NHS Genomic Medicine Service

Annotated patient choice forms

November 2020

Contents

c1 NHS Genomic Medicine Service. Record of Discussion Form version 4.02 (November 2020). To be used for WGS go-live

c2

First name	NHS number (or postcode if not known)
Last name	Date of birth (d d m m y y y y)

c3 01-NGIS-ROD (v4.02)

Record of Discussion Regarding Genomic Testing

r1

This form relates to the person being tested. One form is required for each person.

All of the statements below remain relevant even if the test relates to someone other than yourself, for example your child.

I have discussed genomic testing with my health professional and understand the following

r2

Family and wider implications

1. The results of my test may have implications for me and members of my family. I understand that my results may also be used to help the healthcare of members of my family and others nationally and internationally. This could be done in discussion with me or through a process that will not personally identify me.

Uncertainty

2. The results of my test may have findings that are uncertain and not yet fully understood. To decide whether findings are significant for myself or others, my data may be compared to other patients' results across the country and internationally. I understand that this could change what my results mean for me and my treatment over time.

Unexpected information

3. The results of my test may also reveal unexpected results that are not related to why I am having this test. These may be found by chance and I may need further tests or investigations to understand their significance.

DNA storage

4. Normal NHS laboratory practice is to store the DNA extracted from my sample even after my current testing is complete. My DNA might be used for future analysis and/or to ensure that other testing (for example that of family members) is of high quality.

Data storage

5. The data from my genomic test will be securely stored so that it can be looked at again in the future if necessary.

Health records

6. Results from my genomic test will be part of my patient record, a copy of which is held in a national system only available to healthcare professionals.

Research

7. I understand that I have the opportunity to take part in research which may benefit myself or others, now or in the future. An offer to join a national research opportunity is available on the following page.

For any further questions, my healthcare professional can provide information. More information regarding genomic testing and how my data is protected can be found at www.nhs.uk/conditions/genetics

r3

Please sign on page three to confirm your agreement to the genomic test.

c4 This document is subject to version control and is regularly updated. Please confirm you are using the correct version by contacting your local Genomic Laboratory Hub

Record of Discussion Form

The Record of Discussion form records that

1. A discussion has taken place between the clinician and patient (or patient representative) about the clinical and research implications of having a whole genome sequencing test
2. The patients choice for: a) having the test, and b) participating in research.

The Record of Discussion Form has three pages.

In the following pages the letters and numbers refer to the yellow ellipses and highlighted test on the facing page.

Record of Discussion Form – Page 1

The following information is repeated on every page of the Record of Discussion Form:

c1. **Header Message**. The header message identifies the form being used, the version and release date

c2. **Patient Details**. The patient details should be completed on **every** page of the form. It can either be written on the form or a sticker with the relevant information placed over the patient details grid

c3. **File Name and version**. The filename of this form

c4. **Footer Message**. The footer message describes the version control in place for the form

Specific information:

r1. **Notification**. Notify parents (who are consenting on behalf of their child) and consultees (who are consenting on the part of an adult deemed to be without capacity) that all statements on this page are relevant to the patient and not the parent or consultee

r2. **Genomic Testing Statements**. Each statement should be discussed with the patient as part of the clinical discussion. Detailed information which supports each statement can be found in the clinician's guide

r3. **Genomic Testing Confirmation**. Ask the patient to consider having a genomic test. The patient should confirm their choice by signing the form on page three of the form.

c2

First name	NHS number (or postcode if not known)
Last name	Date of birth (d d m m y y y y)

Genomics england

NHS

c3 01-NGIS-ROD (v4.02)

The National Genomic Research Library

r4

The NHS invites you to contribute to the National Genomic Research Library, managed by Genomics England.

Genomics England was set up in 2013 by the Department of Health and Social Care to work with the NHS to build a library of human genomes for researchers to study. Combining data from many different patients helps researchers to better understand disease and spot patterns in the data.

By agreeing to share your data you might get results which could lead to your own diagnosis, a new treatment, or offers to take part in clinical trials. Your taking part could enable diagnoses for people who don't have one.

Please read the following statements. Feel free to ask any questions before making a decision.

r5

By saying 'yes' to research, I understand the following

The National Genomic Research Library

1. NHS England, on behalf of the Trusts that provided your genomic test, will allow Genomics England to access my personal data including my genomic record.

Security

2. Any samples and data stored by Genomics England and the NHS will always be stored securely. Genomics England will take all reasonable steps to ensure that I cannot be personally identified.

Re-contact

3. My clinical team or Genomics England together with my clinical team, can contact me if the data or samples reveals any clinical trials or other research that I might benefit from.

4. If something is relevant to me or my family, there is a process by which this will be shared with my NHS clinical team.

Data and sample usage

5. Researchers may include national or international scientists, healthcare companies and NHS staff. To access the data, these researchers must all be approved by an independent committee of experts, including health professionals, clinical academics and patients. There will be no access to the data by personal insurers and marketing companies.

Data storage

6. Genomics England will collect different aspects of my health data from the NHS and other data from organisations listed at https://www.genomicsengland.co.uk/privacy-policy/. The collection and analysis of my health data for research will continue across my entire lifetime and beyond.

Withdrawal

7. I can change my mind about taking part at any time.

More information regarding research in the National Genomic Research Library can be found at www.genomicsengland.co.uk For any further questions, my healthcare professional can provide information.

r6

Please use page three to indicate your research choice.

Record of Discussion Form – Page 2

The common information is repeated on this page.

r4. **NGIS Research Summary**. Notify parents (who are consenting on behalf of their child) and consultees (who are consenting on the part of an adult deemed to be without capacity) that all statements on this page are relevant to the patient

r5. **Research Statements**. Each statement should be discussed with the patient as part of the discussion about research. Detailed information which supports each statement can be found in the clinician's guide

r6. **Research Confirmation**. Ask the patient to consider participating in the National Genomics Research Library. The patient should confirm by circling their choices on page three of the form

c1 NHS Genomic Medicine Service. Record of Discussion Form version 4.02 (November 2020). To be used for WGS go-live

c2

First name	NHS number (or postcode if not known)
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Genomics england

NHS

c3 01-NGIS-ROD (v4.02)

Confirmation of Your Genomic Test and Research Choices

I confirm that I have had the opportunity to discuss information about genomic testing, I agree to the genomic test, and my research choice is circled below.

r7 **A.** **I have discussed taking part in the National Genomic Research Library** **YES | NO**
If your answer to A is **NO** *then please ignore B and sign directly below*

r8 **B.** **I agree that my data and remainder sample may contribute to the National Genomic Research Library** **YES | NO**

r9

Patient name	Signature	Date
.....	.....	d d / m m / y y y y

If you are signing this form on behalf of someone else (children, adults without capacity or deceased patients) then please sign below.

r10

Parent | Guardian | Consultee name* *please amend as appropriate	Signature	Date
.....	.....	d d / m m / y y y y

Healthcare professional use only

To be completed by the healthcare professional recording the patient's choices.

r11

Patient category	☐ Adult (signed by themselves) ☐ Adult lacking capacity (signed by consultee) ☐ Child (signed by parent or guardian)	☐ Clinician has agreed to the test (in the patient's best interests) ☐ Deceased (signed on behalf of deceased individual)
Test type	☐ Rare and Inherited Diseases – WGS	☐ Cancer (paired tumour normal) – WGS
If answer to research choice A is *NO*	☐ Patient would like to discuss at a later date ☐ Patient lacks capacity and no consultee available	☐ Inappropriate to have discussion ☐ Other
Responsible clinician		
Hospital number		

r12

Healthcare professional name	Signature	Date
.....	.....	d d / m m / y y y y

c4 This document is subject to version control and is regularly updated. Please confirm you are using the correct version by contacting your local Genomic Laboratory Hub

Record of Discussion Form – Page 3

The common information is repeated on this page.

r7. **Research Discussion Question (Question A)**. Ask the patient (or representative) to consider if they have discussed taking part in this research offer. The patient should circle their answer. If the patient circles 'NO' then ask them to leave the next choice blank and proceed to sign the form. The patient should clearly circle their choice

r8. **Research Agreement Question (Question B)**. Ask the patient (or representative) to consider taking part in the research offer ONLY if they circled 'YES' to the research agreement question. The patient should clearly circle their choice.

If you, the clinician, are signing the Record of Discussion Form in the patient's best interests then all answers for the research questions should be left blank as research is not appropriate in this situation

Please check that the circled answers to the discussion and agreement questions are acceptable. Things to check are:

- Either nothing is circled or only YES or only NO is circled for each question. Circling both answers is not acceptable
- If their answer to the research discussion question is NO then neither of the options for the agreement question should be circled
- If their answer to the research discussion question is YES then one of the options for the agreement question must be circled.

r9. **Patient Confirmation**. If the patient is an adult with capacity please ask them to Print their name, Sign and date the form. It is OK for the clinician to print the patient name here but the patient must sign and date the form themselves.

If the consultation is happening remotely, the clinician can indicate the patient's choice on the form, sign it as a record of the conversation, and send the patient a copy of the form.

If the patient is an adult deemed to be without capacity or a child (less than 16 years of age) the patient confirmation should be left blank or struck through.

If you, the clinician, are signing the Record of Discussion form in the patient's best interests then the patient confirmation should be left blank or struck through

r10. **Other Confirmation**. If the patient is an adult without capacity then a friend or relative can offer their advice on the patient's likely preferences by signing here:

- For an adult without capacity an additional Consultee Declaration Form is mandatory, only if they advise that the patient would wish to take part in research (this is not necessary for the clinical test)
- For a child the *optional* Young Person Assent Form can be completed if the child or young person wishes to document their assent to research participation
- If the patient is an adult with capacity this confirmation should be left blank or struck through.

r11. **Additional Information**. This information is needed to ensure that the correct information can be loaded into the NGIS system. Please complete this section at the same time as the conversation with the patient

r12. **Clinician Confirmation**. Confirmation by the healthcare professional (who recorded the conversation and witnessed the patient choice). This section must contain the clinician's printed name, signature and date the form was signed in dd/mm/yyyy form

c2 First name	NHS number (or postcode if not known)
Last name	Date of birth (d d m m y y y y)

Consultee declaration regarding whole genome sequencing

p1 **Your relative, friend, patient or client has been invited to take part in the National Genomic Research Library. You are being asked to act as a consultee on their behalf.**

Your relative, friend, patient or client is considered to be unable to decide for themselves whether they want their data and samples to be used in research. Someone who can't make this kind of decision for themselves is described as lacking capacity. When we talk about this person, we will refer to 'the person who lacks capacity' or 'the person'.

p2 ## *The role of a consultee*

A consultee is someone who will only consider the likely views and interests of the person who lacks capacity. They must set aside their own personal views about participating in research and consider the person they represent. A consultee cannot be part of the person's NHS clinical team or anyone else acting in a professional or paid capacity (e.g. a person's solicitor).

They must be an adult who is prepared to be consulted on the person's behalf. For example:

- Next of kin (i.e. parent, partner, husband, wife, son or daughter) or friend, family member or carer
- A person holding Lasting Power of Attorney for Personal welfare registered with the Public Guardian
- A deputy appointed by the Court of Protection

The law protects the interests of adults who lack capacity. In England and Wales, it states that a consultee can advise about the person's likely wishes or feelings. If the person does not want to take part, we will respect their wishes. More information about being a consultee and the National Genomic Research Library can be found at www.genomicsengland.co.uk

The consultee agreement

By saying 'yes' to be a consultee, I understand that:

- I must only consider the likely views and interests of the person who lacks capacity
- I must consider the aims of the research, the practicalities, risks and benefits
- I will inform the healthcare team of any decisions the person may have already made about research
- I have been made aware and given an opportunity to get independent advice
- If I feel that the person wishes to be withdrawn, I will notify a healthcare professional
- I might be asked to give advice again in the future, for example if more blood or saliva samples were needed
- Hospital staff will tell me if any future changes to the research might affect the person
- I can stop being a consultee at any time

p3 **Please ask any questions before taking the decisions shown on the following page.**

Consultee Declaration Form

The Consultee declaration form records

1. That information has been made available about the implications of representing a patient deemed 'lacking capacity' in the choice of participating in the research offer
2. The prospective representative's choice for acting as consultee on behalf of the patient.

The Consultee Declaration Form has two pages.

In the following pages the letters and numbers refer to the yellow ellipses and highlighted test on the facing page.

Consultee Declaration Form – Page 1

The following information is repeated on every page of the Consultee Declaration Form:

c1. **Header Message**. The header message identifies the form being used, the version and release date

c2. **Patient Details**. The patient details should be completed on **every** page of the form. It can either be written on the form or a sticker with the relevant information placed over the patient details grid

c3. **File Name and version**. The filename of this form

c4. **Footer Message**. The footer message describes the version control in place for the form

Specific information:

p1. **Notification**. Notify consultees (who are consenting on behalf of their child or another patient) that all statements on this page are relevant to the patient and not the consultee

p2. **Consultee Statements**. Detailed information which supports this information can be found in the guide to research

p3. **Consultee Confirmation**. Ask the consultee whether they have any questions regarding their consenting as a consultee. When any questions have been answered the consultee should confirm their choice by page two of the form

Genomics england

c2

First name	NHS number (or postcode if not known)
Last name	Date of birth (d d m m y y y y)

c3 02-NGIS-CON (v3.01)

Confirmation of decision:

I confirm that I have read and had the opportunity to discuss information about acting as a consultee for the person lacking capacity. My answers are circled below.

p4

1. **I have been consulted about this person's participation in the National Genomic Research Library** — **YES | NO**

   If your answer to 1 is **NO**, *then please ignore 2 and sign below.*

3. **I am willing to accept the role of consultee for this person** — **YES | NO**

p5

Your name (i.e. the Consultee)	Signature	Date
.....	.....	d d / m m / y y y y

Healthcare professional use only

To be completed by the healthcare professional recording the consultee's choices.

p6

Healthcare professional name	Signature	Date
.....	.....	d d / m m / y y y y

Consultee Declaration Form – Page 2

The common information is repeated on this page.

p4. **Consultee Question**. Confirm that the consultee understands the question and that one of the choices has been circled

If the consultee has not circled either option or has circled both please ask the consultee to try again

p5. **Consultee Confirmation.** The consultee will be an adult with capacity. Please ask the consultee to print their name, sign and date the form. It is OK for the clinician to print the consultee name here but the consultee must sign and date the form themselves.

p6. **Clinician Confirmation**. Confirmation by the healthcare professional (who recorded the conversation and witnessed the consultee choice). This section must contain the clinician's printed name, signature and date the form was signed in dd/mm/yyyy form

c1 NHS Genomic Medicine Service. Young Person Assent Form version 3.01 (November 2020). To be used for WGS go-live

c2

First name	NHS number (or postcode if not known)
Last name	Date of birth (d d m m y y y y)

c3 03-NGIS-YPA (v3.01)

National Genomic Research Library Young Person Assent Form (ages 6 – 15)

Feel free to ask any questions before answering the questions below.

y1 *Please circle your choice:*

1. Have you read information or has someone explained the research to you? **YES | NO**
2. Have you asked all the questions you want? **YES | NO**
3. Have you had your questions answered in a way you understand? **YES | NO**
4. Do you understand it's OK to say you don't want to take part – but that your parent(s), or guardian who look after you, will make the final choice? **YES | NO**
5. Are you happy to take part? **YES | NO**

y2 *If ANY of your answers are 'NO', or you don't want to take part:*

- Don't sign your name on this form
- Tell your parents and healthcare team how you feel, so they know

v3 *If ALL of your answers are 'YES':*

- Please write your name, signature, and today's date here:

Your name	Signature	Date
.....	.....	d d / m m / y y y y

c4 This document is subject to version control and is regularly updated. Please confirm you are using the correct version by contacting your local Genomic Laboratory Hub

Young Person Assent Form *(optional)*

The Young Person Assent Form records:

1. That young patients (aged between 6-15 years old) have received information about the options and implications associated with participating in the research offer
2. The young person's choice for participating in the research offer

The Young Person Assent Form consists of a single page.

In the following pages the letters and numbers refer to the yellow ellipses and highlighted test on the facing page.

Young Person Assent Form

The common information is repeated on the Young Person Assent Form:

c1. **Header Message**. The header message identifies the form being used, the version and release date

c2. **Patient Details**. The patient details should be completed on **every** page of the form. It can either be written on the form or a sticker with the relevant information placed over the patient details grid

c3. **File Name and version**. The filename of this form

c4. **Footer Message**. The footer message describes the version control in place for the form

Specific information:

y1. **Questions 1 to 5**. Go through each of the questions with the young person and ask them to circle yes or no for each answer.

Every question should have one answer circled. Please check and follow up with the young person if any of the questions are unanswered or have both options answered

y2. **Non Participation**. If the young person's choice to participate in research differs to their parent, guardian or carer – the decision on how to proceed is expected to require further conversation, facilitated by the healthcare professional

y3. **Young Person's Confirmation.** Confirmation by the young person that they have answered the question and are willing to take part,

Please ask the young person to print their name, sign and date the form. It is OK for the clinician to print the young person's name here but the child must sign and date the form themselves.

c1 NHS Genomic Medicine Service. Withdrawal From Research Form version 3.01 (November 2020). To be used for WGS go-live

c2		
First name	NHS number (or postcode if not known)	
Last name	Date of birth d d m m y y y y	

c3 04-NGIS-WIT (v3.01)

Withdrawal from the National Genomic Research Library

w1 **You, or your child, would like to withdraw from the National Genomic Research Library.**

This document gives you details on the types of withdrawal available to you. Feel free to ask any questions before taking the decisions shown overleaf.

w2 **Please read the following statements:**

1. You can withdraw from the National Genomic Research Library at any time
2. You don't have to give us a reason for your decision
3. Withdrawal will not affect your participation in any other research you are currently taking part in
4. Complete one form per person wishing to withdraw (children under 16 require a parent / guardian to sign)
5. Your withdrawal will be processed as soon as Genomics England have received this form
6. There are two withdrawal options available to you:

w3 ***Option One – Partial Withdrawal (i.e. no further contact)***

- Genomics England will no longer contact you about research.
- Your information will continue to be made available for research in the National Genomic Research Library.
- Genomics England will continue to use any data and samples already collected, and any information from your health records in the future.

w4 ***Option Two – Full Withdrawal (i.e. no further contact or use of samples and data)***

- Genomics England will no longer contact you about research.
- Your existing data will remain in the National Genomic Research Library but will not be made available for new research; this means if your data has already been used in a study, it will continue to be used for this purpose only.
- No further data about you will be collected or stored.
- All existing samples (including DNA) will be destroyed.
- A minimum amount of information will be retained for auditing purposes; your first name, surname, date of birth, address and contact details are some examples.
- If your data has already been used in research which produces information relevant to your healthcare, this will be passed to your healthcare professional for consideration.

If at any point you feel you need more information, please visit www.genomicsengland.co.uk or contact your healthcare professional.

Once completed, please hand the form to your healthcare professional, or post to:

Genomics England
Queen Mary University of London,
Dawson Hall,
London EC1M 6BQ

w5 **Please ask any questions before taking the decisions shown on the following page.**

c4 This document is subject to version control and is regularly updated. Please confirm you are using the correct version by contacting your local Genomic Laboratory Hub

Withdrawal From Research Form

The Withdrawal From Research Form records:

1. That information about options and implications has been made available to a patient considering withdrawing from the National Genomic Research Library
2. The patient choice for a) partially, or b) fully withdrawing from this research

The Withdrawal From Research Form has two pages.

In the following pages the letters and numbers refer to the yellow ellipses and highlighted test on the facing page.

Withdrawal From Research Form – Page 1

The following information is repeated on every page of the Withdrawal From Research Form:

c1. **Header Message**. The header message identifies the form being used, the version and release date

c2. **Patient Details**. The patient details should be completed on **every** page of the form. It can either be written on the form or a sticker with the relevant information placed over the patient details grid

c3. **File Name and version**. The filename of this form

c4. **Footer Message**. The footer message describes the version control in place for the form

Specific information:

w1. **Notification**. Notify parents (who are consenting on behalf of their child) and consultees (who are consenting on the part of an adult deemed to be without capacity) that all statements on this page are relevant to the patient and not the parent or consultee

w2. **Withdrawal Statements**. Each statement should be discussed with the patient as part of the clinical discussion. Detailed information which supports each statement can be found in the clinician's guide

w3. **Partial Withdrawal**. The nature of a partial withdrawal should be discussed

w4. **Full Withdrawal**. The nature of full partial withdrawal should be discussed

w5. **Withdrawal Confirmation**. Ask the patient confirm their withdrawal choice by completing page two of the form

c2

First name	NHS number (or postcode if not known)
Last name	Date of birth (d d m m y y y y)

c3 04-NGIS-WIT (v3.01)

Confirmation of decision to withdraw:

w6 I confirm that I have: Had the opportunity to read and understand the information about withdrawing from the National Genomic Research Library, get further information and ask questions. My withdrawal choice is circled below.

I would like to	Partially Withdraw	Fully Withdraw	my / my child's data and samples from the National Genomic Research Library

w7

Patient name	Signature	Date
.....	.....	d d / m m / y y y y

w8 If you are signing this form on behalf of someone else (children, adults without capacity or deceased patients) then please sign below.

Parent | Guardian | Consultee name* *please amend as appropriate	Signature	Date
.....	.....	d d / m m / y y y y

Healthcare professional use only

To be completed by the healthcare professional recording the participant's decision.

w9

Healthcare professional name	Signature	Date
.....	.....	d d / m m / y y y y

c4 This document is subject to version control and is regularly updated. Please confirm you are using the correct version by contacting your local Genomic Laboratory Hub

Withdrawal From Research Form – Page 2

The common information is repeated on this page.

w6. **Withdrawal Question**. Confirm that the patient (or representative) understands the question and that one of the choices has been circled

w7. **Patient Confirmation**. If the patient is an adult with capacity please ask them to print their name, sign and date the form. It is OK for the clinician to print the patient name here but the patient must sign and date the form themselves.

If the patient is an adult deemed to be without capacity or a child (less than 16 years of age) the patient confirmation should be left blank or struck through.

w8. **Other Confirmation**. If the patient is an adult without capacity then a friend or relative can offer their advice on the patient's likely preferences by signing here:

- For an adult without capacity an additional Consultee Declaration Form is *mandatory* for the patient to be withdrawn from research on the consultee's advice
- For a child the *optional* Young Person Assent Form can be completed if the child or young person wishes to document their assent to research withdrawal
- If the patient is an adult with capacity this confirmation should be left blank or struck through.

w9. **Clinician Confirmation**. Confirmation by the healthcare professional (who recorded the conversation). This section must contain the clinician's printed name, signature and date the form was signed in dd/mm/yyyy form

c1 NHS Genomic Medicine Service. Participation in Research Form version 2.01 (November 2020). To be used for WGS go-live

c2

First name	NHS number (or postcode if not known)
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NHS

c3 05-NGIS-OPT (v2.01)

The National Genomic Research Library

o1

The NHS invites you to contribute to the National Genomic Research Library, managed by Genomics England.

Genomics England was set up in 2013 by the Department of Health and Social Care to work with the NHS to build a library of human genomes for researchers to study. Combining data from many different patients helps researchers to better understand disease and spot patterns in the data.

By agreeing to share your data you might get results which could lead to your own diagnosis, a new treatment, or offers to take part in clinical trials. Your taking part could enable diagnoses for people who don't have one.

Please read the following statements. Feel free to ask any questions before making a decision.

By saying 'yes' to research, I understand the following:

The National Genomic Research Library

o2

1. NHS England, on behalf of the Trusts that provided your genomic test, will allow Genomics England to access my personal data, including my genomic record.

Security

2. Any samples and data stored by Genomics England and the NHS will always be stored securely. Genomics England will take all reasonable steps to ensure that I cannot be personally identified.

Re-contact

3. My clinical team or Genomics England together with my clinical team, can contact me if the data or samples reveals any clinical trials or other research that I might benefit from.

4. If something is relevant to me or my family, there is a process by which this will be shared with my NHS clinical team.

Data and sample usage

5. Researchers may include national or international scientists, healthcare companies and NHS staff. To access the data, these researchers must all be approved by an independent committee of experts, including health professionals, clinical academics and patients. There will be no access to the data by personal insurers and marketing companies.

Data storage

6. Genomics England will collect different aspects of my health data from the NHS and other data from organisations listed at https://www.genomicsengland.co.uk/privacy-policy/. The collection and analysis of my health data for research will continue across my entire lifetime and beyond.

Withdrawal

7. I can change my mind about taking part at any time.

More information regarding research in the National Genomic Research Library can be found at www.genomicsengland.co.uk
For any further questions, my healthcare professional can provide information.

o3 **Please use page two to indicate your research choice.**

c4 This document is subject to version control and is regularly updated. Please confirm you are using the correct version by contacting your local Genomic Laboratory Hub

Participation in Research Form

The Participation in Research Form records:

1. A discussion has taken place between the clinician and patient (or patient representative) about the research implications of having a whole genome sequencing test
2. The patient's choice regarding participating in research.

The Participation in Research Form has two pages.

In the following pages the letters and numbers refer to the yellow ellipses and highlighted test on the facing page.

Participation in Research Form – Page 1

The following information is repeated on every page of the Participation in Research Form:

c1. **Header Message**. The header message identifies the form being used, the version and release date

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c3. **File Name and version**. The filename of this form

c4. **Footer Message**. The footer message describes the version control in place for the form

Specific information:

o1. **NGIS Research Summary**. Notify parents (who are consenting on behalf of their child) and consultees (who are consenting on the part of an adult deemed to be without capacity) that all statements on this page are relevant to the patient

o2. **Research Statements**. Each statement should be discussed with the patient as part of the discussion about research. Detailed information which supports each statement can be found in the clinician's guide

o3. **Research Confirmation**. Ask the patient to consider participating in the National Genomics Research Library. The patient should confirm by circling their choices on page two of the form

c1 NHS Genomic Medicine Service. Participation in Research Form version 2.01 (November 2020). To be used for WGS go-live

c2

First name	NHS number (or postcode if not known)
Last name	Date of birth (d d m m y y y y)

Genomics england

NHS

c3 05-NGIS-OPT (v2.01)

Confirmation of your research choices

My research choice is circled below.

o4

A. **I have discussed taking part in the National Genomic Research Library** — **YES | NO**

If your answer to A is **NO** *then please ignore B and sign directly below*

B. **I agree that my data and remainder sample may contribute to the National Genomic Research Library** — **YES | NO**

o5

Patient name	Signature	Date
.....	.....	d d / m m / y y y y

If you are signing this form on behalf of someone else (children, adults without capacity or deceased patients) then please sign below.

o6

Parent | Guardian | Consultee name* *please amend as appropriate	Signature	Date
.....	.....	d d / m m / y y y y

Healthcare professional use only

To be completed by the healthcare professional recording the patient's choices.

o7

Healthcare professional name	Signature	Date
.....	.....	d d / m m / y y y y

c4 This document is subject to version control and is regularly updated. Please confirm you are using the correct version by contacting your local Genomic Laboratory Hub

Participation in Research Form – Page 2

The common information is repeated on this page.

o4. **Research Choice Question**. Confirm that the patient (or representative) understands the question and that one of the choices has been circled

o5 **Patient Confirmation**. If the patient is an adult with capacity please ask them to Print their name, Sign and date the form. It is OK for the clinician to print the patient name here but the patient must sign and date the form themselves.

If the patient is an adult deemed to be without capacity or a child (less than 16 years of age) the patient confirmation should be left blank or struck through.

o6. **Other Confirmation**. If the patient is an adult without capacity then a friend or relative can offer their advice on the patient's likely preferences by signing here:

- For an adult without capacity an additional Consultee Declaration Form is *mandatory* for the patient to take part in research
- For a child the *optional* Young Person Assent Form can be completed if the child or young person wishes to document their assent to research participation
- If the patient is an adult with capacity this confirmation should be left blank or struck through.

o7. **Clinician Confirmation**. Confirmation by the healthcare professional (who recorded the conversation and witnessed the patient choice). This section must contain the clinician's printed name, signature and date the form was signed in dd/mm/yyyy form