Gaining informed consent

The example consent forms provided below are suitable for research involving adults and children and where anonymous and personal (confidential) data are collected, including the situation where personal data are collected initially (e.g., names of participants, because they will be returning for further tests) and then subsequently disposed of, so that only anonymous data are retained (Confidential-then-Anonymous forms). It may be appropriate to modify the wording and format of these forms to fit your particular research. **Note that consent for participation and use of data should be obtained even in anonymous questionnaire studies.**

For the research data to be anonymous, no identifying information (e.g., name, email address, video-recording) should be recorded, and no link (e.g., via an ID number) should be made between the consent form and the research data. If this is the case, the participant can be asked to sign a consent form that includes the statement that ‘the data I provide will be anonymous.’

Note that gaining informed consent of parents does not obviate the need to gain informed consent or assent from children participating in research. Assent means that the child shows some form of agreement to participate in the research without necessarily comprehending the nature of the research sufficiently to give full informed consent. Investigators working with infants should take special effort to explain the research to the parents and be especially sensitive to any indication of discomfort or avoidance in the infant.

Note that, where practical, it is good practice to ask participants to confirm their consent to participate in the research study and then, having participated, to confirm their consent to keep and make use of the data they have contributed. This allows someone, who for example becomes unhappy about their participation in the research, to prevent their data being used.

**Note that the researcher should keep signed copies of consent forms securely and separately from the research data.** Where practical, participants should also be given a copy of their consent form (signed) to take away with them.

Please note that where it is not possible to obtain written consent due to issues of illiteracy or specific cultural norms verbal consent can be obtained and recorded. If this is the case please justify this approach in you stage 2 ethics application form.

|  |  |
| --- | --- |
| Department of XXXX  Tel: XXXX XXX XXXX  <Contact name>  <Contact telephone and email> | Logo |

CONSENT FORM

<Study title>

## Please answer the following questions to the best of your knowledge

**YES NO**

**Do You confirM That you:**

* <inclusion/exclusion criterion 1> **□ □**
* <inclusion/exclusion criterion 2> **□ □**
* <inclusion/exclusion criterion 3> **□ □**

**Have you:**

* been given information explaining about the study? **□ □**
* had an opportunity to ask questions and discuss this study? **□ □**
* received satisfactory answers to all questions you asked? **□ □**
* received enough information about the study for you to make a decision

about your participation? **□ □**

**Do you understand:**

that you are free to withdraw from the study and free to withdraw your data prior to final consent

* at any time? **□ □**
* without having to give a reason for withdrawing? **□ □**

## I hereby fully and freely consent to my participation in this study

I understand the nature and purpose of the procedures involved in this study. These have been communicated to me on the information sheet accompanying this form.

I understand and acknowledge that the investigation is designed to promote scientific knowledge and that the University of Bristol will use the data I provide for no purpose other than research.

I understand the data I provide will be **anonymous**. No link will be made between my name or other identifying information and my study data.

I understand that the University of Bristol may use the data collected for this study in a future research project but that the conditions on this form under which I have provided the data will still apply.

Participant’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name in BLOCK Letters: ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­

# Final consent

**Having participated in this study**

I agree to the University of Bristol keeping and processing the data I have provided during the course of this study. I understand that these data will be used only for the purpose(s) set out in the information sheet, and my consent is conditional upon the University complying with its duties and obligations under the Data Protection Act.

Participant’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name in BLOCK Letters: ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­

If you have any concerns related to your participation in this study please direct them to the Faculty of XXXX Human Research Ethics Committee, via Liam McKervey, Research Governance and Ethics Officer (Tel: 0117 331 7472 email: Liam.McKervey@bristol.ac.uk ).

|  |  |
| --- | --- |
| Department of XXXX  Tel: XXXX XXX XXXX  <Contact name>  <Contact telephone and email> | Logo |

CONSENT FORM

<Study title>

## Please answer the following questions to the best of your knowledge

**YES NO**

**Do You confirM That you:**

* <inclusion/exclusion criterion 1> **□ □**
* <inclusion/exclusion criterion 2> **□ □**
* <inclusion/exclusion criterion 3> **□ □**

**Have you:**

* been given information explaining about the study? **□ □**
* had an opportunity to ask questions and discuss this study? **□ □**
* received satisfactory answers to all questions you asked? **□ □**
* received enough information about the study for you to make a decision

about your participation? **□ □**

**Do you understand:**

that you are free to withdraw from the study and free to withdraw your data prior to anonymisation

* at any time? **□ □**
* without having to give a reason for withdrawing? **□ □**

## I hereby fully and freely consent to my participation in this study

I understand the nature and purpose of the procedures involved in this study. These have been communicated to me on the information sheet accompanying this form.

I understand and acknowledge that the investigation is designed to promote scientific knowledge and that the University of Bristol will use the data I provide for no purpose other than research.

I understand that the data I provide will be kept **confidential**, and that on completion of the study my data will be **anonymised** by removing all links between my name or other identifying information and my study data. This will be done by <insert date>, and before any presentation or publication of my data.

I understand that the University of Bristol may use the data collected for this project in a future research project but that the conditions on this form under which I have provided the data will still apply.

Participant’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name in BLOCK Letters: ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­

# Final consent

**Having participated in this study**

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Participant’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name in BLOCK Letters: ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­

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|  |  |
| --- | --- |
| Department of XXXX  Tel: XXXX XXX XXXX  <Contact name>  <Contact telephone and email> | Logo |

CONSENT FORM

<Study title>

## Please answer the following questions to the best of your knowledge

**YES NO**

**Do You confirM That you:**

* <inclusion/exclusion criterion 1> **□ □**
* <inclusion/exclusion criterion 2> **□ □**
* <inclusion/exclusion criterion 3> **□ □**

**Have you:**

* been given information explaining about the study? **□ □**
* had an opportunity to ask questions and discuss this study? **□ □**
* received satisfactory answers to all questions you asked? **□ □**
* received enough information about the study for you to make a decision

about your participation? **□ □**

**Do you understand:**

that you are free to withdraw from the study and free to withdraw your data prior to publication

* at any time? **□ □**
* without having to give a reason for withdrawing? **□ □**

## I hereby fully and freely consent to my participation in this study

I understand the nature and purpose of the procedures involved in this study. These have been communicated to me on the information sheet accompanying this form.

I understand and acknowledge that the investigation is designed to promote scientific knowledge and that the University of Bristol will use the data I provide for no purpose other than research.

I understand the data I provide will be kept **confidential**. My name or other identifying information will not be disclosed in any presentation or publication of the research.

I understand that the University of Bristol may use the data collected for this project in a future research project but that the conditions on this form under which I have provided the data will still apply.

Participant’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name in BLOCK Letters: ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­

# Final consent

**Having participated in this study**

I agree to the University of Bristol keeping and processing the data I have provided during the course of this study. I understand that these data will be used only for the purpose(s) set out in the information sheet, and my consent is conditional upon the University complying with its duties and obligations under the Data Protection Act.

Participant’s signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name in BLOCK Letters: ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­

If you have any concerns related to your participation in this study please direct them to the Faculty of XXXX Human Research Ethics Committee, via Liam McKervey, Research Governance and Ethics Officer (Tel: 0117 331 7472 email: Liam.McKervey@bristol.ac.uk ).

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| --- | --- |
| Department of XXXX  Tel: XXXX XXX XXXX  <Contact name>  <Contact telephone and email> | Logo |

CONSENT FORM

<Study title>

## Please answer the following questions to the best of your knowledge

**YES NO**

**Do You confirM That youR Child:**

* <inclusion/exclusion criterion 1> **□ □**
* <inclusion/exclusion criterion 2> **□ □**
* <inclusion/exclusion criterion 3> **□ □**

**Have you:**

* read the <information sheet> explaining about the study? **□ □**

**Do you understand:**

that you are free to withdraw your consent at any time during the study and free to withdraw your

child’s data from the study prior to publication? **□ □**

* without having to give a reason for withdrawing? **□ □**
* and that the session will stop if your child asks or appears uncomfortable? **□ □**

## I hereby fully and freely consent to my child’s participation in this study

I understand the nature and purpose of the procedures involved in this study as communicated to me on the <*information sheet*>.

I understand that the investigation is designed to promote scientific knowledge and I agree that the University of Bristol can keep and use the data my family provide for research purposes only.

I understand that the data my family provide will be kept **confidential**, and that my consent is conditional upon the University complying with its obligations under the Data Protection Act.

I understand that my child’s name and any other identifying information will not be disclosed in any presentation or publication of the research.

Parent/Guardian signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_

Name in BLOCK Letters: ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­

Child’s name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­ Child’s DoB: \_\_\_\_\_\_\_\_\_\_\_\_\_

**YES NO**

I agree to my child’s data being passed to his/her school, if requested? **□ □**

I agree to being contacted again with information about further research studies? **□ □**

Daytime contact number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| Department of XXXX  Tel: XXXX XXX XXXX  <Contact name>  <Contact telephone and email> | Logo |

CONSENT FORM

<Study title>

## Please answer the following questions to the best of your knowledge

**YES NO**

**Do You confirM That youR Child:**

* <inclusion/exclusion criterion 1> **□ □**
* <inclusion/exclusion criterion 2> **□ □**
* <inclusion/exclusion criterion 3> **□ □**

**Have you:**

* read the <information sheet> explaining about the study? **□ □**

**Do you understand:**

* that you are free to withdraw your consent for the study at any time during the study,

but prior to the data being anonymised? **□ □**

* without having to give a reason for withdrawing? **□ □**
* that testing will stop if your child asks or appears uncomfortable? **□ □**

## I hereby fully and freely consent to my child’s participation in this study

I understand the nature and purpose of the procedures involved in this study as communicated to me on the <*information sheet*>.

I understand that the investigation is designed to promote scientific knowledge and I agree that the University of Bristol can keep and use the data my family provide for research purposes only.

I understand that the data my family provide will be kept **confidential**, and that consent is conditional upon the University complying with its obligations under the Data Protection Act.

I understand that on completion of the study my child’s data will be **anonymised** by removing all links between his/her name and his/her study data. This will be done by <*insert date*>, and before any presentation or publication of data.

Parent/Guardian signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_

Name in BLOCK Letters: ­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­

Child’s name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­ Child’s DoB: \_\_\_\_\_\_\_\_\_\_\_\_\_

**YES NO**

I agree to my child’s data being passed to his/her school, if requested? **□ □**