Access Review Committee (ARC) Application Guidance

The Access Review Committee (ARC) is made up of participants, clinicians and data experts. Its role is to provide an independent review and approval of requests to access the genomic and health data held in the National Genomic Research Library (NGRL), via Genomics England’s trusted Research Environment (RE). The ARC ensure that requests are in line with Acceptable Uses, as outlined in the NGRL [Protocol](https://www.genomicsengland.co.uk/patients-participants/data), assess the level of public and participant involvement in proposed research, weigh up risks and benefits, and maintain transparency of all research undertaken at Genomics England . They make the final decision on who has access to the dataset.

When reviewing your application, the ARC want to see that you have considered and justified your responses. All projects are different and the ARC use their knowledge and experience to come to a conclusion rather than use a strict marking criteria.

Their areas of focus will be:

* Research aims and methods
* The involvement of participants, patients and service users
* Risk and benefit
* Integrity
* Transparency

Quality

The ARC expect that all applications are of sufficient quality. As such, a number of internal quality checks will be applied to the application by the Partnership Development Team to ensure that the following criteria are met before your application is sent to the ARC:

* All relevant sections of the application are complete.
* There are no spelling or grammatical errors.
* The application is in appropriately accessible language. (Not applicable to the technical sections)
* The terminology used in the application is in line with the [Participant Panel Language Guide.](https://files.genomicsengland.co.uk/documents/Genomics-England-Language-Guide.pdf)
1. The application is feasible i.e. there is likely sufficient data in the NGRL to feasibly support the research proposed?
2. The proposal and the partner are aligned with Genomics England’s strategy and mission.
* The application is in line with acceptable uses as outlined in the NGRL Protocol.

When these criteria are met the application will be put forward for ARC Review.

All subsequent research applications from the same company will be assessed against the same criteria by the Genomics England Research Management team.



Question Specific Guidance

1. Organisation Overview

1.1 Organisation details

Please provide information on your organisation and the name of the person responsible for the application process.

1.2 Please give an overview of the type of research the organisation is interested in carrying out within the Research Environment in terms that a non-scientist would be able to understand (Please see the guidance notes for an exemplar of an explainable summary, 200 words max)

The ARC pay particular attention to this section of the application. It is important because there are a number of participants (of the 100,000 Genomes Project) on the ARC who do not have a scientific background and they need to be able to understand your intentions in working with their (and others) data.

Please avoid highly technical language and acronyms, where this isn’t possible please explain what the word(s)/term(s) mean(s).

We understand the importance of commercial sensitivity and as such this section does not need to be specific to targets, condition or other sensitive information but does need to provide a clear overview of you aims and broad areas of interest.

Example:

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|  Our aim is to combine insights from the microbiome – the microbes, including bacteria, viruses and fungi and their DNA that naturally reside within us – with the genomic data collected by Genomics England to understand why people respond to drugs differently. Using genomic sequencing data of tumour samples, we can infer the microbiome composition within the tumour, and further understand downstream effects on disease progression and response to treatments. This could help us to develop more personalised treatments for patient with diseases, such as cancer, and improve the likelihood of a treatment outcome being successful. The team is led by xxxxx, a clinician-scientist, principal investigator and consultant neurologist with a background in computational medical research based in London. Our research combines expertise from clinicians, engineers and biologists to develop complex computer simulations of drug-microbe interactions to predict drug response, with the ultimate aim of translating these insights to the clinical setting. An example of this is in breast cancer patients, where we successfully identified treatment responders through an understanding of the tumour and its links to expression of genes implicated in cancer [Basgaran et al., 2023]. We have a number of active clinical trials within our portfolio, emphasising our commitment to patient-centred research and confidence in our predictive modelling systems. With the addition of the data in the NGRL, we would be able to establish links between the microbiome and the human genome, adding a further layer of resolution to our model. We would harness insights from these microbiome-genome interactions to predict differential responses to medical treatments, including cancer therapies. We would also be able to probe the human genome for evidence of microbial DNA integration, an emerging topic of scientific interest with implications for the dynamics between humans and bacteria, at the DNA level. A key component of the human microbiome that differentiates it from the human genome, is that it is directly modifiable, for example with antibiotics, probiotics or the introduction of new microbes into the ecosystem. This means that there is an avenue to potentially alter an individual’s microbiome to improve their chance of them responding well to a medication, or reduce their chance of developing a toxic side-effect of the drug. This is broadly applicable in medicine, but we believe it is especially relevant to cancer care. |

1.3 Which part of the Research & Development pipeline best describes your interests?

Please choose the stage of development you are operating in. This helps the ARC focus its review and understand what is possible and adequate for answers to later questions.



1.4 Which Datasets do you wish to access?

Genomics England enables access, via the trusted Research Environment (RE), to a number of datasets within the National Genomic Research Library. You can choose as many types of data as you like but you will need to justify their use throughout the application.

Please check all relevant boxes.

1.5 Which type of data do you wish to access?

The National Genomic Research Library holds a number of different types of data (including WGS, vcfs, HES, RNAseq etc. from participants of programmes including the 100,000 Genomes Project, the NHS Genomic Medicine Service and others). You can choose as many datasets as you like but you will need to justify their use throughout the application.

Please check all relevant boxes.

1. Research project

Please provide the title of your research project in the box provided.

Please describe the specific project that you will initially undertake

Please provide a summary of your initial research proposal in both accessible and technical language

2.1 Accessible Language summary

Please provide a summary your initial research proposal in language that either avoids or clearly explains the use of scientific technical terms and acronyms. Include reference to any potential downstream benefits to patients or, if this is early stage research, set out why you are pursuing this avenue of research. This summary will be made publicly available so please do not include any commercially sensitive information. (max 200 words)

The ARC pay particular attention to this section of the application. It is important for a number of reasons: there are participants (of Genomics England programmes, whose personal genomic and clinical data would be made available to successful applicants) on the ARC, and this is the section that will be made public of the Genomics England Research Registry.

We respect the need for commercial sensitivity. The ARC need to understand the aims and methods of your research but do not need to know specifics. If you are undertaking hypothesis-free research please be explicit about this and why it is important to widely analyse data in order to, for example, look for new potential drug targets.

It is important that you justify the use of the data here, the committee want reassurance that you are not simply being opportunistic in your analysis and that there is an aim and rationale for your methods.

Example

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| --- |
| People living with cancer have different responses to treatment. We do not know which people and what treatment will work or cause side effects. The bacteria residing within our bodies, called the microbiome, may play an important role. There is 100-times the quantity of genetic material in the human microbiome than in the human genome, and there is evidence that this can impact cancer development, immune regulation, and response to treatment. Our research will harness XXXXXX unique capabilities to determine the tumour microbiome – the microbiome within the cancer itself – from the cancer genome, using the cancer dataset within the NGRL. We will evaluate whether differences in the tumour microbiome can predict the response of cancer patients to treatments including chemotherapy, targeted therapy, and immunotherapy. We will also explore how genes interact with bacteria, and the impact this has on the human genome - evaluating the total set of whole genomes sequenced to date by Genomics England for evidence of bacterial DNA. With such a broad-ranging database, we would seek expertise from patient advocates in targeting the areas of greatest need. Ultimately, knowledge from our study could empower patients and practitioners to select treatments that are more effective, less toxic, and truly personalised.  |

2.2 Technical summary

Information from this summary is for internal purposes only. It must be sufficiently detailed to allow Genomics England to assess whether the data it holds can meet the research requirements, e.g. Type of analysis, development stage, variants and phenotypes of interest.

This information will only be used in internal processing and will not be made public. This information allows us to undertake feasibility on your project. It needs to be detailed to allow us to ascertain if the project can run within the Research Environment and you can therefore be given access to the data.

2.3 Additional data and technical requirements

Please specify any additional datasets, software or models that will require import into Genomics England’s Research Environment. We may need to undertake additional feasibility assessments before final project approval is granted.

In order to undertake technical feasibility we need to understand if you have any additional data or technical requirements for your research. This will allow us to work with internal colleagues to facilitate your requests.

As with question 2.2 this is for internal purposes only and will not be made public.

3. Research team and compliance

3.1. Please provide details of the research team

Please provide name, job title and department of the lead researcher. For other personnel involved, please provide their name, email address and whether they will require direct access to participant data for the project.

3.2 Please describe the track record of the organisation and/or the researchers who will be seeking access to participant data in the NGRL (e.g. what disease areas have they worked in, what are their credentials, what active programmes do they have, what impacts have they had to date?)

The ARC needs some evidence of scientific competence and credibility for the organisation in order for it to undertake the kind of research it is proposing.

This should not just be a list of publications; if you wish to reference publications then there will need to be a narrative in you answer in order to give background and context to the ARC as to why the publication is relevant to translational R&D.

Think about impact that is patient, public or society based as well as any scientific/academic impact.

Please provide a balanced overview- inflated impact is not received well by the ARC who view it unfavourably as a ‘sales pitch’ or ‘marketing’.

3.3 Will any subsidiary or affiliate organisations be seeking access to data within the Research Environment as part of this proposal? If so, please set out the relationship between the company and the subsidiary, clarifying who will be responsible for which aspects of the research.

The ARC want to understand how responsibilities will be shared and data access will be minimised. If data are to be shared please outline any measures to minimise the likelihood of reidentification of participants.

If you are not working with a subsidiary or affiliate please enter “N/A”.

3.4 Has the organisation, or any of its staff or subsidiaries previously contravened any policies concerning the use of the Research Environment, data security, or data protection? If yes, please give details

Please outline any breaches of data protection or research misconduct for the organisation or individuals. It is important that any such contraventions are raised and explained by the applicants, to avoid these later being discovered directly by the ARC or Genomics England, raising concerns around the integrity of the applicants.

4. Benefits, Engagement & Transparency

4.1 What are the potential benefits for participants, or for advances in healthcare, of undertaking this research?(Please explain the unmet medical need and any short and long term benefits to patients and healthcare that this research may lead to. If this is early-stage research, do acknowledge this. Refer to the guidance notes for further information on articulating ‘benefit’)

Benefit can be across a spectrum from an individual to public health.

* Some research may have a direct benefit to an individual where a diagnosis is being made or a n=1 treatment is being developed.
* Some research may have a benefit across a condition where, for example, druggable targets are being identified or validated. Meanwhile other research projects may provide more limited benefit scope to specific rare conditions or a particular subset of cancer. Benefit can be articulated at a function level (e.g. respiratory or liver) as well as a condition level.
* Other research may be at a public health level for example looking at variants responsible to severity of or susceptibility to infectious disease.

The ARC would like to understand at what level any potential benefit will occur as well as the time it might take to realise these benefits. For very early stage research, for example target selection, there may be no way to describe immediate benefit at all or it may be hard to predict who might benefit directly down the line.

What the ARC would like to see is that you have considered benefit even at the very earliest stages of research. Even if, at this stage of research, there will be no obvious benefit to patients and participants, the ARC would like to know that you have thought about it and addressed it in your application.

4.2 Public and patient involvement is essential for translating scientific discoveries, made using participant data held by Genomics England in the National Genomics Research Library (NGRL), into patient benefits.

By ‘**public and patient’**, we mean individuals with lived experience of a health condition — whether they are participants in the NGRL, current patients or former patients, or carers) — as well as, in some cases, representatives of patient advocacy organisations.

By ‘**involvement in research’**, we refer to the National Institute for Health and Care Research (NIHR) definition, which emphasises that research is conducted **‘with’ or ‘by’** members of the public rather than **‘to,’ ‘about,’ or ‘for’** them. This involvement represents an active partnership between participants, patients, carers, and researchers, allowing them to influence and shape the research.

**Embedding public and patient involvement in your research**

If you have partnered with patients or the public, highlight any groups you have worked with or plan to work with, including discussions with those who may benefit from the research.

Although not exhaustive, examples of public and patient involvement include consulting on research design, co-developing information materials, or sharing research findings with relevant patient groups and communities.

The pathway below illustrates how public and patient involvement can be integrated throughout a research project, ensuring patient and public perspectives are central at every stage.

While meaningful public and patient involvement may not always be feasible in the early stages of the research pathway – such as during target selection when a specific patient population has not yet been identified – efforts should be made to involve patients and the public at later stages. In such cases, please outline your plans for involving patients and the public once a relevant population has been identified.

We therefore ask that you provide the following information in your application:

* *How have you involved the public and patients so far?*
* *How will you involve the public and patients going forward?*
* *If you do not plan to involve the public and patients, please explain why.*

**Useful resources**

1. Briefing notes for researchers - public involvement in NHS, health and social care research (2021): <https://www.nihr.ac.uk/briefing-notes-researchers-public-involvement-nhs-health-and-social-care-research>
2. UK Standards for Public Involvement (2019): <https://sites.google.com/nihr.ac.uk/pi-standards/home>
3. Imperial Experience Research Centre - Public Involvement: <https://www.imperial.ac.uk/patient-experience-research-centre/ppi/>
4. Rare Disease Research UK – Patient and Public Involvement and Engagement resources for researchers

<https://rd-research.org.uk/resources/>



4.3 What level of ethical or methodological review has been undertaken on the proposal?

Please provide details of any internal scrutiny, review by advisors, funders or supervisors, or an external process such as a Research Ethics Committee

Genomics England do not undertake a scientific or ethical review of projects, it is expected that this has already been undertaken by applicants ahead of submission to the ARC.

Please describe how and by whom your project has been reviewed for methodological & scientific validity and ethics.

Although you will not have access to identifiable participant data this does not mean that there are no scientific and/or ethical issues. For example if you were looking for a presymptomatic population of participants with a known association for a condition there may be diagnostic and clinical management implications. If you are not feeding back findings then what justification is there for not returning findings to these participants? Here the justification could be that there is a lack of population/epidemiological level evidence which your research is trying to fill.

4.4 How are you planning to publish the results of your research?

Please articulate how you plan to be transparent about the outcomes and impacts of your research (this applies to negative results also). Outline any ways of making results public, e.g. via journal articles. This could include routes that are not via a publication.

As a minimum you will be asked to provide an annual progress summary and end of project report to Genomics England via the Genomics England research audit survey.

The impact of your research can be measured in a number of ways. The ARC want to understand how you will be making the results of your research public. As well as publication in peer reviewed journals and conference presentations the ARC is interested in your efforts to inform participants, patients and the public of your results.

The participants whose data is stored within the NGRL are always interested in the results of research that has used their data. Genomics England can facilitate news stories to participants and the media.

Please ensure you are familiar with [publication guidelines and policy](https://www.genomicsengland.co.uk/about-gecip/publications/). Clearing publication checks can be a lengthy process, we recommend declaring intention to publish results of any projects as early as possible to avoid delays.