Developing local patient documentation relating to the National Genomic Research Library (NGRL) for the NHS Genomic Medicine Service (GMS).

We understand the value of providing a tailored service to your patients. You know your patients best. The consent process for sequencing and donation to the NGRL is complex from a regulatory perspective blurring the lines between clinical care and research. We need to ensure that all of the documentation for the NGRL is in line with our Research Ethics Committee Approval.

Standard, REC approved patient information sheets are available at: www.genomicsengland.co.uk/clinicians/resources.

This includes a long version, as well as a short 1-page leaflet. Short videos are also in development. However, we appreciate that clinical teams may wish to develop additional ways of presenting information about the NGRL, so we have put this short guide together to help ensure that that wording is in line with approvals whilst also giving you the flexibility to develop your own material.

Please do not develop your own wording when describing the NGRL.

Please use the following wording (*on page 2*) when referring to the Research element of consent for clinical whole genome sequencing.

What is the National Genomic Research Library?

The Library is a secure national database managed by Genomics England, a company set up and owned by the UK Department of Health and Social Care. It allows approved researchers to access data and samples to study conditions and look for new treatments that might help you and others now or in the future.

What is included in the National Genomic Research Library?

Importantly, your data in the Library is kept in secure systems and is de-identified, meaning any information that could personally identify you is removed and replaced with an individual reference number. Data includes information about your genomic test, your genomic sequence, and electronic copies of your health records that will continue to be collected.

How would my data be used and kept safe?

The Library is only accessible to researchers who are trying to better understand diseases and how to treat them. They must be approved by Genomics England, and through an independent review committee that includes clinical experts and participants. Your data is never used by insurers, for marketing purposes or for speculative searches.

The data stays within a secure environment where all research activity is continually monitored. A committee within Genomics England reviews any summary data or findings that could come out of this environment so that this can be done safely and with strict controls.

Please use the URL or QR code below when signposting to more information about the NGRL:

https://www.genomicsengland.co.uk/patients-participants/data

Please note that currently in the NHS GMS, the NGRL is only applicable to patients who are being offered whole genome sequencing.

If you require any support with the wording around the NGRL or Genomics England for your patient material please do get in contact with us at:

ethics@genomicsengland.co.uk

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