reading this! If you do decide to participate your help will be very valuable to us.**

1. **SUBSTUDY CONSENT FORM FOR PARENTS/CARERS**

**Title of study:** BREATHER Qualitative study- Young people and HIV treatment adherence.

*Please initial each box if you agree:*

|  |  |
| --- | --- |
| I have read and understood the information sheet on the BREATHER qualitative study, version…….. |  |
| I have been given the opportunity to ask questions and I am satisfied with the answers that you have given me. |  |
| I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree to my child taking part in this study. |  |
| I agree to my contact details being given to the qualitative study team and understand that they will contact me should my child be selected to take part in the study. |  |
| I understand that the researcher will interview my child two to three times over the course of the study. This will involve them talking with my child for about an hour each time about my child’s experience of HIV treatment |  |
| I agree to this interview being audio-recorded. |  |
| I know that my child does not have to talk about things that he/she does not want to talk about. My child can stop talking to the researchers at any time and without giving a reason for this. |  |
| I understand that everything that my child talks to the researchers about is confidential. However if the researchers are told that a young person is at serious risk of harm, they may have to pass this information on to someone else. |  |
| I agree to my child keeping an audio diary for the study, if he/ she would like to. |  |
| I agree to my child giving a copy of her personal diary as it relates to HIV and their treatment, if he/ she would like to. |  |
| I agree that anonymous direct quotes from the interviews or diaries may be used |  |

My questions have been answered by ……………………………………………………………

Name of child………………………………………………………………………………………………..

Name of Parent/ Guardian………………………………………………………………………………

Signature of Parent/ Guardian (or thumbprint)……………………………………. Date……………………

Name of Witness (if thumbprint used above)…………………………………………………………………………

Signature of Witness (if thumbprint used above)……………………………………. Date…………………..

Name of Clinician………………………………………………….. .. Date……………………

Signature of Clinician……………………………………………….. Date…………………..

1. **SUBSTUDY CONSENT FORM FOR YOUNG ADULTS**

**Title of study:** BREATHER Qualitative study- Young people and HIV treatment adherence.

*Please initial each box if you agree:*

|  |  |
| --- | --- |
| I have read and understood the information sheet on the BREATHER qualitative study, version…….. |  |
| I have been given the opportunity to ask questions and I am satisfied with the answers that you have given me. |  |
| I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree to taking part in this study. |  |
| I agree to my contact details being given to the qualitative study team and understand that they will contact me should my child be selected to take part in the study. |  |
| I understand that the researcher will interview me two to three times over the course of the study. This will involve them talking with me for about an hour each time about my experience of taking HIV treatment. |  |
| I agree to this interview being audio-recorded. |  |
| I know that I do not have to talk about things that I do not want to talk about. I understand that I can stop talking to the researchers at any time and without giving a reason for this. |  |
| I understand that everything that I talk to the researchers about is confidential. |  |
| I agree to keeping an audio diary for the study. |  |
| I agree to giving a copy of my personal diary as it relates to HIV and my treatment. |  |
| I agree that anonymous direct quotes from the interviews or diaries may be used. |  |

My questions have been answered by ……………………………………………………………

Name ………………………………………………………………………………

Signature (or thumbprint)………………………………………………………….. Date……………………

Name of Witness (if thumbprint used above)…………………………………………………………………………

Signature of Witness (if thumbprint used above)……………………………………. Date…………………

Name of Clinician………………………………………………… Date……………………

Signature of Clinician………………………………………….. Date…………………..

1. **SUBSTUDY CONSENT FORM FOR YOUNG ADULTS**

**Young adults 16-17 years old**

**Title of study:** BREATHER Qualitative study- Young people and HIV treatment adherence.

*Please initial each box if you agree:*

|  |  |
| --- | --- |
| I have read and understood the information sheet on the BREATHER qualitative study, version…….. |  |
| I have been given the opportunity to ask questions and I am satisfied with the answers that you have given me. |  |
| I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree to taking part in this study. |  |
| I agree to my contact details being given to the qualitative study team and understand that they will contact me should my child be selected to take part in the study. |  |
| I understand that the researcher will interview me two to three times over the course of the study. This will involve them talking with me for about an hour each time about my experience of taking HIV treatment. |  |
| I agree to this interview being audio-recorded. |  |
| I know that I do not have to talk about things that I do not want to talk about. I understand that I can stop talking to the researchers at any time and without giving a reason for this. |  |
| I understand that everything that I talk to the researchers about is confidential. However if the researchers are told that a child is at serious risk of harm, they may have to pass this information on to someone else. |  |
| I agree to keeping an audio diary for the study. |  |
| I agree to giving a copy of my personal diary as it relates to HIV and my treatment. |  |
| I agree that anonymous direct quotes from the interviews or diaries may be used. |  |

My questions have been answered by ……………………………………………………………

Name ………………………………………………………………………………

Signature (or thumbprint) …………………………………….. Date……………………

Name of Witness (if thumbprint used above)……………………………………………………………………………

Signature of Witness (if thumbprint used above)……………………………………. Date…………………..

Name of Clinician………………………………………………… Date……………………

Signature of Clinician………………………………………….. Date…………………..

1. **CONSENT FORM for Carers’ interview**

**Title of study:** PENTA Breather Qualitative study- Young people and HIV treatment adherence.

Date:

Version:

I have read and understood the information sheet on the

PENTA Breather qualitative study, version…….. YES NO

I have been given the opportunity to ask questions and I am

satisfied with the answers that you have given me. YES NO

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree to taking part in this study.

I agree to my contact details being given to the qualitative study team

and understand that they will contact me. YES NO

I understand that the researcher will interview me once. This will involve

them talking with me for about an hour about my experiences of caring

for a child taking HIV treatment and their participation in the trial. YES NO

I agree to this interview being audio-recorded. YES NO

I know that I do not have to talk about things that I do not want to talk about.

I understand that I can stop talking to the researchers at any time and without

giving a reason for this. YES NO

I understand that everything that I talk to the researchers about is confidential. YES NO

I agree that anonymised direct quotes from the interviews or diaries may be used. YES NO

My questions have been answered by ……………………………………………………………

Signature (or thumbprint) …………………………………….. Date……………………

Name of Witness (if thumbprint used above)……………………………………………………………………………

Signature of Witness (if thumbprint used above)…………………………………….

Date…………………..

1. **SUBSTUDY ASSENT FORM**

**Title of study:** BREATHER Qualitative study- Young people and HIV treatment adherence.

*Please tick ONE box for each question:*

|  |  |
| --- | --- |
| 1. Have you read (or had read to you) the information about this study? | YES NO |
| 2. Has somebody explained the study to you? | YES NO |
| 3. Do you understand what the study is about? | YES NO |
| 4. Have you asked all the questions you want? | YES NO |
| 5. Have your questions been answered in a way you understand? | YES NO |
| 6. Do you understand it’s OK to stop taking part at any time? | YES NO |
| 7. Do you understand that you don’t have to answer any questions that you do not want to? | YES NO |
| 8. Do you agree to this interview being audio-recorded? | YES NO |
| *For the next two questions you can answer no and still take part in the study.* |  |
| 9. Do you want to keep an audio diary for this study? | YES NO |
| 10. Do you want your personal diary to be included in the study? | YES NO |
| And finally,  11. Are you happy to take part? | YES NO |

If you **do** want to take part, you can sign your name below.

Your name (or thumbprint where appropriate)…………………………………………………………….. Date………………………………

Name of Witness (if thumbprint used above)……………………………………………………………….

Signature of Witness (if thumbprint used above)………………………. Date………………….

The doctor who explained the project to you needs to sign too:

Doctor’s name (print) …………………………………………….

Signature …………………………………………………………………… Date …………………………….

1. **BREATHER Qualitative study- Young people and HIV treatment adherence**

**Focus group: an information sheet for parents/ carers**

We have listened carefully to what your child and the other young people have told us. We would now like to invite your child to participate in a focus group to find out what they think of the results of the qualitative study. We would also like to hear what they think that we should do with our results.

We appreciate the time and effort they have given to the study so far.

Before you decide if you are happy for them to take part in these focus groups please read this information sheet carefully and ask any questions you may have.

**What is a focus group?**

A focus group is a lot like an interview, but instead of being just your child and the researcher having a conversation, like before, it will be with a group of people. This means that there will be 5-8 young people, who have been taking part in the same study as your child, and they will all be taking part in the discussion with the researcher.

**How is it different to what they have done before in the study?**

We will ask questions but everyone in the group will be able to answer. Your child will still be able to have their say, but they will also be able to hear and respond to what the other young people say.

**What would I be asked to do?**

The focus group will last no more than two hours. There will be about 5-8 young people there. [researcher names] will ask questions about what everyone in the group thinks about the results of the study and what should be done with them to best support young people taking HIV treatment. As in the rest of the qualitative study your child does not have to answer any questions that they do not want to. They can also stop taking part at any time.

**Is the research confidential?**

**Yes**, everything that is said will be treated in the same way as the other information that they have given us. This means that any information that your child share with us will only be seen by members of the research team. Whenever we write or talk about anything your child has told us we never use their real name. All information about you will be stored securely.

The only exception to this is if they tell us something that makes us worried about their or another young person’s safety, such as physical harm or neglect.

Everyone taking part will be asked to keep all the information they hear during the focus group private. So they should not talk about the details of the focus group afterwards with their friends or anyone other than the staff at their clinic and the study team. If they would like to talk about anything from the focus group they will be able to talk about it with them.

**Why are we holding focus groups?**

We think it’s important for young people to be involved in every stage of the research, including dissemination. We will talk about the findings of the research and ask the group questions about how they think the research should be used. In particular we would like to learn how your child thinks the research can best be used to inform the design and implementation of adherence interventions for young people. We would also like to learn about how they found being part of the study to inform future approaches to conducting paediatric HIV treatment studies.

**What are the benefits and risks to taking part?**

All the young people taking part in the focus group will be HIV positive. Your child might find that hearing about other young people’s experiences is helpful. Your child will also have the opportunity to be involved in thinking about how to use the research which will mean they are helping to improve services for young people.

By taking part in the focus group your child will be disclosing to the other young people in the room that they are also HIV positive. Your child and all the young people taking part will be asked to agree to respect the confidentiality of the others in the focus group.

**Does my child** **have to take part?**

**No**, your child does not have to take part in a focus group. It will not affect any of the services they currently receive.

**Will my child receive anything for taking part?**

Yes, your child will receive a £15 gift-voucher. *[Country specific, delete if not applicable]*

**Can I have some more information before I decide?**

If you would like to find out more before deciding the staff at your clinic can arrange for you to speak to the research team more about it.

**Ok, I’m happy to take part. Now what?**

Please sign the consent form. [researcher names] will then contact you to arrange the focus group.

**Thank you for reading this!**

1. **BREATHER Qualitative study- Young people and HIV treatment adherence**

**Focus group: an information sheet for young adults**

Thank you for taking part in the qualitative study so far. We really appreciate the time and energy you have put into it. We have listened carefully to what you and the other young people have told us. We would now like to invite you to a focus group to find out what you think of our results. We would also like to hear from you what you think that we should do with our results.

Before you decide if you want to take part in these focus groups please read this information sheet carefully and ask any questions you may have.

**What is a focus group?**

A focus group is a lot like an interview, but instead of being just you and the researcher having a conversation, like before, it will be with a group of people. This means that there will be 5-8 young people, who have been taking part in the same study as you, all taking part in the discussion with the researcher.

**How is it different to what I have done before in the study?**

We will ask questions but everyone in the group will be able to answer. You will still be able to have your say, but you will also be able to hear and respond to what the other young people say.

**What would I be asked to do?**

The focus group will last no more than two hours. There will be about 5-7 other young people there. [researcher names] will ask questions about what everyone in the group thinks about the results of the study and what should be done with them to best support young people taking HIV treatment. You do not have to answer any questions that you do not want to and can stop taking part at any time.

**Is the research confidential?**

**Yes**, everything that is said will be treated in the same way as the other information that you have given us. This means that any information that you share with us will only be seen by members of the research team. Whenever we write or talk about anything you have told us we never use your real name. All information about you will be stored securely.

The only exception to this is if you tell us something that makes us worried about you or another young person’s safety, such as physical harm or neglect.

Everyone taking part will be asked to keep all the information they hear during the focus group private. So, like you, they will not be allowed to talk about the focus group afterwards with anyone other than the staff at their clinic and the study team. If you would like to talk about anything from the focus group it will be fine to talk about it with them.

**Why are we holding focus groups?**

We think it’s important for you to be involved in every stage of the research, including dissemination. We will talk about the findings of the research and ask you questions about how you think the research should be used. In particular we would like to learn how you think the research can best be used to inform the design and implementation of adherence interventions for young people.

**What are the benefits and risks to taking part?**

All the young people taking part in the focus group are also HIV positive. You might find that hearing about other young people’s experiences is helpful. You will also have the opportunity to be involved in thinking about how to use the research which will mean you are helping to improve services for young people.

By taking part in the focus group you will be disclosing to the other young people in the room that you are HIV positive. Like you, all the young people will be asked to respect the right to confidentiality of everyone in the focus group.

**Do I have to take part?**

**No**, you do not have to take part in a focus group. It will not affect any of the services you currently receive. Thank you for all your help by taking part in the qualitative study.

**Will I receive anything for taking part?**

Yes, you will receive a £15 gift-voucher. *[Country specific, delete if not applicable]*

**Can I have some more information before I decide?**

If you would like to find out more before deciding the staff at your clinic can arrange for you to speak to the research team more about it.

**Ok, I’m happy to take part. Now what?**

Please sign the consent form. [researcher names] will contact you to arrange the focus group.

**Thank you for reading this!**

**If you do decide to take part your help will be very helpful to us.**

1. **BREATHER Qualitative study- Young people and HIV treatment adherence**

**Focus group: an information sheet for young people**

Thank you for taking part in the qualitative study so far. We really appreciate the time and energy you have put into it. We have listened carefully to what you and the other young people have told us. We would now like to invite you to a focus group to find out what you think of our results. We would also like to hear from you what you think that we should do with our results.

Before you decide if you want to take part in these focus groups please read this information sheet carefully and ask any questions you may have.

**What is a focus group?**

A focus group is a lot like an interview, but instead of being just you and the researcher having a conversation, like before, it will be with a group of people. This means that there will be 5-8 young people, who have been taking part in the same study as you, all taking part in the discussion with the researcher.

**How is it different to what I have done before in the study?**

We will ask questions but everyone in the group will be able to answer. You will still be able to have your say, but you will also be able to hear and respond to what the other young people say.

**What would I be asked to do?**

The focus group will last no more than two hours. There will be about 5-7 other young people there. [researcher names] will ask questions about what everyone in the group thinks about the results of the study and what should be done with them to best support young people taking HIV treatment. You do not have to answer any questions that you do not want to and can stop taking part at any time.

**Is the research confidential?**

**Yes**, everything that is said will be treated in the same way as the other information that you have given us. This means that any information that you share with us will only be seen by members of the research team. Whenever we write or talk about anything you have told us we never use your real name. All information about you will be stored securely.

The only exception to this is if you tell us something that makes us worried about you or another young person’s safety, such as physical harm or neglect.

Everyone taking part will be asked to keep all the information they hear during the focus group private. So, like you, they will not be allowed to talk about the focus group afterwards with anyone other than the staff at their clinic and the study team. If you would like to talk about anything from the focus group it will be fine to talk about it with them.

**Why are we holding focus groups?**

We would like you to help us make the findings as helpful to other young people and their families as we can. The focus group will be an opportunity for you to hear about what all the young people in the study think about what it is like taking HIV treatment. The information from the focus group will be used to guide how we think about how best to use the research to support young people.

**What are the benefits and risks to taking part?**

All the young people taking part in the focus group are also HIV positive. You might find that hearing about other young people’s experiences is helpful. You will also have the opportunity to be involved in thinking about how to use the research which will mean you are helping to improve services for young people.

By taking part in the focus group you will be disclosing to the other young people in the room that you are HIV positive. Like you, all the young people will be asked to respect the confidentiality of everyone in the focus group.

**Do I have to take part?**

**No**, you do not have to take part in a focus group. It will not affect any of the services you currently receive. Thank you for all your help by taking part in the qualitative study.

**Will I receive anything for taking part?**

Yes, you will receive a £15 gift-voucher. *[Country specific, delete if not applicable]*

**Can I have some more information before I decide?**

If you would like to find out more before deciding the staff at your clinic can arrange for you to speak to the research team more about it.

**Ok, I’m happy to take part. Now what?**

Please sign the assent form. [researcher names] will contact you and your parents/ carer to arrange the focus group.

**Thank you for reading this!**

**If you do decide to take part your help will be very helpful to us.**

1. **SUBSTUDY CONSENT FORM FOR PARENTS/CARERS**

**Participating in a focus group**

**Title of study:** BREATHER Qualitative study- Young people and HIV treatment adherence.

*Please initial each box if you agree:*

|  |  |
| --- | --- |
| I have read and understood the information sheet on the focus groups for the BREATHER qualitative study, version…….. |  |
| I have been given the opportunity to ask questions and I am satisfied with the answers that you have given me. |  |
| I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree to my child taking part in this focus group. |  |
| I understand that my child will take part in a focus group with other young people. This will involve them talking as a group for about an hour. I agree to this interview being audio-recorded. |  |
| I know that my child does not have to talk about things that he/she does not want to talk about. My child can stop talking to the researchers at any time and without giving a reason for this. |  |
| I understand that everything that my child talks to the researchers about is confidential. However if the researchers are told that a child is at serious risk of harm, they may have to pass this information on to someone else. |  |
| I understand that by participating in the focus group my child will be disclosing to the rest of the group that they are HIV positive. All the participants will be asked to agree to not discuss what they hear from other young people in the focus group with anyone outside the study or their clinic. |  |
| I agree that anonymous direct quotes from the focus group may be used. |  |

My questions have been answered by ……………………………………………………………

Name of child……………………………………………………………………………………………….

Name of Parent/ Guardian………………………………………………………………………………

Signature of Parent/ Guardian (or thumbprint) …………………………………….. Date……………………

Name of Witness (if thumbprint used above)…………………………………………………..

Signature of Witness (if thumbprint used above)…………………………………………. Date……………….

Name of Clinician……………………………………………………….. Date……………………

Signature of Clinician………………………………………………….. Date…………………..

1. **SUBSTUDY CONSENT FORM FOR YOUNG ADULTS**

**Participating in a focus group**

**Title of study:** BREATHER Qualitative study- Young people and HIV treatment adherence.

*Please initial each box if you agree:*

|  |  |
| --- | --- |
| I have read and understood the information sheet on the focus groups for the BREATHER qualitative study, version…….. |  |
| I have been given the opportunity to ask questions and I am satisfied with the answers that you have given me. |  |
| I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree to take part in this focus group. |  |
| I agree to this interview being audio-recorded. |  |
| I know that I do not have to talk about things that I do not want to talk about. I can stop talking to the researchers at any time and without giving a reason for this. |  |
| I understand that everything that I and the other young people in the focus group talk to the researchers about is confidential. However if the researchers are told that a child is at serious risk of harm, they may have to pass this information on to someone else. |  |
| All the participants will be asked to agree to not discuss what they hear from other young people in the focus group with anyone outside the study or clinic. I understand that by participating in the focus group I will be disclosing to the rest of the group that I am HIV positive. |  |
| I agree to respect the confidentiality of the others in the focus group. I will not discuss what I hear in the focus group with anyone outside of the study or clinic team. |  |
| I agree that anonymous direct quotes from the focus group may be used. |  |

My questions have been answered by ……………………………………………………………

Name ………………………………………………………………………………

Signature (or thumbprint)…………………………………….. Date……………………

Name of witness (if thumbprint used above)…………………………………………………………………………

Signature of Witness…………………………………………………………… Date……………………

Name of Clinician………………………………………………… Date……………………

Signature of Clinician………………………………………….. Date…………………..

1. **SUBSTUDY ASSENT FORM for focus groups**

**Title of study:** BREATHER Qualitative study- Young people and HIV treatment adherence.

*Please tick ONE box for each question:*

|  |  |
| --- | --- |
| Have you read (or had read to you) the information sheet about the focus groups? | YES NO |
| Has somebody explained the focus groups to you? | YES NO |
| Have you asked all the questions you want? | YES NO |
| Have your questions been answered in a way you understand? | YES NO |
| Do you understand it’s OK to stop taking part at any time? | YES NO |
| Do you agree to this interview being audio-recorded? | YES NO |
| Do you understand that you don’t have to answer any questions that you do not want to? | YES NO |
| Do you understand that by taking part in this focus group the other young people will know that you are HIV positive? | YES NO |
| Do you understand that you must keep what you hear about other people in the focus group private, but that you are able to talk about it to the study team and the staff at your clinic? | YES NO |
| Are you happy to take part? | YES NO |

If you **do** want to take part, you can sign your name below.

Your name (or thumbprint if appropriate)………………………………………………… Date……………………

Name of Witness (if thumbprint used above)……………………………………………………………………………

Signature of Witness (if thumbprint used above)………………………………………. Date…………………..

The doctor who explained the project to you needs to sign too:

Doctor’s name (print) …………………………………………….

Signature …………………………………………………………………… Date …………………………….

**Thank you for your help.**