

Adaptations to seeking and recording patient choices in the Genomic Medicine Service in the context of increased remote working



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Document management

1.1 Revision history

| Version | Date | Author | Summary of changes |
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| 0.1 | 05.08.2020 | Ellen Thomas | Document created |
| 1.0 | 06.08.2020 | Ellen Thomas | Comments incorporated |
| 2.0 | | Ellen Thomas | Update to research consent procedures |
| | | | |

1.2 Reviewers

This document must be reviewed by the following people:

| Reviewer name | Title/responsibility | Date | Version |
|-------------------|--|------------|---------|
| Alexandra Pickard | Head of Policy and Strategy, Genomics Unit | 05.08.2020 | 1.0 |
| Debbie Porter | Head of Implementation | 05.08.2020 | 1.0 |

1.3 Approved by

This document must be approved by the following people:

| Name | Signature | Title | Date | Version |
|-------------------------|-----------|--|------------|---------|
| Professor Dame Sue Hill | | Chief Scientific Officer & SRO for Genomics, NHS England & NHS Improvement | 05.08.2020 | 1.0 |
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1.4 Document control

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Scope

This document relates to seeking and recording patients' choices when they are having a diagnostic whole genome sequencing (WGS) test in the Genomic Medicine Service (GMS) to investigate their cancer or rare disease. It builds on previous guidance as produced by the NHS England and NHS Improvement Patient Choice Working Group.

Principles

1. All patients should be aware that their data is being processed through a national system if they are having a WGS test. This expectation was set by the National Data Guardian's office (NDG) when they were consulted on the Genomic Medicine Service, to fulfil the criterion that **patients should not be surprised** by use of their data in the course of their clinical care.
2. All **standard expectations** of any diagnostic test and the conversation that precedes it apply to genomic testing, in addition to the NDG expectations.
3. All patients having a WGS test should be provided the **opportunity to take part in research** (the National Genomic Research Library, NGRL); this can be at the same time as being asked about the clinical test or later in the pathway. Regardless of the route used to record consent, the opportunity to take part in research should be accompanied by appropriate written / online information and the chance to ask questions about the research offer, in addition to information about the clinical test.

Implementation planning

1. The Genomic Laboratory Hub (GLH) laboratory needs to know that the patient choice status is suitable to initiate the test.
2. When testing is arranged through remote appointments, this may require a change of standard approach, or flexibility to adopt different approaches (it is noted that most patients, but not all, will need to attend phlebotomy to have WGS testing initiated).
3. GLH capacity to chase up patient choice information arriving by different routes may be limited; this must be balanced against the need for flexibility related to remote consultations.

Options

1. **Adapt existing patient choice pathway:** e.g. a phone conversation to agree that the test will take place and discuss research participation; post or email the Record of Discussion (RoD) form and supporting information materials to the patient; the patient signs and either posts the form back or brings it to their phlebotomy appointment; the form travels to the laboratory from the clinician or with the sample, and is uploaded to NGIS (form to follow pathway* available if needed to avoid delays to testing).
2. **Use of locally-developed electronic tools:** some GLHs were already planning to incorporate electronic record of consent into local electronic patient records; this is confirmed as acceptable for diagnostic and research purposes and could potentially be adapted for remote use if local systems allow.

3. **Remote recording of patient choices:** see below for pathway details.

Note that GLHs can implement one or more of these options to meet local needs.

*Form to follow pathway:

- Patient agrees verbally to the test going ahead
- Clinician ticks the box on the request form to say 'conversation happened, record of discussion form to follow'
- GLH initiates test using the 'form to follow' workflow in NGIS
- When the RoD form arrives in the GLH lab this is uploaded to NGIS
- Results are not released to the GLH until the RoD form has been uploaded

Please see the SOP 'Record of Discussion requirements for the progression of Whole Genome Sequencing result data into the Interpretation Portal' for further information on this process and the release of WGS results to the GLH via the interpretation portal.

Remote recording of patient choices

1. Remote discussion between patient and clinician about initiating a WGS test (content of the discussion is the same as for face-to-face consultations):
 - a. Verbal consent for **diagnostic** WGS testing is taken from the patient during the remote consultation, and the content of the conversation is documented by the clinician in the medical record; emailed consent would also be acceptable where a written record is preferred.
 - b. Information regarding the **research** offer is provided verbally and through emailed, posted or online written materials, which can be sent prior to the appointment or after it as appropriate.
2. Once verbal or emailed consent has been obtained to go ahead with the clinical test, the **clinician completes and signs a Record of Discussion (RoD) form:**
 - a. The RoD form indicates the patient's acceptance of the **diagnostic** test.
 - b. For the **research** choice, depending on the nature and outcome of the conversation with the patient in the remote consultation, the clinician completes the yes, no or 'research not yet discussed' options on the RoD form. The patient will need a route to ask any questions about the research offer if they wish to, before making a positive decision to take part in research.
 - c. The clinician signs the form in the usual clinician box. The patient signature box is left blank, and the clinician writes on the form that the patient has provided consent remotely.
3. The clinician sends a copy of the RoD form to the GLH, puts a copy in the local medical records, and **sends a copy to the patient with their clinic letter**, to ensure the patient can double-check their choices and there is visibility of those choices throughout the system.
4. When transcribing the test request into NGIS, the GLH transcriber ticks the box to indicate that the **patient has agreed to the test**, and uploads the form to NGIS. The box indicating that the test is proceeding in the patient's best interests should NOT be ticked, as this indicates that the patient has not been able to provide consent to the test, which is not the case (it is merely the method of recording the consent which differs with the remote pathway).
5. For the research choice, the transcriber should transcribe the patient's research choice from the RoD form as per standard process.

6. If the patient wishes to change their mind about taking part in research after the consultation, they can post or email a completed withdrawal form or a completed research consent form, and their **consent preference can then be updated** and the signed form can be uploaded to NGIS. This can happen at any time during or after the clinical test, and will have no impact on the return of diagnostic results.