

Ubacc Intro Form

Subject ID

_____ (please scan the ID of the parent giving consent)

Site

South Africa Kenya

Relationship of the respondent to the child

Mother Father Other

If "Other", please explain:

Language of consent

Afrikaans English Kigiryama Kiswahili Xhosa Other

Other language:

Ubacc Multi Trial South Africa

Subject ID

(please scan the ID of the parent giving consent)

Directions:

The UBACC is to be filled out after the study staff member has reviewed the consent form with the child's parent or guardian.

Trial 1

1. What is the purpose of the study that was just described to you?

Response: Two key concepts:

- (1) collect samples of DNA;
- (2) to look at possible causes of social or thought problems

Neither concept One concept - either (1) OR (2) Link both concepts (1) TO (2)

2. What makes you want to consider participating in this study?

Response: Two or Three key concepts:

- (1) Increase people's knowledge about the human body and/or problems making relationships or learning;
- (2) Possibility to make better treatments in the future;
- (3) South Africa Only: find out what caused my child's condition

Neither concept, Give my blood and/or saliva or time for money, or get treatment One concept
 Two or more concepts

3. Do you believe this is primarily research or primarily treatment?

Treatment; I don't know; both Research

4. Is your participation in this study voluntary?

No; I don't know Yes

5. If you withdraw from the study, will you be treated the same at the clinic/at school?

No; I don't know Yes

6. If you participate in this study, what are the things that you are agreeing to?

Response: Tasks:

- (1) Allow researchers to look at my child's medical records;
- (2) Answer questions about my child's health;
- (3) Give a sample of my child's blood

None of the above One or two tasks All three tasks

7. What parts of the study can you choose not to do and still be in the study?

Response:

- (1) Have my child photographed
- (2) Create cell lines from my child's blood (South Africa only)
- (3) Agree to be re-contacted
- (4) Give my own blood and do an assessment of my reasoning

None of the above One or two tasks Three or more tasks

8. Please describe some of the risks or discomforts that people may experience if they participate in this study?

Response: Four key concepts:

- (1) Having blood drawn could hurt, cause a bruise, or an infection;
- (2) My personal information may be disclosed unintentionally;
- (3) We don't know how samples may be used in future genetic research;
- (4) Having to answer uncomfortable questions about my child

None of the above One or two concepts Three or more concepts

9. Is it possible that being in this study will not have any benefit to you?

- No; the study will definitely find answers to my child's condition Yes it is possible (and probable) that the study will have no direct benefit
-

10. If you agree to be in this study, where will your blood sample go and who will use it?

Response:

- (1) It will be stored in cell libraries in the United States & possibly in Africa
- (2) It may be used by other researchers to study other questions, not only about mental health

I don't know One concept Both concepts

11. (Not counted in the total score) If you allow us to make cell lines from a sample of your child's blood, how long will your child's sample be kept?

- It will be kept until the study is over It may be kept forever
-

Trial 1 Score: _____

NEXT STEPS FOR STUDY STAFF MEMBER

**** This person scored below 20. ****

While the cutoff for participation in the study is a score of 14.5 or higher, it is important to re-address any concepts that the participant may not fully understand, regardless of their score.

Please review and re-administer the question(s) below that were not fully understood by the participant.

This person has scored a perfect 20. No additional trials are required. The subject should be invited to continue to participate in the study.

Trial 2

1. What is the purpose of the study that was just described to you?

Response: Two key concepts:

- (1) collect samples of DNA;
- (2) to look at possible causes of social or thought problems

Neither concept One concept - either (1) OR (2) Link both concepts (1) TO (2)

2. What makes you want to consider participating in this study?

Response: Two or Three key concepts:

- (1) Increase people's knowledge about the human body and/or problems making relationships or learning;
- (2) Possibility to make better treatments in the future;
- (3) South Africa Only: find out what caused my child's condition

Neither concept, Give my blood and/or saliva or time for money, or get treatment One concept
 Two or more concepts

3. Do you believe this is primarily research or primarily treatment?

Treatment; I don't know; both Research

4. Is your participation in this study voluntary?

No; I don't know Yes

5. If you withdraw from the study, will you be treated the same at the clinic/at school?

No; I don't know Yes

6. If you participate in this study, what are the things that you are agreeing to?

Response: Tasks:

- (1) Allow researchers to look at my child's medical records;
- (2) Answer questions about my child's health;
- (3) Give a sample of my child's blood

None of the above One or two tasks All three tasks

7. What parts of the study can you choose not to do and still be in the study?

Response:

- (1) Have my child photographed
- (2) Create cell lines from my child's blood (South Africa only)
- (3) Agree to be re-contacted
- (4) Give my own blood and do an assessment of my reasoning

None of the above One or two tasks Three or more tasks

8. Please describe some of the risks or discomforts that people may experience if they participate in this study?

Response: Four key concepts:

- (1) Having blood drawn could hurt, cause a bruise, or an infection;
- (2) My personal information may be disclosed unintentionally;
- (3) We don't know how samples may be used in future genetic research;
- (4) Having to answer uncomfortable questions about my child

None of the above One or two concepts Three or more concepts

9. Is it possible that being in this study will not have any benefit to you?

- No; the study will definitely find answers to my child's condition Yes it is possible (and probable) that the study will have no direct benefit

10. If you agree to be in this study, where will your blood sample go and who will use it?

Response:

(1) It will be stored in cell libraries in the United States & possibly in Africa

(2) It may be used by other researchers to study other questions, not only about mental health

- I don't know One concept Both concepts

11. (Not counted in the total score) If you allow us to make cell lines from a sample of your child's blood, how long will your child's sample be kept?

- It will be kept until the study is over It may be kept forever

Trial 2 Score: _____

NEXT STEPS FOR STUDY STAFF MEMBER

This person has scored below the 14.5 cut-off after their second trial. It is important to re-address any concepts that the participant may not fully understand.

Please review and re-administer the question(s) below that were not fully understood by the participant.

Trial 3

1. What is the purpose of the study that was just described to you?

Response: Two key concepts:

(1) collect samples of DNA;

(2) to look at possible causes of social or thought problems

- Neither concept One concept - either (1) OR (2) Link both concepts (1) TO (2)

2. What makes you want to consider participating in this study?

Response: Two or Three key concepts:

(1) Increase people's knowledge about the human body and/or problems making relationships or learning;

(2) Possibility to make better treatments in the future;

(3) South Africa Only: find out what caused my child's condition

- Neither concept, Give my blood and/or saliva or time for money, or get treatment One concept
 Two or more concepts

3. Do you believe this is primarily research or primarily treatment?

- Treatment; I don't know; both Research

4. Is your participation in this study voluntary?

- No; I don't know Yes

5. If you withdraw from the study, will you be treated the same at the clinic/at school?

- No; I don't know Yes
-

6. If you participate in this study, what are the things that you are agreeing to?

Response: Tasks:

- (1) Allow researchers to look at my child's medical records;
- (2) Answer questions about my child's health;
- (3) Give a sample of my child's blood

- None of the above One or two tasks All three tasks
-

7. What parts of the study can you choose not to do and still be in the study?

Response:

- (1) Have my child photographed
- (2) Create cell lines from my child's blood (South Africa only)
- (3) Agree to be re-contacted
- (4) Give my own blood and do an assessment of my reasoning

- None of the above One or two tasks Three or more tasks
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8. Please describe some of the risks or discomforts that people may experience if they participate in this study?

Response: Four key concepts:

- (1) Having blood drawn could hurt, cause a bruise, or an infection;
- (2) My personal information may be disclosed unintentionally;
- (3) We don't know how samples may be used in future genetic research;
- (4) Having to answer uncomfortable questions about my child

- None of the above One or two concepts Three or more concepts
-

9. Is it possible that being in this study will not have any benefit to you?

- No; the study will definitely find answers to my child's condition Yes it is possible (and probable) that the study will have no direct benefit
-

10. If you agree to be in this study, where will your blood sample go and who will use it?

Response:

- (1) It will be stored in cell libraries in the United States & possibly in Africa
- (2) It may be used by other researchers to study other questions, not only about mental health

- I don't know One concept Both concepts
-

11. (Not counted in the total score) If you allow us to make cell lines from a sample of your child's blood, how long will your child's sample be kept?

- It will be kept until the study is over It may be kept forever
-

Trial 3 Score: _____

NEXT STEPS FOR STUDY STAFF MEMBER

This person has scored below the 14.5 cut-off after their third trial.

Please review and re-administer the question(s) below that were not fully understood by the participant one final time.

Trial 4

1. What is the purpose of the study that was just described to you?

Response: Two key concepts:

- (1) collect samples of DNA;
- (2) to look at possible causes of social or thought problems

Neither concept One concept - either (1) OR (2) Link both concepts (1) TO (2)

2. What makes you want to consider participating in this study?

Response: Two or Three key concepts:

- (1) Increase people's knowledge about the human body and/or problems making relationships or learning;
- (2) Possibility to make better treatments in the future;
- (3) South Africa Only: find out what caused my child's condition

Neither concept, Give my blood and/or saliva or time for money, or get treatment One concept
 Two or more concepts

3. Do you believe this is primarily research or primarily treatment?

Treatment; I don't know; both Research

4. Is your participation in this study voluntary?

No; I don't know Yes

5. If you withdraw from the study, will you be treated the same at the clinic/at school?

No; I don't know Yes

6. If you participate in this study, what are the things that you are agreeing to?

Response: Tasks:

- (1) Allow researchers to look at my child's medical records;
- (2) Answer questions about my child's health;
- (3) Give a sample of my child's blood

None of the above One or two tasks All three tasks

7. What parts of the study can you choose not to do and still be in the study?

Response:

- (1) Have my child photographed
- (2) Create cell lines from my child's blood (South Africa only)
- (3) Agree to be re-contacted
- (4) Give my own blood and do an assessment of my reasoning

None of the above One or two tasks Three or more tasks

8. Please describe some of the risks or discomforts that people may experience if they participate in this study?

Response: Four key concepts:

- (1) Having blood drawn could hurt, cause a bruise, or an infection;
- (2) My personal information may be disclosed unintentionally;
- (3) We don't know how samples may be used in future genetic research;
- (4) Having to answer uncomfortable questions about my child

None of the above One or two concepts Three or more concepts

9. Is it possible that being in this study will not have any benefit to you?

- No; the study will definitely find answers to my child's condition Yes it is possible (and probable) that the study will have no direct benefit
-

10. If you agree to be in this study, where will your blood sample go and who will use it?

Response:

- (1) It will be stored in cell libraries in the United States & possibly in Africa
- (2) It may be used by other researchers to study other questions, not only about mental health

I don't know One concept Both concepts

11. (Not counted in the total score) If you allow us to make cell lines from a sample of your child's blood, how long will your child's sample be kept?

- It will be kept until the study is over It may be kept forever
-

Trial 4 Score: _____

NEXT STEPS FOR STUDY STAFF MEMBER

This person has scored below the 14.5 cut-off after their fourth trial.

He or she may not fully understand the study and should therefore not be invited to continue.

This person has scored greater than the 14.5 cutoff and therefore should be invited to continue to participate in the study.

Reason for failure

- Language barrier Comprehension of study Other
-

Notes

Form completed by _____

Ubacc Multi Trial Kenya

Subject ID

(please scan the ID of the parent giving consent)

Directions:

The UBACC is to be filled out after the study staff member has reviewed the consent form with the child's parent or guardian.

Trial 1

1. What is the purpose of the study that was just described to you?

Response: Key concepts:

(1) collect samples of DNA;

(2) to look at possible causes of social or thought problems

Neither concept One concept - either (1) or (2) Both concepts

2. What makes you want to consider participating in this study?

Response: Key concepts:

(1) Increasing people's knowledge about the human body and/or problems making relationships or learning;

(2) Possibility of making better treatments in the future

Neither concept, Give my blood and/or saliva or time for money, or get treatment One concept
 Both concepts

3. Do you believe this is primarily research or primarily treatment?

Treatment; I don't know; both Research

4. Is your participation in this study voluntary?

No; I don't know Yes

5. If you withdraw from the study, will you be treated the same at the clinic/at school?

No; I don't know Yes

6. If you participate in this study, what are the things that you are agreeing to do?

Response: Tasks:

(1) Allow researchers to look at my child's medical records;

(2) Answer questions about my child's health;

(3) Give a sample of my child's blood;

(4) Have photos taken of my child

None of the above One or two tasks Three or more tasks

7. Which study activities are optional?

Response:

- (1) Agree to be re-contacted
- (2) Give my own blood and do an assessment of my reasoning
- (3) Have my child photographed

None of the above One task Both tasks

8. Please describe some of the risks or discomforts that people may experience if they participate in this study.

Response: Four key concepts:

- (1) Having blood drawn could hurt, cause a bruise, or an infection;
- (2) My personal information may be disclosed unintentionally;
- (3) We don't know how samples may be used in future genetic research;
- (4) Having to answer uncomfortable questions about my child

None of the above One or two concepts Three or more concepts

9. Is it possible that being in this study will not have any benefit to you?

- No; the study will definitely find answers to my child's condition Yes it is possible (and probable) that the study will have no direct benefit
-

10. If you agree to be in this study, where will your blood sample go and who will use it?

Response: Concepts:

- (1) It will be stored in biobanks in the United States & in Africa
- (2) It may be used by other researchers to study other questions, not only about mental health

I don't know One concept Both concepts

Trial 1 Score: _____

NEXT STEPS FOR STUDY STAFF MEMBER

**** This person scored below 20. ****

While the cutoff for participation in the study is a score of 14.5 or higher, it is important to re-address any concepts that the participant may not fully understand, regardless of their score.

Please review and re-administer the question(s) below that were not fully understood by the participant.

This person has scored a perfect 20. No additional trials are required. The subject should be invited to continue to participate in the study.

Trial 2

1. What is the purpose of the study that was just described to you?

Response: Key concepts:

- (1) collect samples of DNA;
- (2) to look at possible causes of social or thought problems

Neither concept One concept - either (1) or (2) Both concepts

2. What makes you want to consider participating in this study?

Response: Key concepts:

- (1) Increasing people's knowledge about the human body and/or problems making relationships or learning;
- (2) Possibility of making better treatments in the future

- Neither concept, Give my blood and/or saliva or time for money, or get treatment One concept
 Both concepts
-

3. Do you believe this is primarily research or primarily treatment?

- Treatment; I don't know; both Research
-

4. Is your participation in this study voluntary?

- No; I don't know Yes
-

5. If you withdraw from the study, will you be treated the same at the clinic/at school?

- No; I don't know Yes
-

6. If you participate in this study, what are the things that you are agreeing to do?

Response: Tasks:

- (1) Allow researchers to look at my child's medical records;
- (2) Answer questions about my child's health;
- (3) Give a sample of my child's blood;
- (4) Have photos taken of my child

- None of the above One or two tasks Three or more tasks
-

7. Which study activities are optional?

Response:

- (1) Agree to be re-contacted
- (2) Give my own blood and do an assessment of my reasoning

- None of the above One task Both tasks
-

8. Please describe some of the risks or discomforts that people may experience if they participate in this study.

Response: Four key concepts:

- (1) Having blood drawn could hurt, cause a bruise, or an infection;
- (2) My personal information may be disclosed unintentionally;
- (3) We don't know how samples may be used in future genetic research;
- (4) Having to answer uncomfortable questions about my child

- None of the above One or two concepts Three or more concepts
-

9. Is it possible that being in this study will not have any benefit to you?

- No; the study will definitely find answers to my child's condition Yes it is possible (and probable) that the study will have no direct benefit

10. If you agree to be in this study, where will your blood sample go and who will use it?

Response: Concepts:

(1) It will be stored in biobanks in the United States & in Africa

(2) It may be used by other researchers to study other questions, not only about mental health

I don't know One concept Both concepts

Trial 2 Score: _____

NEXT STEPS FOR STUDY STAFF MEMBER

This person has scored below the 14.5 cut-off after their second trial. It is important to re-address any concepts that the participant may not fully understand.

Please review and re-administer the question(s) below that were not fully understood by the participant.

Trial 3

1. What is the purpose of the study that was just described to you?

Response: Key concepts:

(1) collect samples of DNA;

(2) to look at possible causes of social or thought problems

Neither concept One concept - either (1) or (2) Both concepts

2. What makes you want to consider participating in this study?

Response: Key concepts:

(1) Increasing people's knowledge about the human body and/or problems making relationships or learning;

(2) Possibility of making better treatments in the future

Neither concept, Give my blood and/or saliva or time for money, or get treatment One concept
 Both concepts

3. Do you believe this is primarily research or primarily treatment?

Treatment; I don't know; both Research

4. Is your participation in this study voluntary?

No; I don't know Yes

5. If you withdraw from the study, will you be treated the same at the clinic/at school?

No; I don't know Yes

6. If you participate in this study, what are the things that you are agreeing to do?

Response: Tasks:

(1) Allow researchers to look at my child's medical records;

(2) Answer questions about my child's health;

(3) Give a sample of my child's blood;

(4) Have photos taken of my child

None of the above One or two tasks Three or more tasks

7. Which study activities are optional?

Response:

- (1) Agree to be re-contacted
- (2) Give my own blood and do an assessment of my reasoning

None of the above One task Both tasks

8. Please describe some of the risks or discomforts that people may experience if they participate in this study.

Response: Four key concepts:

- (1) Having blood drawn could hurt, cause a bruise, or an infection;
- (2) My personal information may be disclosed unintentionally;
- (3) We don't know how samples may be used in future genetic research;
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None of the above One or two concepts Three or more concepts

9. Is it possible that being in this study will not have any benefit to you?

- No; the study will definitely find answers to my child's condition Yes it is possible (and probable) that the study will have no direct benefit
-

10. If you agree to be in this study, where will your blood sample go and who will use it?

Response: Concepts:

- (1) It will be stored in biobanks in the United States & in Africa
- (2) It may be used by other researchers to study other questions, not only about mental health

I don't know One concept Both concepts

Trial 3 Score: _____

NEXT STEPS FOR STUDY STAFF MEMBER

This person has scored below the 14.5 cut-off after their third trial.

Please review and re-administer the question(s) below that were not fully understood by the participant one final time.

Trial 4

1. What is the purpose of the study that was just described to you?

Response: Key concepts:

- (1) collect samples of DNA;
- (2) to look at possible causes of social or thought problems

Neither concept One concept - either (1) or (2) Both concepts

2. What makes you want to consider participating in this study?

Response: Key concepts:

- (1) Increasing people's knowledge about the human body and/or problems making relationships or learning;
- (2) Possibility of making better treatments in the future

Neither concept, Give my blood and/or saliva or time for money, or get treatment One concept
 Both concepts

3. Do you believe this is primarily research or primarily treatment?

Treatment; I don't know; both Research

4. Is your participation in this study voluntary?

No; I don't know Yes

5. If you withdraw from the study, will you be treated the same at the clinic/at school?

No; I don't know Yes

6. If you participate in this study, what are the things that you are agreeing to do?

Response: Tasks:

- (1) Allow researchers to look at my child's medical records;
- (2) Answer questions about my child's health;
- (3) Give a sample of my child's blood;
- (4) Have photos taken of my child

None of the above One or two tasks Three or more tasks

7. Which study activities are optional?

Response:

- (1) Agree to be re-contacted
- (2) Give my own blood and do an assessment of my reasoning

None of the above One task Both tasks

8. Please describe some of the risks or discomforts that people may experience if they participate in this study.

Response: Four key concepts:

- (1) Having blood drawn could hurt, cause a bruise, or an infection;
- (2) My personal information may be disclosed unintentionally;
- (3) We don't know how samples may be used in future genetic research;
- (4) Having to answer uncomfortable questions about my child

None of the above One or two concepts Three or more concepts

9. Is it possible that being in this study will not have any benefit to you?

No; the study will definitely find answers to my child's condition Yes it is possible (and probable) that the study will have no direct benefit

10. If you agree to be in this study, where will your blood sample go and who will use it?

Response: Concepts:

- (1) It will be stored in biobanks in the United States & in Africa
- (2) It may be used by other researchers to study other questions, not only about mental health

I don't know One concept Both concepts

Trial 4 Score: _____

NEXT STEPS FOR STUDY STAFF MEMBER

This person has scored below the 14.5 cut-off after their fourth trial.

He or she may not fully understand the study and should therefore not be invited to continue.

This person has scored greater than the 14.5 cutoff and therefore should be invited to continue to participate in the study.

Reason for failure

- Language barrier
- Comprehension of study
- Other

Notes

Form completed by _____