



Medical
Research
Council

Guidance for Applicants 2020



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1. Who can apply and how to apply

The MRC reserves the right to make funding decisions based on independent scientific judgments of its board and panel chairs, deputy chairs and members.

Please note that decisions of any MRC board or panel will not be open to appeal and applicants should refer to the resubmissions section (1.5.2).

The MRC reserves the right to amend the application process.

1.1 Types of research organisations (ROs)

The principal investigator (PI) must be based at the lead organisation, which should be one of the following:

- **Higher education institutions**
All UK higher education institutions (HEI) that receive grant funding from one of the UK higher education funding bodies are eligible to receive funds for research, postgraduate training and associated activities. These bodies consist of Research England, Higher Education Funding Council for Wales (HEFCW), Scottish Funding Council (SFC) and the Northern Ireland Department for the Economy (DfE).
- **Independent research organisations (IROs) and NHS Bodies**
A number of IROs are also eligible to apply for funding. A full list of IROs and the application process to become an IRO can be found on *the UKRI website*.

NHS Bodies with research capacity (the Board, NHS Clinical Commissioning Group, NHS Special Authority, NHS Trust, NHS Foundation Trust, NHS Local Health Board) are eligible to apply as lead applicants.
- **Government-funded organisations (other than MRC units and institutes)**
Government-funded organisations such as PHE or the Met Office can apply for MRC funding only as a co-investigator (CoI). 80 per cent of full economic costs (FEC) will be awarded in the same way as all other CoIs (please note that some awards are made at different FEC rates eg global health funding opportunities).
- **MRC institutes (MRC Harwell, MRC London Institute of Medical Sciences and MRC Laboratory of Molecular Biology)**
MRC institutes may apply for MRC grants (except programme and centre grants). Funding is available to support research that is clearly additional to existing 'core' support and 100% of direct costs will be awarded. Applications to MRC Research Boards are not normally expected and require prior agreement between the Institute Director and MRC Head of Theme. See *section 3.8* for more information.
- **MRC units and Partnership Institutes**
MRC units and partnership institutes (Francis Crick Institute, Health Data Research UK, UK Dementia Research Institute) may apply for MRC grants (except Programme and Centre grants). Funding is available to support research that is clearly additional to existing 'core' support and will be awarded following usual FEC rules. MRC units apply as a department of the University See *section 3.9* for more information.
- **Institutes and units funded by other research councils** are eligible to apply as a lead applicant for MRC funding due to a reciprocal arrangement between councils. They should also apply for 80 per cent of full economic costs.

1.2 Responsibilities of research organisations

Submitting a proposal to the MRC indicates the RO's formal acceptance of the proposal, and the approval of the salaries and resources sought. Submission also signifies that the RO accepts the *terms and conditions of Research Council fEC Grants*, the *MRC additional terms and conditions* and any award-specific terms and conditions, as specified on the award letter, for the entire life of the award.

Administrative authorities have responsibility for ensuring that the salaries and resources cited in the proposals are sufficient to undertake the proposed research, to attract sufficiently experienced and skilled staff, and represent good value for money.

1.3 Applicants

Research teams include a range of individuals and grant applicants will have one of the following roles. For guidance on detailing the research staff that will be involved see *section 3.2.1*.

A Principal Investigator (PI) or Co-Investigator (CoI) must have a contract of employment with the RO for the duration of the grant prior to application (except NIRGs and fellowships). If a PI or a CoI is to leave their post prior to a project ending, the RO has responsibility for ensuring there are suitable arrangements in place to replace that PI or CoI.

Individuals can be involved in more than one MRC grant at a time. The award of a grant does not guarantee any further commitment to funding by the MRC.

1.3.1 The Principal Investigator

Each proposal must have one Principal Investigator (PI). The PI is usually responsible for the intellectual leadership of the research project and for the overall management of the research. If intellectual leadership of the research is shared, the PI should be the individual who will act as the MRC's main contact and coordinator.

By the time the grant starts, the PI must be based in the UK at the eligible RO at which the grant will be administered (the lead organisation). The PI must have a verified joint electronic-submission system (Je-S) account to apply.

We will consider proposals for research grants from any researcher who can demonstrate they will direct the proposed research and be actively engaged in carrying it through. The minimum formal qualification required is a graduate degree, most applicants are also expected to have a PhD. Proposals from less experienced PIs should normally include a senior colleague as a Co-I (unless applying for a NIRG or Fellowship).

If the PI leaves the RO for any reason, the RO must notify us and seek permission for a named replacement. If possible, one of the Co-Investigators usually takes on the role of PI. If the PI is moving to another RO it may be possible to transfer the grant subject to the agreement of both organisations. If the PI wishes to do this, they need to contact us (see *Guidance for MRC award holders* for more information).

An Emeritus Professor can be a PI. Please refer to *section 3.2.1* for how they should be included on applications.

1.3.2 Co-Investigators

Research is often undertaken by teams and the PI may be supported by one or more individuals who can be named on the application as Co-Investigators (Cols). A Col assists the PI in the management and leadership of the research. Cols should normally be able to meet the eligibility criteria for PIs and be based in the UK at an eligible RO. All Cols must have a verified Je-S account.

Researchers from overseas research organisations may be a Col if they provide expertise not available in the UK. Inclusion of an overseas Col must be discussed and agreed with the relevant programme manager in advance of application. Please provide details of the agreement in a cover letter. For more information on how to include costs for work undertaken at an overseas organisation please see *Section 3.3*.

Collaborations with Co-Investigators from China or India must have global or regional development impact as the primary objective, with local or national impacts within China or India as secondary objectives. It is expected that Co-Investigators from China and India make a significant contribution to their own research costs, including covering their own overheads. Please note it is not possible for Co-Investigators from China or India to be hosted by local or national government departments, or by international intergovernmental organisations

1.3.3 Researcher Co-Investigator

A Researcher Co-Investigator (RCol) is someone who has made a substantial intellectual contribution to the formulation and development of the project but is not eligible to be either PI or Col in their own right (they do not have a contract of employment with the RO of the PI or any of Col(s)).

Research staff this could apply to include post-doctoral research assistants, clinical fellows and technology specialists or equivalent roles.

A RCol will be:

- Working on the proposed research project as a postdoctoral research assistant or equivalent;
- Making a substantial intellectual contribution to the formulation and development of the project;
- Employed on the project up to 100% FTE by and based at, the RO of either the PI or any Col(s);
- Given intellectual ownership (e.g. through corresponding authorship) and grant management duties in relation to the ensuing research;

The PI and the RO need to identify and explain how the RCol will be supported in their career and personal development throughout the duration of the project and a Letter of Support from the PI should highlight this support. A mentor who is not the PI or a Col should be appointed to provide the RCol with independent career guidance.

Please note that Researcher Co-Investigators are not permitted on New Investigator Research Grants. Further information on RColS can be found *here*.

1.3.4 Project partners

MRC encourages and supports collaborative research projects and team approaches, especially between academic and industry researchers. Collaborators based in different organisations to the investigators or in industry can be formally recognised in applications as named project partners.

A project partner provides a substantial intellectual contribution to the project, and their organisation may also provide resources either in-kind or financially, project partners are not expected to request MRC funding to participate. The contribution and involvement of project partners should be acknowledged in the project partner section of the application form and described in detail in the case for support (*see section 2.2.3*), where the whole team and their skills/expertise and responsibilities should be set out for the benefit of assessors.

Please note project partners do not need to be based at an eligible RO or have a verified Je-S account.

Each project partner must provide a letter of support (*see section 2.2.7*).

If the project partner is from industry, applicants must follow the guidance relating to the MRC Industry Collaboration Agreement (MICA).

Please note the role of a subcontractor is distinct from a project partner. Subcontractors should not be named as part of the project team. They carry out a specific piece of work on behalf of the investigators on a fee-for-service basis, with no potential claim as an inventor over any arising intellectual property (IP). Details of any subcontracts should be specified in the Case for Support and fully justified in the Justification of Resources (*see sections 2.2.3, 2.2.4 and 3.2.2.3*).

1.4 Responsibilities of applicants, including declaration of interests

The MRC expects all funded researchers, both clinical and non-clinical, to adopt the highest achievable standards in the conduct of their research. This means exhibiting impeccable scientific integrity and following the principles of good research practice detailed in the *MRC Good Research Practice guidelines*.

As part of this, any private, personal or commercial interests relating to an application for funding to the Research Councils must be declared in a covering letter included as an application attachment.

Where the MRC is involved directly with a co-funder, the co-funder will be named in the guidance for the MRC call for proposals and the applicant should state if there is any potential conflict of interest. This should be included in the covering letter and be discussed with the relevant programme manager before application.

What constitutes a conflict of interest?

A conflict of interest is a situation in which a person named on the application (or a senior member of the lead organisation who may be involved in the management of the grant) is in a position to derive personal benefit from actions or decisions made in their capacity as grant holder, or has interests which might influence their objectivity in conducting the research or reporting the findings.

What interests should be declared?

Applicants should declare any interests which anyone named on the application (or a senior member of the lead organisation who may be involved in the management of the grant) has with any individual, organisation, project partner or supplier involved in the research, or any interest that might be perceived to influence the applicant's objectivity in conducting the research.

- 1. Personal Remuneration from organisations or project partners involved in the proposed research (other than the named employing organisation)**
Includes consultancies, directorships, honoraria (both past and present) from organisations other than that listed within the application as the employer.
Example: a consultancy, directorship or significant research collaboration with a company that makes a drug, treatment or piece of equipment that will be evaluated or used during the research.
- 2. Significant Shareholdings or other Financial Interests in organisations which are involved in or might benefit from the research**
Include the name of the company and the nature of the interests. Indirect shareholder interests (eg via unit trusts or pension funds managed by others) need not be declared.
Example: shareholdings with a market value equal to or greater than £10,000 or represent more than 1% of the total shares in the company.
- 3. Research support (financial or in kind) from commercial organisations involved in the grant or which might benefit from the outcome of the research that are not mentioned in the application**
Also include ownership of intellectual property whose value may be affected by the outcome of the research
- 4. Un-remunerated involvement with any organisation named on the application or which might benefit from the research or its outcomes**
This may include non-executive and advisory positions, directorships and other positions of authority.
- 5. Political/pressure group associations**
Any relevant political/pressure group associations of the applicants (including paid posts and high-profile unpaid roles) should be declared.
Example: trusteeship of a charity with interests relevant to the area of research in the application.
- 6. Family**
Declarations should also include any relevant known interests of immediate family members and any persons living in the same household. Applicants should also consider whether they need to disclose relevant known interests of any other person with whom they have a relationship which is likely to appear, to a reasonable person, to influence his/her independence and objectivity. Please indicate which category of interest applies. Family members do not need to be identified, either by name or their relationship to the applicants.
Example: a family member or close friend who works in sales for (or has a significant financial interest in) a company that is a potential supplier of major equipment or materials that will be purchased using the grant funding.

Managing Conflicts

Research Council terms and conditions include a requirement for ROs to have effective processes in place to manage conflicts of interest. Where the applicant or RO considers that an interest does give rise to a clear conflict, a proposed plan for managing that conflict

should be included in the covering letter. If new conflicts arise once an award has been made these should be declared and managed using the ROs established processes.

Interests declared will be scrutinised by Research Council staff and drawn to the attention of members of panels or boards making the decision on funding. Conditions relating to how conflicts should be managed may be attached to awards.

1.5 Multiple applications

1.5.1 Applications to MRC

Each PI may submit a maximum of two grant proposals to each board or panel deadline. However, applicants are strongly advised to seek funding on the basis of quality rather than the number that can be submitted.

Applicants may only have one NIRG or fellowship proposal under consideration by MRC at any time.

1.5.2 Resubmissions and Renewals

Applications previously declined by the MRC, another research council or other funding body, will not be considered by the MRC within 12 months (from the original submission date), unless invited in writing to resubmit by the MRC.

Please note this time restriction does not apply to outline applications except for our Developmental Pathway Funding Scheme (DPFS). Please refer to our scheme specific guidance.

Related proposals

Follow up to an outline application	Quote outline grant reference in the 'Related Proposals' section
Resubmission	Quote previous grant reference in the 'Related Proposals' section Submit a cover letter explaining the differences as an attachment.
Renewal (centre grants, programme grants)	Quote the previous grant reference in the 'Related Proposals' section Submit a progress report as an attachment.

1.5.3 Applying to MRC and other funders for Research Grants

By submitting a proposal to the MRC the applicant confirms the resources requested are proportionate and the research proposed is not already supported by the MRC or any other funding body. If the MRC has concerns about the credibility of resources requested in an application it will be rejected.

The same or a substantially similar research grant application, in terms of objectives or resources, cannot be submitted at the same time to MRC and any other UK or international funding body. This includes all research councils, the Department of Health (including NHS and NIHR), charities such as the Wellcome Trust and Cancer Research UK, European Research Council etc. (this list is not exhaustive). The MRC will immediately reject any grant application we receive that is already being assessed elsewhere.

Applicants submitting a substantially different but related research grant application to another funder in parallel should take care to explain the relationship between applications, especially if they are related scientifically or through use of common or shared resources. All support from other sources that has been awarded or applied for must be listed in the 'Other Support' section of the MRC application (see *section 2.1*). MRC reserves the right to request the full details of the applications and awards listed. Concerns about overlap of objectives or resources between a parallel application and an MRC application may lead to the MRC application being rejected.

Applicants must inform the relevant programme manager about progress of all related applications and detail the funding decision and the impact on MRC resources as soon as possible (usually within 10 days of provisional notification of the funding outcome and prior to the scheduled MRC board/panel meeting). If not appropriately notified the MRC application may be rejected or existing MRC awards suspended.

1.5.4 Applying to MRC and other funders for Fellowships

Fellowship applicants may simultaneously apply to MRC and other funders' fellowship schemes.

Please refer to the *Guidance for Fellowship Applicants* for further information.

1.6 What can be applied for by whom

1.6.1 Studentships

The MRC supports students by providing block grants and individual studentship awards, via competitions such as CASE, direct to ROs who then recruit and manage the students. We do not award grants directly to individual students. Studentships can also be included on centre grants and must not be included on research grants. Refer to information on *Studentships* for further details.

1.6.2 New Investigators

New investigators can apply for a fellowship, a New Investigator Research Grant (NIRG) or research grant.

1.6.3 Experienced Investigators

Please refer to *Browse funding opportunities* for details of other types of grants which are available.

1.7 How to apply - submission process

It is the applicant's responsibility to ensure they apply to the correct funding call/board/type of grant and that their application is submitted with adequate time to allow their research organisation, to complete necessary checks and complete the final submission (through Je-S), to the **MRC by 16:00 (GMT/BST)**, on the advertised MRC submission deadline.

The applicant must read and understand all guidance. If in doubt, please contact the relevant programme manager for further information. Incorrect selection will incur significant delay and is likely to cause deferral to a later meeting – typically a delay of four months or more.

For some schemes or calls applicants may need to submit outline proposals before making full proposals. Usually feedback will be given at the end of the outline stage. Such feedback is designed to help applicants improve the quality of their subsequent full proposal (if invited) to strengthen its competitiveness.

1.7.1 Using the joint electronic-submission system (Je-S)

Proposals for MRC grant schemes must be submitted through the (Je-S) system (to the MRC), by 16:00 (GMT/BST), on the advertised call closing date.

Please also note the following: All Investigators (PI & Co-I) are required to have a verified Je-S account type, when applying for a 'Standard or Outline Proposal'.

New Je-S users should select (Create Account - Terms and Conditions) to commence the create account process and gain access to the Je-S System.

Should applicants require assistance with any Je-S related matter, please contact the (Je-S) Helpdesk, which is the first point of contact for the Research Councils.

Email: JeSHelp@je-s.ukri.org

Phone: +44 (0) 1793 44 4164*

The Je-S Helpdesk is staffed Monday to Thursday 8.30am to 5pm and Fridays 8.30am to 4.30pm (excluding bank holidays and other holidays)

*Phone calls that cannot be answered during working hours will be redirected after 30 seconds to Voice Mail. The helpdesk will normally return your call within 3 hours.

1.7.2 Applying for a funding opportunity

Applicants can only access the proposal forms via Je-S between the opportunity opening date and the deadline date. Please refer to MRC *application deadlines* for a list of forthcoming funding opportunities and their respective opening and deadline dates.

Applicants are responsible for ensuring the selection of the correct Je-S form and Call when they follow the create function within their 'Documents' section. This allows them to create a 'New Document' within Je-S and then select the correct Research Council, Document Type, Scheme and Call to enable the creation of the correct Je-S form and final submission to the correct MRC funding opportunity.

Where proposals to a specific call cover a wide science remit e.g. MRC Research Boards. MRC require applicants to indicate the Board and Science Area of their project, to ensure each submitted proposal is directed to the correct Teams for examination and assessment. Applicants indicate these by completing the Je-S Proforma section 'Board or Panel Portfolio'. Completing this section requires applicants to firstly select the most appropriate 'Board/Panel' from the list of options made available by MRC. Following selection of the most relevant MRC Board/Panel, the applicant is required to indicate the 'Panel' (MRC Science Area), most appropriate to their proposal.

If appropriate to the MRC funding opportunity, the MRC also require the applicant to complete the Je-S Proforma section 'Grant Type'. This is again to assist MRC during the assessment process of the proposal, helping us to identify the type of application being submitted. The 'Grant Type' section includes a list of all options appropriate to the MRC

'Call' selected within 'Project Details' of the Je-S form. Applicants are required to select one of the available options from the list, which is most relevant to their proposal.

Please note if the application is not being submitted to a board eg Biomedical Catalyst: Developmental Pathway Funding Scheme (BMC:DPFS) then the scheme and call will reflect this accordingly and the correct options should be chosen. These will be obvious and reflect what is being applied for. If you are unsure, please contact the MRC for guidance.

When applying to any of the four MRC Research Boards, applicants have two calls to select from, 'New Investigator Research Grant (NIRG)' and 'Research Boards Submissions'. It should be noted that the 'New Investigator' grant is aimed at researchers who are capable of becoming independent Principal Investigators and who are ready to take the next step towards that goal. For further information regarding New Investigator eligibility please see the *MRC website*.

MRC also require applicants to indicate the type of grant they are submitting for consideration. This selection is indicated within the 'Grant Type' section of the Je-S form. Applicants will then select the most appropriate 'Grant Type' option available from the list of selections.

New Investigators applying to the NIRG call complete the 'Grant Type' section by selecting and saving the 'New Investigator Research Grant' option.

MRC applicants applying to the Research Boards (+ Month + Year) Submissions call, select the most appropriate grant type option applicable to their application:

- Centre grant
- Methodology research panel
- Partnership grant
- Programme grant
- Research grant

If the incorrect grant type is chosen, MRC will return the application to the applicant for amendment. For further information in regards to the above Grant Types please refer to "*How we fund research*" Applicants from MRC Units and Institutes may not apply for Centre and Programme grant types.

Applicants considering the submission of either a Programme or Partnership Grant, should note the additional requirement to contact MRC at least 6 weeks before the submission deadline, to discuss their application. This contact will allow MRC to ensure the application fits the scheme requirements. For further information, please see the MRC website:

Programme Grant
Partnership Grant

1.7.3 Who can submit

Please note that when an application is submitted through Je-S it does not pass directly to the MRC, but to the Research Councils Grants Team who will then process the submission for the MRC.

The submission process (and therefore which Research Organisations are eligible to submit funding proposals), can vary depending on the specific eligibility requirements of an individual MRC funding opportunity (call). Where call specific guidance has not been provided by MRC applicants should follow the below guidance within this section.

All applications need to be submitted through the lead RO which in turn must be Je-S registered. Further information and guidance is available on the *Je-S help pages* (please use the 'show' link in the top left corner of the screen).

Technical information on accessing and navigating Je-S is available through the Je-S help pages (please use the 'show' link in the top left corner of the screen).

All applicants should consult the team responsible (e.g. Research Office), for proposal submissions at their RO, to confirm how much time they will need to process the application and complete the final submission process. All applications must be submitted to the MRC via the Research Council Je-S system by 4pm on the advertised closing date.

Applications received after the advertised *deadline* will not be considered.

2. The Application

2.1 The proposal form

The proposal form provides a summary of the whole project.

The main headings include the following (further guidance is available through the Je-S help text provided for each section):

Heading	Information required
Organisation where the grant should be held	This should be the lead RO responsible for administering the grant.
Project title	This should be no more than 150 characters and reflect the aim of the project.
Start date and duration	The anticipated start date should be realistic and would normally be between one month and six months after the date of the decision-making board or panel. Please refer to call guidance as this may vary. The duration of a grant will typically be from 12 to 60 months. It should reflect the work to be undertaken and may be, restricted/specified in the call/scheme guidance. Once a grant has been issued, grant holders are required to make every effort to start on the agreed date. The start of the grant may be delayed by up to 3 months from the start date shown in the offer letter, the duration of the grant remaining unchanged. The grant may lapse if it is not started within this period.
Applicants	This should include the PI and all CoIs involved in the project.
Objectives	What is the project aiming to achieve? The objectives of the proposed project should be listed in order of priority and should be those that the investigators would wish the MRC to use as the basis for evaluation of work upon completion of any grant awarded.
Summary*	A plain English (layman's) summary of the proposed work, explaining: <ul style="list-style-type: none"> • The context of the aims and objectives of the research • The potential applications and benefits

Official Development Assistance (ODA) transparency and reporting

As part of the government's commitment to ODA transparency and in line with DfID ODA reporting requirements, UKRI is responsible for publishing information about UKRI ODA grants including project titles and summaries via the International Aid Transparency Initiative (IATI) registry and via DfID's national statistics. The purpose of publishing information via the IATI registry is to make information about ODA easily accessible to governments, stakeholders and other relevant groups in beneficiary countries. All UKRI funded projects from this programme will be published in this way. Please therefore write your project title and summary in such a way that they are meaningful and accessible to non-specialist audiences, following publication. We would be grateful if you would ensure that the project title and summary are written in plain English and avoid the use of jargon, acronyms, puns and plays on words.

Please also make clear in your project title and summary how your project is ODA compliant, for example by identifying the development challenge(s) being addressed, the aims of the project and the beneficiary countries.

Technical summary*	A more in-depth summary aimed at reviewers who have some knowledge of the area of science involved.
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Academic beneficiaries	How will the research benefit other researchers in the field? Identify whether there are any academic beneficiaries in other disciplines and if so, how they will benefit? What will be done to ensure they benefit?
Communication plan	This should include potential impacts for academic and non-academic users. The MRC attaches great importance to the communication of research findings both within and beyond the academic community.
Summary of resources required for the project	Staffing, equipment and other resources required to carry out the project.
Other Support	Support on current projects from other sources. Applicants will often be already holding grants from the MRC and other funding bodies for research related to the topic for which new funds are being sought. Applicants must declare any relevant financial support which has been awarded or applied for. This should also include any funding that has been obtained or requested for any aspect of the project currently being applied for within the same research field during the past three years.
Technical and ethical considerations	Please complete each of these sections with the required information by ticking the appropriate boxes.

* These summaries, including your name and institution, will be published on publicly available sites should the project be funded. Please ensure confidential information is not included in these summaries. If you do include information on the use of animals, please be aware that this information will be freely available to all external users.

2.2 Attachments

All full applications require a completed proposal form accompanied by a number of mandatory attachments. Attachments must conform to the following requirements:

- All attachments must be completed in a sans-serif typeface (Arial or equivalent, not Arial Narrow) and font size of 11pt, excluding text on diagrams and the use of mathematical symbols.
- A minimum of single line spacing and standard character spacing must be used.
- Margins must not be less than 2cm.

Failure to provide required components or information may mean that your proposal will be delayed and/or returned, or its assessment prejudiced.

Applications will be checked soon after the closing date. Any component(s) of an application which do not meet these rules will be returned for amendment before being validated for peer review. A late response in amending returned elements of the application will result in the application being withdrawn from the round.

When uploading PDF documents, please ensure they are given a logical file name and description so that information can be found easily. Also ensure that all pages of each document are numbered.

Mandatory attachments	Conditions
CVs*	A maximum of two sides of A4
Publications	One side of A4 per named person
Case for support	Length varies, see <i>case for support</i> table for more information
Justification of resources	A maximum of two sides of A4
Data management plan	Length varies, see <i>section 2.2.8</i> for more information

*For New Investigator Research Grants the NIRG CV and Salary Template must be used

In addition each call may specify additional attached components, which will be specified on the call guidance.

Additional attachments	Conditions
Covering letter	A maximum of two sides of A4 using a sans-serif typeface (Arial or equivalent) and font size of 11pt
MICA form	For more information see <i>MRC Industry Collaboration Agreement (MICA)</i>
Heads of terms	For more information see <i>MRC Industry Collaboration Agreement (MICA)</i>
Schedule of Events Cost Attribution Template (SoECAT)	Upload as 'letter of support' For more information see <i>section 3.5.1 Excess Treatment Costs of Studies Involving Human Participants</i>
Letters of support	A maximum of two sides of A4 or equivalent on headed paper or sent by email
Technical Assessment	A maximum of two sides of A4 For more information see <i>section 2.3 Research Council facilities</i>

Final/Interim Report	Programme Grant renewals only. For more information see <i>Programme Grant renewals: additional requirements</i>
Gantt Chart/Work Plan	A maximum of one side of A4 Only allowed as a separate attachment on certain calls eg DPFS.
Additional questions on the use of animals overseas	A maximum of two sides of A4 See <i>section 4.4.7</i> .

All outline applications should only include:

- Outline proposal form
- Case for support
- CVs and publications
- Any additional attachments that are requested in the specific guidance for the relevant call

2.2.1 CVs

Please note that CVs and publications should be uploaded as separate attachments.

CVs should be a maximum of two sides of A4. The CV should cover:

- Employment history:
 - A description of your current post and the source(s) of funding for this post (including dates)
 - List and description of previous posts (including dates)
 - Educational qualifications (including dates)
- Please also state whether you are:
 - Clinically qualified
 - Clinically active

The CV should only include information relevant to the application. Unnecessary personal data (eg home address, date of birth, personal phone numbers and emails) should NOT be included.

The CV should explain any breaks in employment or publication record, for example as a result of a career break or parental leave. The MRC is committed to eliminating unjustified discrimination and promoting equal opportunities as detailed in our *equality and diversity policy*.

For New Investigator Research Grants the NIRG CV and Salary Template must be used.

When attaching multiple CVs to an application, please include separate CVs and list of publications for each of the following:

- Principal Investigators
- Co-Investigators
- Named individual research staff

2.2.2 Publications

Please note that CVs and publications should be uploaded as separate attachments.

The publications list should highlight relevant and recent publications and should be a maximum of one side of A4.

The MRC welcomes the inclusion of preprints in publication lists. For more information please see '*MRC supports preprints*'.

As part of our commitment to support the recommendations and principles set out by the San Francisco Declaration on Research Assessment (DORA; <https://sfdora.org/read/>), UKRI reviewers and panel members are advised not to use journal-based metrics, such as journal impact factors, as a surrogate measure of the quality of individual research articles, to assess an investigator's contributions, or to make funding decisions.

The content of a paper is more important than publication metrics, or the identity of the journal, in which it was published, especially for early-stage researchers. Peer review and panel members are encouraged to consider the value and impact of all research outputs (including datasets, software, inventions, patents, preprints, other commercial activities, etc.) in addition to research publications. We advise our peer reviewers and panel members to consider a broad range of impact measures including qualitative indicators of research impact, such as influence on policy and practice.

More information on peer review at the MRC can be found on our *Peer review webpages*.

2.2.3 Case for support

2.2.3.1 General guidance

The case for support should be a self-contained description of the proposed work with relevant background and should not depend on additional information. MRC reserves the right to withdraw proposals that contain links to additional information which extends the case for support.

Please note justification of resources is not required in the case for support. This is a separate document which should be attached to each Je-S application.

The contents of the case for support will depend on the specific funding scheme. The guidelines below list general points that should be addressed when writing the case for support. There is additional guidance for *Programme* and *Partnership* grants. However, each proposal is unique, and it is the responsibility of the applicant to ensure that all the reasonable questions that the reviewers and MRC research boards need to address are answered in the proposal – especially if the plan or resources are unusual or complex.

The scientific case should be set out under each of the headings specified in the guidance notes for the specific funding scheme.

This guidance should be read in conjunction with the information on the assessment criteria, which provides detailed information on what reviewers, boards and panels are looking for. All information that the applicant wishes to be considered as part of their research proposal (within the page limits stipulated) must be attached with their proposal form. **The proposal cannot be supplemented by further information beyond the deadline for submissions.**

The proposal and case for support will be sent out to a number of reviewers to read. Feedback from reviewers has shown that they are keen to see clarity, succinctness and accessibility.

Proposals which do not meet the following requirements will be returned unprocessed, for submission to a subsequent board meeting:

- Use sans-serif typeface (Arial or equivalent), font size of 11pt (this includes any references listed within the case for support) and margins of 2cm on all sides.
- Only include one PDF document for the case for support, which must be within the page limits stipulated below.
- The only acceptable annexes are:
 - Reproducibility and statistical design (see section 2.2.3.4)
 - Progress report on previous MRC grants where applicants are MRC staff

Limited additional annexes may be allowed **in exceptional circumstances** for proposals addressing large population studies, including clinical trials.

Proposals containing additional annexes which have not been previously discussed with the relevant Programme Manager will be rejected.

- Any unpublished data must be included in the case for support. For applications submitted to closing dates on or after 1 April 2017 preprints may be included in publication lists. Manuscripts in press or submitted to journals should not be included.

2.2.3.2 Page length

Each scheme has its own limits on the number of pages in the case for support. In the case of specific call for proposals, you must adhere to the specific call guidelines produced.

Your proposal will be returned if you submit a proposal over the maximum page limit.

Page limits in case for support PDF documents:

Scheme	Page limit
Centre grant – outline	Eight
Centre grant – full	Size will reflect the complexity of the grant – please refer to the relevant programme manager for further guidance
Developmental Pathway Funding Scheme – outline and full	N/A – Please refer to the <i>Case for Support Form</i> for details of the character limits
Global health – outline and full	Please refer to the call guidance for details
New investigator research grant award	Eight
Partnership grant – three years or less	Eight
Partnership Grant – more than three years or involves large facilities	Twelve
Programme grant – full	Twelve
Research grant – three years or less	Eight
Research grant – more than three years	Twelve

These page limits include references, but not allowable annexes.

2.2.3.3 Case for support content

- The case for support must not exceed 10MB. All other attachment types have a 5MB size limit. Avoid the use of large colour figures as these will increase file size. There is no guarantee that documents will be reproduced in colour for the peer review process.

- UKRI also requires information on public engagement in science. Applications involving Public Engagement should complete the Proposal Classifications section of the Je-S application proforma, indicating the Project Engagement by sector, applicable to their project:
 - Academic Users
 - Business Sector
 - Central and Local Government
 - General Public
 - NHS Health Prof & Social Serv
 - Other Public Sector
 - Press and Media
 - Professional/Statutory Bodies
 - Student Teachers & Undergrads
 - Third Sector
 -
- Please attach as a PDF document, especially if mathematical symbols are used in the content.

Please note that specific areas need to be covered in the case for support for Programme Grants and Partnership Grants. Please see our *guidance on Programme Grants and Partnership Grants* for more information.

Title	The title of of the proposed project
Importance	<p>Explain the need for research in this area, and the rationale for the particular lines of research planned.</p> <ul style="list-style-type: none"> Justify the research, either through its importance for human health, or its contribution to relevant areas of basic biomedical science. Give sufficient details of other past and current research to show that the aims are scientifically justified, and to show that the work will add distinct value to what is already known, or in progress. Where relevant, explain how plans benefit, fulfill unmet needs or contribute to current plans in the health service or industry. Where the research plans involve creating resources or facilities, or forming consortia, networks or centres of excellence, the case will need to address the potential added value, as well as issues of ownership, direction and sustainability.
Scientific potential	<p><i>People and track record</i></p> <ul style="list-style-type: none"> Each of the CVs will be uploaded separately as attachments in Je-S. If it is not obvious, the applicant may elaborate on why the group is well qualified to do this research in the case for support. Explain how each of the investigators named in the proposal will work together and outline other major collaborations important for the research. The applicant should acknowledge any previous or current MRC funding and describe progress-to-date on delivery of this research. The quality and productivity of the recent work will be a factor in assessing the likely quality of future work eg for applications involving a clinical trial, the track record of the applicant(s) in registering and publishing previous trials will be considered before making further awards. If the applicant has not been active in research recently, simply state this. Describe any other factors which the applicant considers may promote delivery of the proposal. <p><i>Environment</i></p> <ul style="list-style-type: none"> Describe how the scientific or clinical environment(s) in which the research will be done will promote delivery of the proposed research. Explain how the research will benefit from facilities provided by the host RO. Describe any clinical, commercial, or organisational dependencies necessary to support the research, or to help translate it into practice. <p><i>Research plans</i></p> <ul style="list-style-type: none"> Give details of the general experimental approaches, study designs, and techniques that will be used (the one-page 'Reproducibility and statistical design' annex should be used to supplement information in this section, where necessary and as appropriate. See Section 2.2.3.4 for further details). It is not necessary to

	<p>describe each experiment, but give enough detail to show why the research is likely to be competitive in its field. For example:</p> <ul style="list-style-type: none"> ○ Highlight plans which are particularly original or unique ○ Describe all foreseeable human studies and animal experiments (in as much detail as possible at this stage) ○ Explain in greater detail how new techniques, or particularly difficult or risky studies, will be tackled, and alternative approaches should these fail ○ Identify facilities or resources you will need to access ○ Give sufficient detail to justify the resources requested <ul style="list-style-type: none"> ● If this is a pilot work or proof of principle proposal, give a brief description of likely subsequent proposals if the work is successful. Please note that any proposals that are intended to lead directly to a clinical trial must be discussed at an early stage with the relevant MRC programme manager ● Explain opportunities or plans for pursuing commercial exploitation
<p>Ethics and research governance</p>	<ul style="list-style-type: none"> ● Describe briefly the ethical issues arising from any involvement of people, human samples or personal data in the research proposal. Please give details of how any specific risks to human participants will be controlled, and of any new animal research the MRC would be supporting. Please refer to Ethics section for further guidance. ● Describe the ethical review and research governance arrangements that would apply to the work done. <p><u>Clinical Trials involving human subjects</u></p> <ul style="list-style-type: none"> ● Where a project involves a clinical trial involving human subjects the case for support should include plans to publish the project's findings and/or make them publicly available without unreasonable delay (usually within 12 months of trial completion). Applicants should also confirm that they will regularly update the clinical trials ISRCTN registry and provide a link to their protocol and main results. ●
<p>Exploitation and dissemination</p>	<ul style="list-style-type: none"> ● Is the proposed research likely to generate commercially exploitable results? ● What arrangements and experience does the research group or the host research organisation have to take forward the commercial exploitation of research in this area? ● Other than publication in peer reviewed journals, indicate how any results arising from the research will be disseminated so as to promote or facilitate take up by users in the health services.
<p>Project partners (see also section 2.2.7)</p>	<ul style="list-style-type: none"> ● All partner contributions, whether in cash or in-kind, should be explained in detail, including the equivalent value of any in-kind contributions ● In-kind contributions can include staff time, access to equipment, sites or facilities, the provision of data, software or materials.

- The financial value of the contribution should be included on the Je-S form. Where the input is important to the project but has no significant financial value, a nominal sum of £1 may be entered as the value of the contribution.

2.2.3.4 Impact

From 1 March 2020 applications will no longer require a Pathways to Impact attachment and Impact Statement. This change is designed to simplify bureaucracy at the point of application as well as to help streamline our systems for applicants. It also enables impact to be truly embedded throughout applications as appropriate.

The impact agenda remains incredibly important. UK Research and Innovation exists to fund the researchers who generate the knowledge that society needs, and the innovators who can turn this knowledge into public benefit. Impact remains a central consideration in how UKRI makes funding decisions. Applicants should still consider how they will or might achieve impact throughout their projects and include this as part of their Case for Support. Appropriate resources to facilitate this impact within applications should be requested. These should be justified in the Justification of Resources attachment

Academic impact:

The demonstrable contribution that excellent research makes to academic advances, across and within disciplines, including significant advances in understanding, methods, theory and application.

When applying for research council funding via Je-S, pathways towards academic impact are expected to be outlined in the academic beneficiaries and appropriate case for support sections. An exception to this is where academic impact forms part of the critical pathway to economic and societal impact.

Economic and societal impacts:

The demonstrable contribution that excellent research makes to society and the economy. Economic and societal impacts embrace the diverse ways in which research-related knowledge and skills benefit individuals, organisations and nations. These include:

- Fostering global economic performance, specifically the economic competitiveness of the United Kingdom
- Increasing the effectiveness of public services and policy
- Enhancing quality of life, health and creative output

Public engagement:

Public engagement is included within the above definitions. Engaging the public with your research can improve the quality of research and its impact, raise your profile, and develop your skills. It also enables members of the public to act as informed citizens and can inspire the next generation of researchers.

Well planned public engagement activities related to the research within the grant are encouraged. If public engagement activities are proposed the case for support should detail:

- which group(s) will be targeted
- how will they benefit
- How will activities be evaluated

2.2.3.5 Assessment

All applications to the MRC will continue to be assessed according to the following criteria:

1. Importance: how important are the questions, or gaps in knowledge, that are being addressed?
2. Scientific potential: what are the prospects for good scientific progress?
3. Resources requested: are the funds requested essential for the work, and do the importance and scientific potential justify funding on the scale requested?

As part of their assessment of the proposal, reviewers and board/panel members will be asked to consider the potential economic and societal impact of the proposed research, including:

- identification of realistic potential improvements to human or population health
- contribution to relieving disease/disability burden and/or improving quality of life
- identification of potential impacts of research and plans to deliver these

More information on MRC's assessment criteria can be found *here*.

2.2.3.6 Reproducibility and statistical design (recommended annex)

The purpose of this annex is to provide important additional information on reproducibility, and to explain the steps taken to ensure the reliability and robustness of the chosen methodology and experimental design. Please note in this context, methodology refers to the rationale for choosing which method to use and not the provision of detailed descriptions of the methods to be used.

It is **strongly advised** that a one-page annex to the case for support is included, in addition to the page limits in Section 2.2.3.2, to provide additional information specifically relating to the statistical analyses, methodology and experimental design aspects of the proposal (beyond that contained in the main case for support). Please note that you should not duplicate information presented elsewhere in the application.

This information must be provided as a clearly marked annex at the end of the main case for support, entitled 'Reproducibility and statistical design annex' and should not be added as a separate attachment. Standard formatting guidance applies. Applications not adhering to these conditions will be returned unprocessed.

Applications that do not provide sufficient detail to convince peer reviewers and Research Boards and Panels that the proposed experiments will be carried out appropriately to produce robust and reproducible research will be rejected for funding on these grounds and subject to the usual limits on resubmission.

To see worked examples of experimental design: <https://mrc.ukri.org/documents/pdf/worked-examples-experimental-design/>.

The NC3Rs have developed a free online tool to guide researchers through the design of their experiments, helping to ensure that they use the minimum number of animals consistent with their scientific objectives, methods to reduce subjective bias, and appropriate statistical analysis. The NC3R's Experimental Design Assistant can be found on the NC3R's

website. Applicants are encouraged to consider embedding the summary diagram of this tool, representing their experimental plan, into their one-page annex.

What to include in the annex

It is expected that professional statistical (or other relevant) advice would be sought in putting this section together. Each experiment does not need to be described in detail, but sufficient information must be included that reviewers are readily able to understand the experimental plan. Where appropriate, the use of figures, tables and/or diagrams is encouraged.

The following table highlights the key points you should include in the annex.

<p>Experimental approach to address objectives.</p> <p>This information may be provided in diagrammatic or tabular form if appropriate.</p>	<ul style="list-style-type: none"> • Primary and secondary experimental outcomes to be assessed (e.g. cell death, molecular markers, behaviour change) and how these relate to experimental objectives • Number of experimental and control groups • A clear definition of the 'experimental unit' in the analysis and the implications thereof (i.e. there is a difference between N samples from one animal, as distinct from one sample from each of N animals, or combining samples from multiple animals) • Number of 'experimental units' in each experimental group. • Total number of 'experimental units' to be measured • Number of times each 'experimental unit' will be measured • Number of independent replications of each experiment. • Steps taken to minimise the effects of bias (e.g. blinding, randomisation) or an explanation of why this would not be appropriate • Breeding strategies may be included here, if applicable.
<p>Justification of model(s) chosen (e.g. animal model, cell line etc.</p>	<ul style="list-style-type: none"> • How and why the models and/or methods are appropriate to address the scientific objectives
<p>Sample sizes</p>	<ul style="list-style-type: none"> • Show clearly how effect sizes have been calculated and justify how they are biologically relevant • Demonstrate that statistical power calculations are grounded in justifiable and explicit assumptions about both anticipated effect size and variability of the experimental effects • If statistical power calculations cannot reasonably be applied, applicants should provide a principled explanation of the choice of numbers • Explanations based solely in terms of 'usual practice' or with reference solely to previously published data will not be considered adequate.

Planned statistical analyses and their relation to the choice of sample size

- Overview of the planned statistical analyses in relation to the sample size
- Details of any statistical/methodological design advice sought (you may cost a relevant expert, e.g. statistician, into your proposal if necessary and justified). A letter of support from the expert involved is permitted, but not mandatory

If your proposal includes the use of animals, please also refer to Section 4.1.4., in addition to the guidance above, for more information on the key points you may wish to include in the annex.

What not to include in the annex

The annex should not be used as a simple continuation of the methods set out in the case for support; please do not include detailed descriptions of the methods. Applications misusing the annex in this way will be returned. The case for support should be a self-contained description of the proposed work with relevant background, and should not depend on additional information.

For proposals involving animal use, information on the rationale for using animals, choice of species, information about the animals used (e.g. weight, sex), animal costs and procedure severity information should be provided elsewhere in the application as detailed in the table at Section 4.1.8 for full details).

2.2.4 Justification of resources

Cross council guidance on writing a good justification of resources (JoR) document is available on the Je-S help pages.

The role of the JoR is to aid reviewers when assessing proposals so that they can make an informed judgment on whether the resources requested are appropriate for the research posed.

The JoR is a mandatory attachment to the proposal and should be no more than two sides of A4. It should take into account the nature and complexity of the research proposal. It should not simply be a list of the resources required (already defined in the Je-S form). All items requested in the Je-S form must be justified in the JoR.

The JoR is a free text document. We recommend that you match the costs to the proposal headings below (where appropriate) so that you do not miss any costings from the Je-S form or any justifications for the items requested.

Cost to the proposal	Justification needed	Questions to consider and answer in the justification
<p>Staff – directly incurred posts Researcher/technician</p>	<p>Justify why a researcher/technician is needed for the proposed work and why the proposed time input is appropriate.</p>	<p>Is the work of appropriate scientific technical difficulty to warrant employing a research assistant? Why has the level requested for the RA been asked for?</p>
<p>Staff – directly allocated posts Principal investigator (PI), co-investigator (Col) and research co-investigator time (unless working 100 per cent of their hours on the grant eg fellows)</p>	<p>Justify the time that the PI and Col spend on the grant. A PI or Col cannot request time for supervising postgraduate research students, writing publications after the end of the project, writing grant applications or peer review.</p>	<p>How much time do you intend to dedicate to the project? Will you be doing all the research yourself? What work packages are the PI and Cols involved with and why? Have you factored in enough time to work with project partners or visiting researchers and collaborators? Are you managing the staff on the project only?</p>
<p>Travel and subsistence</p>	<p>Give a full breakdown of the costs in the Je-S form. For example how many people are travelling, where are they going and why?</p>	<p>If you are planning to visit people to discuss your research, you should explain why those are the right people to talk to and how they can contribute to you meeting your objectives. If you plan to attend conferences, you should comment on the advantages of conference attendance. Give an indication of the number you want to attend during the grant, who will attend these and the type you want to go to eg national/international/general/subject-specific. We would expect funds to be requested for one UK/European conference per year, and one major international conference every other year (expecting 1 per 3-year grant and 2 per 5-year grant). Travel costs incurred when using facilities should be included where necessary.</p>
<p>Other directly incurred costs</p>	<p>Give a description of what has been requested and why?</p>	<p>Justify the need for any item requested. Explain what the item will be needed for and also justify the cost. For example if you are asking for a desktop and a laptop, then justify why both are needed. We expect that the university will provide computers and laptops for the PIs and Cols and other research staff on continuing contracts. You must provide a breakdown of any costs which are incurred for bulk items.</p>

Directly incurred equipment Impact	<p>Why is the item needed?</p> <p>Justify any resources requested to support realising impact . For example:</p> <ul style="list-style-type: none"> • staff time, travel and subsistence • consultancy fees 	<p>Why can the item not be used/borrowed from elsewhere</p> <p>Full justification (what it is and why you need it) of each item requested.</p> <p>Please note: patent costs and other IP costs are not eligible; Universities already receive funding for these from HEIF.</p> <p>Also estate and indirect costs should not be requested for Technology Transfer Officers (TTOs). These are project-specific resources.</p>
Other directly allocated costs	Justify the need for resources.	Explain what these are and why you need to use them. In some cases, such as internal facilities and shared costs, the basis of costing does not need to be justified.
Estates and indirect costs	Does not need to be justified.	Must not be included for technicians, research support staff, or staff employed at MRC units/ institutes
Research facilities (at research organisations)	Justify time only.	Explain what you are using the facility for and why you need to use this particular facility.
Pooled technicians	For example workshop or laboratory technicians based at the university. Usually not named.	We would expect these costs to be included in the estates/indirect costs for the RO. Where the technicians used are of a specialist nature and not included in the states/indirect costs for the RO, they should be fully justified in the JoR as to why they are required and why the costs are not included in the ROs estate/ indirect costs.
Infrastructure technicians	For example health and safety officer at university. Cost should be displayed separately to estate and indirect costs in the other directly allocated costs box.	Where the post is to fulfil a legal requirement, then the post does not need to be justified.
Exceptions eg PhD student	Justify why a PhD student is needed for the proposed work.	Will a student be skilled enough to tackle the research problems? Will it be feasible for them to produce a thesis? Costs for PhD studentships can only be requested on centre grants.
Exceptions	Please see Section 3.2.5	

2.2.5 Covering letter

A covering letter may be included as part of an application. It should be no more than two A4 pages using sans-serif typeface (Arial or equivalent) and font size of 11pt.

The covering letter can be used to cover details such as conflicts of interest and names of conflicted experts that you request not to be used as reviewers. If detailing conflicted experts, the following information must be provided in the covering letter:

1. The name of the person not to approach
2. The RO(s) they are based at
3. A clear reason why the person would not be able to provide an unbiased and evidence-based review

The decision on whether or not to honor a request to exclude a reviewer lies with the MRC following consideration of the justification provided. Requests submitted without a justification will not be considered.

If the application is a resubmission it should also include details of how this application differs from that submitted previously. It **must not** be used to cover anything which should be included in the proposal form, case for support or other required attachments.

2.2.6 Project partner letter of support

Each project partner must provide a project partner letter of support, a maximum of two sides of A4 (or equivalent) on headed paper or by email. The letter must be an integral part of the application and must focus on the proposal it accompanies. The individual named as contact for the project partner organisation cannot also be named as staff, for example co-investigator on the grant proposal.

Applicants should:

- Include the letter or email as an attachment to the grant on submission via Je-S. Please note that the Project Partner Letter of Support should only be added to the Project Partners section of the Je-S application form and should not be uploaded to the attachments section of the application as document/attachment type 'Letter of Support'.
- Draft the letter or email when the proposal is being prepared; it should be targeted specifically to the project and must therefore be dated within six months of the date of submission of the proposal.
- Get the letter or email signed by the named contact, stating the capacity in which they are providing the sign off to provide assurance that the project partner has authorised the proposed contribution or commitment (project partner letters of support that merely indicate that an organisation is interested in the research are not permitted).

A well written project partner letter of support will confirm the organisation's commitment to the proposed project by articulating the benefits of the collaboration, its relevance and potential impact. The project partner letter or email should also identify:

- The value, relevance and possible benefits of the proposed work to the partner
- One or more names of key experts / investigators

- Where relevant to the project, details should be provided of the projected market size, customer sales and how the organisation will commercialise the technology beyond the project.
- The period of support
- The full nature of the collaboration/support. Project partner contributions, whether in cash or in-kind, should be explained in detail in the case for support (see section 2.2.3). Detail of how this support relates to the proposal as a whole should be included in the case for support.
- How the partner will provide added value.

The project partners should not submit any other ordinary letters of support unless in exceptional cases and where this has been agreed to with the research council. The research councils reserve the right to remove all other letters of support from the proposal. Applicants should refer to the research council or call guidance for additional information regarding acceptable letters of support.

Additional information requirements where human tissue/participants are being provided

Where the project partner (whether an individual or organisation) is responsible for recruitment of people as research participants and/or providing human tissue, list them as a project partner on the proposal form and enter a nominal sum of £1 for the value of the contribution. Details should be included in the case for support. A letter of support must be attached to the application and include the following information:

- Agreement that the project partner will recruit the participants/provide tissue
- That what is being supplied is suitable for the research being undertaken
- That the quantity of tissue (where relevant) being supplied is suitable, but not excessive for achieving meaningful results

2.2.7 Data management plans (DMP)

All applicants submitting funding proposals (research and fellowship grants) to the MRC must include a data management plan (DMP) as an attachment to their application on Je-S. This includes applications for the renewal of existing funding. The DMP should comply with the MRC's policy on research data sharing. MRC institutes and units are required to submit a DMP as part of the Quinquennial Review (QQR) report.

The DMP should demonstrate how the PI will meet, or already meets, their responsibilities for research data quality, sharing and security. It should refer to any institutional and study data policies, systems and procedures and be regularly reviewed throughout the research cycle. Where the organisation is ISO 27001 compliant, the registration number should also be included.

The DMP is reviewed by peer reviewers alongside the case for support. It is advisable that all DMPs use the *template* to ensure consistency and make it easier to review. Carefully read and adhere to guidance; the quality of the DMP may have an impact on peer review and whether the application proceeds to board/panel.

For **population and patient-based studies** the DMP should indicate how the study meets the requirements of the MRC's detailed guidance on data sharing for population and patient

studies, particularly around access criteria and independent oversight (the means for ensuring the study and its variables are readily discoverable) and specifically about use of formal data standards.

For **intervention studies involving human participants** (such as clinical trials, clinical intervention studies, and studies of public health or behavioural interventions) the DMP should indicate how the study meets the requirements of the MRC’s policy on Open Research Data: clinical trials and public health interventions (2016), which include

- Registration in the ISRCTN registry within 12 months of the trial starting
- Addition of the trial protocol (or a link to it) to the ISRCTN registry within 12 months of the trial starting,
- Timely public reporting or publication of trial results within 24 months of study completion,
- Preparing data for sharing or re-use.

Partnership grants reliant on sharing and/or reusing research data must include a brief summary of how access to existing data will be managed and how newly generated data will be accessed and preserved throughout the duration of the award.

For **MRC institutes and units** a DMP is developed as part of the Quinquennial Review (QQR) report (directors may choose to develop more than one DMP, specific to particular programmes).

Level of risk

Where the research involves human participants, their data or tissues or where the research team holds identifiable data about these research participants, the level of risk regarding data management is much higher. In these instances, the DMP should be more detailed and include information on how these risks will be managed.

Length of data management plan

Type of study	Page length
Population cohorts, genetic, omics and imaging data, biobanks, and other collections that are potentially a rich resource for the wider research community.	Up to three A4 pages
Longitudinal studies, involving a series of data collections	Up to four A4 pages (unless agreed otherwise with the MRC prior to submitting the application)
All other research	For less complex research the DMP may be as short as quarter of a page up to a maximum of 3 x A4 pages

How should it be written?

The DMP should be written for two audiences: (a) scientists in the broad field of the area of science covered in the application; and (b) technical experts who are familiar with the prevailing data management practices. Most of the readers will be of type (a).

The information must be concise. The detail should be proportionate to the complexity of the study, the types of data being managed, their anticipated long-term value, and the anticipated data security requirements.

What to include

The DMP template should be used to develop a plan to accompany a research proposal. If you do use the template, ensure to address all the topics listed on the template.

For studies with a history of active data sharing, the DMP should include brief summary statistics on the performance and outputs of sharing (*see section on reporting on data sharing*)

We expect you to seek advice from data management experts in your organisation and use other sources of good practice to improve and innovate data management. If this means your DMP departs from some aspect of this guidance (or that on data sharing), explain succinctly why and how this is more appropriate. It will aid your DMP if you can show that the infrastructure and good practice is already in place at your RO.

Custodians of previously collected/generated research data ('legacy data'), applying for funds to use legacy data as part of a new funding request, should ensure that the DMP covers both existing and new data collection/generation.

Multiple funding agencies

Where research is co-funded between the MRC and another organisation, our data sharing policy and these guidelines on the DMP will still apply. The relevant policies of the major UK funders of biomedical research are aligned on principles and most of their detailed requirements. Any apparent conflict in co-policies should be discussed with your programme manager, or by emailing corporate@mrc.ukri.org

Cost of data sharing

You should include the costs related to your data sharing in the resources section of the proposal form. This may include people, equipment, infrastructure and tools to manage, store, analyse and provide access to data.

Where the costs of managing legacy data and sharing are substantial, the proposal should differentiate the resources and funding for the following activities:

- Collecting and 'cleaning' new data
- Own research on newly-acquired and legacy data
- Ongoing data curation and preservation
- Providing access and data sharing

2.2.8 Additional requirements for New Investigator Research Grants

2.2.8.1 Statement of support

A signed statement of support (maximum of 2 sides of A4) from a senior authority within the host RO on headed paper should be attached to all NIRG applications. For more information please refer to our guidance on *NIRGs*.

It will be important for the proposed host organisation to demonstrate its commitment to the applicant as a potential future PI. The suitability of the environment and the organisation's commitment are significant factors in the Boards' consideration of NIRG proposals.

2.2.8.2 Declaration

All NIRG proposals must also include a declaration that the applicant has originated the research question and written the research proposal. This should be in the form of a letter to be uploaded separately as a 'Letter of Support'.

2.2.9 Additional requirements for GCRF and Newton Fund calls

2.2.9.1 Gender Equality Statement

It is mandatory for all applications to GCRF and Newton Fund calls/competitions announced and published after the 1st April 2019 to provide a Gender Equality Statement. This statement must outline how applicants have taken meaningful yet proportionate consideration as to how the project will contribute to reducing gender inequalities, as required under the International Development (Gender Equality) Act.

This should be no longer than one page, and should be attached as a 'non-UK Component' through Je-S.

It is expected that some projects will have less impact on gender and gender relations and professional judgement of the applicants should be exercised to ensure appropriate consideration of the context and intended aims of the project. Applicants are able to reference other parts of your application within this statement, if relevant. Applicants are required to address the below criteria, with an understanding that, depending on the nature of their research and innovation, not all questions will be applicable.

Criteria to address while considering gender impact:

- Have measures been put in place to ensure equal and meaningful opportunities for people of different genders to be involved throughout the project? This includes the development of the project, the participants of the research and innovation and the beneficiaries of the research and innovation.
- The expected impact of the project (benefits and losses) on people of different genders, both throughout the project and beyond.
- The impact on the relations between people of different genders and people of the same gender. For example, changing roles and responsibilities in households, society, economy, politics, power, etc.
- How will any risks and unintended negative consequences on gender equality be avoided or mitigated against, and monitored?
- Are there any relevant outcomes and outputs being measured, with data disaggregated by age and gender (where disclosed)?

Please refer to the *UKRI Gender Equality Statement Guidance*.

2.3 Research Council Facilities

Should they be required as part of the research project, applicants can choose one of two Research Council national facilities.

- *Ion Beam Centre - University of Surrey - Guildford*
- *The UK 850 MHz Solid-State NMR Facility at Warwick*

If you are planning to use a national research council facility as part of the proposed research, you'll be asked to provide a technical assessment from the service provider. You are required to contact the facility before applying to the MRC to check if your proposed research is feasible and obtain a technical assessment which needs to be attached to the application.

When you have completed the 'Research Council Facilities' section of the Je-S form and added either of the above detailed two facilities, you will then be required to attach the 'Technical Assessment' form completed by the service provider.

Please note that the 'Technical Assessment' attachment type is added via the attachments section of the Je-S application. This attachment type is only made available to select following the addition of either NMR Facility or Ion Beams Centre to the Je-S form.

The technical assessment is required to detail the outline discussions that have taken place with the research facility, to ensure the facility will be available to you at the required time. Please also confirm the start and end date of use of the facility, support requirements and a brief summary of the facilities use and importance of their use for the project. Please include any other information you consider relevant.

Please ensure the technical assessment attachment does not exceed a maximum of two pages.

2.4 Application checking - common reasons for returning applications to research offices

- Attachments over permitted page length (eg CV, publication list, Case for Support, Justification of Resources)
- CV and publications uploaded as one attachment
- Missing CV for researcher named on grant
- Letter of support not dated
- Letter of support not signed
- Letter of support for human tissue use not provided (see *Ethics and approvals section*)
- Publishing/open access cost requested
- Equipment costs requested at 100 per cent with no justification
- Equipment broken down into component parts to avoid £10K limit
- Unauthorised attachments (eg Gantt chart in separate document rather than in case for support)
- Track changes on document
- Insufficient animal use justification
- NIRG RO letter of support does not include salary details
- NIRG CV not on template
- MICA Heads of Terms or MICA Form missing

2.5 Peer review

When the application is received, it will be peer reviewed by independent scientific experts from the UK and overseas.

UKRI recognises that the COVID-19 pandemic has caused major interruptions and disruptions across our communities and are committed to ensuring that individual applicants and their wider team, including partners and networks, are not penalised for any disruption to their career(s) such as breaks and delays, disruptive working patterns and conditions, the loss of on-going work, and role changes that may have been caused by the pandemic.

Reviewers and panel members will be advised to consider the unequal impacts of the impact that COVID-19 related disruption might have had on the track record and career development of those individuals included in the proposal and will be asked to consider the capability of the applicant and their wider team to deliver the research they are proposing. Where disruptions have occurred applicants can highlight this within their application, if they

wish, but there is no requirement to detail the specific circumstances that caused the disruption

More information on *Peer review at the MRC* can be found on our *Peer review webpages*.

2.5.1 Nominating peer reviewers

Applicants can nominate up to 3 independent reviewers whom MRC may approach for assessment of the research proposal.

Please note only one of the three nominated reviewers will be approached and we may decide not to approach any of the applicant's nominated reviewers.

- Nominated reviewers must be experts in the research field and/or be able to provide an expert view on the value and benefits of the research proposal.
- Investigators shall not provide reviewers from their own organisation, or from current or proposed project co-funders, or where any possible conflict of interest may arise.
- International reviewers can be included.

Please note the MRC considers possible conflicts of interest when selecting experts to review a proposal. Reviewers are asked to identify any possible conflicts of interest before they begin reviewing a proposal and to decline to review a proposal if there are any. The MRC treat any such disclosures appropriately and fairly. The covering letter can be used to name conflicted experts that you request not to be used as reviewers (see section 2.2.6).

2.5.2 Applicants' response to reviewers' comments

When a **research grant** application has been short listed for a Board Meeting, Principal Investigators have up to 3 pages (A4) within which to respond to the comments given by the reviewers.

When a **programme grant** application has been shortlisted for a Board Meeting, Principal Investigators have up to 4 pages (A4) within which to respond to the comments given by the reviewers.

- The response should be clearly presented, concise and should not exceed three pages, irrespective of the number of reviews / additional points made by the triage/shortlisting panel that applicants should respond to (eg with reference to experimental design). Additional page(s) will only be granted if the triage panel have requested eg a Gantt chart, flow chart, diagram that requires additional space.
- Use an A4 format with Arial typeface and a minimum font size of 11pt.
- The response is to all reviews received. A subsequent response to any late reviews must also retain response text on all earlier reviews and not exceed the specified page format.

- If the response needs to be amended e.g. because of further later peer review comments, the existing copy will need to be removed and a new version uploaded.

You may like to read our blog post on “10 expert tips for responding to peer review comments”. 3. Resources

Research proposals will be assessed on the quality of the research and value for money in terms of the resources requested, including whether or not the funds requested are essential and adequate for the work and justified by the importance and scientific potential of the research. For more information on assessment criteria please see *our Guidance for Peer Reviewers*.

Costs sought should be specified as far as possible in the research proposal. As a general principle, any cost or activity that can be directly attributed to the research project that is being undertaken is considered to be an allowable cost, so long as it is fully justified. Information on justification of resources can be found in Section 2.2.4.

UKRI acknowledges that it is a challenge for applicants to determine the future impacts of COVID-19 while the pandemic continues to evolve. Applications should be based on the information available at the point of submission and, if applicable, the known application specific impacts of COVID-19 should be accounted for. Where known impacts have occurred, these should be highlighted in the application, including the assumptions/information at the point of submission. There is no need to include contingency plans for the potential impacts of COVID-19. Requests for travel both domestically and internationally can be included in accordance to the relevant scheme guidelines, noting the above advice.

Reviewers will receive instructions to assume that changes that arise from the COVID-19 pandemic, post-submission, will be resolved and complications related to COVID-19 should not affect their scores.

Where an application is successful, any changes in circumstances that affect the proposal will be managed as a post-award issue

3.1 Full economic cost/Transparent approach to costing

All grants and fellowships (except pre-doctoral *Clinical Research Training Fellowships*) should be costed on the basis of the full economic costs (FEC) necessary to deliver the research. If a grant is awarded, the MRC will typically fund 80 per cent of the FEC and the RO(s) must agree to find the balance of FEC from other resources. Some awards are made at different FEC rates e.g. global health. Applicants should refer to the specific call guidance for further information.

Universities and other HEIs will use transparent approach to costing (TRAC) methodology to calculate FEC. Dispensation rates can be used by those ROs who do not comply with TRAC. More information can be found *here*.

3.2 Fund types

Under FEC, costs must be presented within four fund types in the Je-S proposal form (see *section 1.7.1 on using Je-S*). The fund heading and type will depend on the nature of the cost incurred.

Fund type	Fund headings	Examples
<p>Directly Incurred (DI): Costs that are explicitly identifiable as arising from the conduct of a project.</p> <p>Charged to projects as the cash value actually spent and supported by an auditable record.</p>	<ul style="list-style-type: none"> • DI - Staff • DI - Travel & Subsistence • DI - Equipment • DI - Other Costs 	<ul style="list-style-type: none"> • Salary of any member of the research team (eg PI, Col, postdocs, technicians, statisticians, technologists, methodologists etc.) working 100% of their time on this project or where their time is supported by a full audit trail • Consumables (includes small items of equipment costing <£10k inc VAT) • Consultancy fees • Subcontractor costs • Recruitment costs • Equipment specific to the project (>£10k inc VAT) • Costs for registering a trial in the ISRCTN registry
<p>Directly Allocated (DA): Costs of resources used by a project that are shared by other activities.</p> <p>Charged to projects on the basis of estimates. Do not represent directly auditable costs on a project-by-project basis.</p>	<ul style="list-style-type: none"> • DA - Investigators • DA - Estates Costs • DA- Other Directly Allocated (includes pool staff, infrastructure technicians and other staff) 	<ul style="list-style-type: none"> • Salary of PI and Cols if they are working on several projects and activities • Salary of postdocs, technicians, statisticians, technologists, methodologists working within core facilities and shared with other activities (when not included within the ROs estates or indirect cost rates) • Facility usage costs • Estates costs (set rate agreed for each RO)
<p>Indirect Costs: RO overhead costs</p>	<p>Indirect Costs</p>	<p>Costs of the RO's administration such as staff, finance, library and some departmental services (set rate agreed for each RO).</p>
<p>Exceptions: Costs that would normally come within the Directly Incurred heading but the Research Council will fund at 100 per cent of FEC.</p>	<ul style="list-style-type: none"> • Exception - Staff • Exception - Travel & Subsistence • Exception - Other Costs 	<ul style="list-style-type: none"> • Costs incurred by overseas organisations, including salary costs and contribution towards indirect and estates costs where the research is being undertaken in a developing country

		<ul style="list-style-type: none">• Costs directly incurred by an MRC institute (see section 3.8 for more information)• Studentships on centre grants• Externally contracted Gene sequencing (see 3.2.2.3 for more information)• Externally contracted social surveys• Biomedical Catalyst calls only: certain costs in excess of £50,000 for sub-contracts with contract ROs (see Section 3.6 for more information)
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Costs that are NOT eligible include:

- Publication costs (see section 3.7 Open access publishing)
- Computers can be requested but we expect that the university will provide computers and laptops for research staff on continuing contracts (including PIs and CoIs).
- Patent costs and other IP costs are not eligible as universities already receive funding for these from Higher Education Innovation Funding.

3.2.1 Research staff costs

MRC encourages and supports collaborative research projects and team approaches. Salaries may be sought for any member of staff who will be involved in delivering the aims and objectives of the proposed research. This may include postdocs, research fellows, research assistants, research nurses, technicians, statisticians, technologists, methodologists etc. (this list is not exhaustive).

The costs associated with the different members of the research team may appear as a Directly Incurred (DI) or Directly Allocated (DA) cost depending on their contribution to the project. There is no limit on the number of research staff included in a project as this will depend on the nature of the research being undertaken. However, applications will be assessed on the basis that the number of staff and their stated time commitment to the work is appropriate and sufficient. See section below on '**Researcher salary costs charged to the project**'.

Researchers should be included under the DI heading if the costs are actual, auditable and verifiable eg a researcher will dedicate 100% of time to the project. Where a researcher will not work 100% of their time on one project they can still be included under the DI heading but their time needs to be supported by a full audit trail eg timesheets or project records.

Researchers should be included under the DA heading if the time spent on the project is estimated eg a researcher working on several projects and activities.

The Je-S proposal form allows research staff to be included in 3 different sections. The table below shows where and how different team members should be included.

Section of Je-S proposal form	Role	Fund type
Investigator	Principal Investigator	DI if spending 100% of their time on this project OR if actual time known and supported by a full audit trail eg timesheets or project records. DA if the time spent on the project is estimated and will not be supported by an auditable record. Please note that although a PI can claim 100% of their time on one research project PIs would normally spread their time across several projects and other academic/clinical/administrative duties.
	Co-Investigator	DI if spending 100% of their time on this project OR if actual time known and supported by a full audit trail eg timesheets or project records.

		<p>DA if the time spent on the project is estimated and will not be supported by an auditable record.</p> <p>Exceptions if based overseas.</p>
Staff	<p>Researcher</p> <p>This category can include any member of the project team that is not PI or Col eg postdocs, research fellows, research assistants, research nurses, technicians, statisticians, technologists, methodologists etc. (this list is not exhaustive).</p>	<p>DI if spending 100% of their time on this project OR if actual time known and supported by a full audit trail eg timesheets or project records</p> <p>DA if the time spent on the project is estimated and will not be supported by an auditable record</p> <p>Exceptions if based overseas</p>
	<p>Technician*</p> <p>Can either be part of a pool of technician effort (should be included as cost/hour) OR specific (named or unnamed) technician post</p>	<p>Only where NOT included within estates or indirect cost rates:</p> <p>DI if spending 100% of their time on this project OR if actual time known and supported by a full audit trail eg timesheets or project records</p> <p>DA if the time spent on the project is estimated and will not be supported by an auditable record</p>
	<p>Other staff</p>	
Other Directly Allocated Costs	<p>Pool staff</p> <p>Pooled staff effort is usually taken to mean access to staff effort where the specific individuals/posts work on several projects or activities</p>	<p>Only where NOT included within estates or indirect cost rates</p> <p>DI if timesheets are in use</p> <p>DA if the time spent on the project is estimated and will not be supported by an auditable record</p>
	<p>Infrastructure technicians</p>	<p>If the institution uses calculated infrastructure technician rates (separate from estate rates), they should be added to the proposal in the same way as estates and indirect rates, which is as a standard rate/research FTE.</p>

	Other	
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* Not included in FTE multiplier for indirect and estates

Researcher time charged to the project: The maximum number of hours which may be charged to Research Council and other public-funded projects by researchers is 1,650 hours per annum (equivalent to 37.5 hours a week, 44 weeks a year). All staff information throughout the proposal should be entered using this formula when answering questions regarding percentage of time worked.

Proposals need to show the costs of time to be charged to the project by investigators (PI or CoI). This will be derived from hours on the project and relevant salary rate (which could be based on an average or pool rate). Investigator time, not cost, must be justified in the proposal.

It is the responsibility of the RO to have a process in place to monitor the time claimed by any researcher to ensure that no more than the maximum amount of time is claimed over all grants in which that individual is involved. They should also ensure that estates costs for any individual do not exceed 100 per cent FTE across all grants by all Research Councils.

Research Council grant terms and conditions allows researchers employed on grants 6 hours per week for teaching and demonstrating work. MRC has *widened the range of development activities* eligible under the grant conditions to support career development and future careers of researchers in science and other sectors recognising the good practice already in place at many research organisations.

Researcher salary costs charged to the project: Salaries should be sought at a level commensurate with the skills, responsibilities and expertise necessary to carry out the proposed research activity. This must be justified in the proposal.

If an application includes provision for a named individual this should reflect their current salary and take into account their previous experience, professional contribution and research responsibilities. The level requested must be justified in the proposal.

If the proposal is to be submitted before the RO has agreed details of any pending pay revisions, the Research Councils expect that the proposal will be costed on the basis of the organisation's present pay structure. Salary increments over the period of the project should be taken into account, but future pay awards should not be anticipated.

Clinical trainee salaries should be costed to be commensurate with the appropriate NHS pay scale and training stage for the candidate.

Indirect and estate costs: Only individuals categorised as research staff on the proposal form attract an indirect and estate cost. Technicians and other research support staff, such as computer officers, project managers, engineers etc., are not regarded as research staff

and therefore are not included in the FTE multiplier for calculating indirect and estates. The *TRAC Guidance* provides details.

In exceptional cases individuals employed as technicians, nurses etc. can be treated by the RO as research staff, and categorised as such on the proposal form; in such cases the staff would attract an indirect and estate cost.

Investigator's time and salary is already wholly (100 per cent) supported eg via active research grants, MRC Unit/Institute funding, or single separate fellowship provided by the Research Councils (includes MRC External Scientific Staff: The application must make it clear that their time and salary has already been wholly funded (in Justification of Resources) and request zero salary (under DA).

MRC External Scientific Staff (ESS) should ensure that the ESS box is ticked on the proposal form. Estates and Indirect costs relating to ESS can be requested at the normal rate for the RO where they are located.

Investigator is retired/emeritus/honorary staff: If a PI or Col is retired/emeritus, the expectation is that their involvement in the project would be covered by a contract within the RO. Where the contract includes reimbursement of time, that cost can be included (up to a maximum equivalent of 37.5 hours a week) on the grant, usually under DI staff costs. If the investigator is not paid a salary by the RO then the application should show their hours attributed to the project but with zero salary requested. Estates and Indirect costs can be requested regardless of whether they are getting a salary/payment or not.

Where a PI is due to retire before the grant has ended, then the grant must also include details of a costed replacement for the remaining period.

PIs and Cols whose working time is not fully funded either from other Research Council grants or from another source and are not paid a salary by the RO (eg honorary staff), should show their hours attributed to the project, but with zero salary cost request.

Collaborative researchers: The MRC will consider meeting the salary costs of senior collaborative researchers, invited from a recognised centre in the UK or abroad, to work in the UK for up to one year giving full-time advice or assistance on the research project. Salaries should be included under the DI fund type and calculated in relation to staff of equivalent status in the host RO.

3.2.2 Directly Incurred Costs

These are any cost that is explicitly identifiable as arising from the conduct of a project. Cost will be charged as the cash value actually spent and supported by an auditable record.

3.2.2.1 Travel and subsistence

An application may include funds for travel and subsistence for staff assigned to the project where these are required by the nature of the work. Travel costs should be based on the most suitable and economical form of travel. In line with government instruction as of 24 May 2010, no travel should be undertaken by first class (by train), business class (by plane) or

the equivalent thereof. All train travel should be by standard class and any flights should be at the economy rate. All applicants should actively seek best value for money where it is practical and feasible and should fully justify why the transport is required.

Costs for attendances at conferences may be included, where such attendance will be of direct benefit to the research. Conferences should, as far as possible, be individually identified in the proposal and attendance justified. We would expect funds to be requested for one UK/European conference per year, and one major international conference every other year (expecting 1 per 3-year grant and 2 per 5-year grant). Please note that costs associated with a conference where the date of the conference falls after the end date of the grant cannot be claimed.

Additional child care costs beyond that required to meet the normal contracted requirements of the job, and that are directly related to the project, may be requested if the institutional policy is to reimburse them. This may include attendance at conferences and workshops that are directly related to the project. Childcare costs associated with normal working patterns may not be sought.

The MRC will also consider requests to meet the costs of travel and living expenses for:

- Collaborative working visits on the proposed research
- Learning of special techniques

Subsistence and any catering costs for events should reflect the normal rates applying to the host RO and will need to be fully justified in the justification for resources. Alcohol can only be included if accompanying a meal.

3.2.2.2 Equipment

The MRC will meet the costs of new equipment (including computers and software), the costs of equipment repairs and major spares, the costs of external maintenance agreements and the cost of equipment relocation and installation, where required by the proposed research.

Where equipment purchased under a previous MRC grant is to be used in the new project, a share of the continuing maintenance cost attributable to the new work can be sought unless already provided by other grant support.

Equipment purchased by universities and colleges on MRC grants is normally eligible for VAT relief, and VAT should therefore be excluded from proposals.

The host institution should make its own arrangements for applying for exemption from import duty.

Costs to meet externally commissioned surveys (through a procurement/contract with a professional provider) may also be included, providing that the survey is not undertaken by the PI or a Col. Externally contracted social surveys are funded within the Exceptions heading at 100%.

All equipment must be justified in the 'Justification of Resources' attachment as part of your application. Please see Research Council's equipment *guidance* for further information.

Single items of equipment costing between £10,000 (£8.33k ex VAT) and £138k (£115k ex VAT)

Any equipment bought or leased for the project which costs £10,000 (inc VAT) or above should be included under the DI 'Equipment' fund type heading. Please note the £10,000 includes all component parts of the equipment requested.

Where the call is a capital call, costings over £10,000 such as refurbishment should also be included as equipment.

Applicants are asked to request that their institution contributes towards the cost of any capital items or equipment over £10,000 (inc VAT). The RO is expected to contribute 50 per cent of the cost. Funding boards/panels do look at RO contributions and any RO contribution of less than 50 per cent should be fully justified or it may be viewed as the RO being less committed to the PI.

Items of equipment costing between £10,000 (£8.33k ex VAT) and £138k (£115k ex VAT) require explanation in the 'justification of resources' attachment.

Single items of equipment costing over £138k (£115k ex VAT)

Should be included under the DI 'Equipment' fund type heading.

From 1 April 2016 the upper equipment threshold will be £138k (£115k ex VAT; the limit was formerly £113,057 ex VAT). Items of equipment costing between £10,000 (£8.33k ex VAT) and £138k (£115k ex VAT) require explanation in the justification of resources. Items of equipment above £138k (£115k ex VAT) require a two-page business case outlining the strategic need for the equipment and three quotations for each individual item. Please see Je-S help pages or www.ukri.org/files/funding/tcs/equipment-guidance-pdf/ for more information on meeting this requirement.

Please note where it is not possible to provide 3 quotes e.g. due to the specialist nature of the item concerned, the RO must upload dummy quotes in addition to the actual quote(s) to enable the application to be submitted.

Equipment for instrument development

Items of equipment for instrument development will be funded at 100 per cent FEC, although the MRC reserves the right to request institutional contributions in exceptional circumstances. This only applies to individual pieces of equipment. Other equipment requested on the proposal not related to the instrument development will be subject to MRC rules for equipment.

A proposal will be classed as instrument development where it is wholly or mainly focused on creating a novel instrument that will either enable research capability not available using any existing instrument, or will substantially improve research capability beyond what currently exists, in a way that opens up significant new scientific opportunities.

The equipment section in costings should be completed as outlined below. All fields must be completed for each entry when making an application and costings should be at current prices with no allowance for inflation.

Heading	Description
Description	A brief description of the equipment so that what is being requested can be identified
Country of manufacture	The country where the item was manufactured
Delivery date	Please estimate this if not known
Basic price	Not including VAT
Import duty	Mark as 0 if none has been incurred
VAT	Mark as 0 when it can be reclaimed by the RO
Total	Total cost (excluding any VAT etc that can be reclaimed)
Amount sought	Total amount requested (this will normally be 50 per cent of total cost)

3.2.2.3 Other costs

Other allowable costs include any costs that are explicitly identifiable as arising from the conduct of a project.

Animal costs

These costs may be shown as either DI or DA. Applications must include a breakdown of animal costs, including weekly maintenance charges, in the Je-S application form in the section 'Resources – Animal costs. See the relevant Je-S help page for more information.

A more detailed justification of the costs incurred should be given in the 'justification of resources' attachment. This should detail the total number of animals requested, and justify the resources requested for purchasing, breeding, maintaining and using the chosen number of animals. No experimental or statistical details should be included in this section (see *Section 4.1 'Use of animals'*),

In some cases, adherence to the principles defined in *Section 4.1* will require additional resources e.g. for identification of animals (by microchip for example), increased maintenance charges resulting from randomisation procedures, or salary costs associated with obtaining statistical support. The MRC recognises this and will support such costs where fully justified in the appropriate sections.

Sub-contractors

A sub-contractor is contracted by the lead organisation to carry out work or provide a service for the project. They are being paid a set amount for a set piece of work. This should be costed as one sum on the application and must not include any indirect or estates costs. Subcontracting will be funded at the standard full economic costing (FEC) rate for the call (usually 80 per cent).

RO collaboration, Cols and project partners are not sub-contractors and should be included in the appropriate section of the application.

All sub-contracted work should be subjected to external competition to ensure best value for money through competitive purchasing processes. Where this is not possible because of the specialist nature of the work involved, it must be fully justified in the justification of resources.

Following the introduction of full economic costing (fEC) the resources for DNA sequencing requested through research grants can be supported at either 100% fEC or 80% fEC. In order to qualify for the resources to be granted at 100% fEC, the sequencing will need to be carried out through a contract to an institution or organisation ineligible to apply for MRC

funding. Funds for sequencing must be applied for and will be awarded in £ Sterling; any grant made will include 100% of the costs only; no indexation will be applied and no further funds will be granted for this activity to cover, for example, currency fluctuations. It is possible to request support for other activities associated with DNA sequencing such as annotation of the sequence, but in order for this to qualify for 100% fEC, it must also be undertaken by an organisation not eligible for MRC funding.

Other Directly Incurred Costs

Other costs directly attributable to the project may include:

- Consumables
- Recruitment and advertising costs for staff directly employed on the project, provided they occur after the date of the award letter
- Relocation costs may be included for named staff who will be moving, provided the RO has a general policy in place to pay relocation costs and they are not already included as part of indirect costs
- Additional childcare, beyond that required to meet the normal contracted requirements of the job, and that are directly related to the project, may be requested if the institutional policy is to reimburse them. However, childcare costs associated with normal working patterns may not be sought.
- Scanning/surveys
- Cost of the International Standard Randomised Controlled Trial Number (ISRCTN) registration fee

Please note that publication costs should not be included. See section 3.7 Open access publishing for more information.

3.2.3 Directly Allocated costs

These comprise any direct cost that will be calculated on the basis of estimates.

3.2.3.1 Estates

Estate costs provide a share of the cost of providing the physical infrastructure for research. These costs may include building and premises costs, basic services and utilities and any clerical staff and equipment maintenance or operational costs that have not been included under other cost headings.

Estates rates will be calculated by each RO using TRAC methodology, so will vary between ROs and also between departments within ROs. A single figure will be required at time of application.

Only individuals categorised as research staff on the proposal form attract an estate cost. Technicians and other research support staff, such as computer officers, project managers, engineers etc., are not regarded as research staff and therefore are not included in the FTE multiplier for calculating estates costs.

Where any named individual will be working away from the RO on long-term secondment for over six months during the project, estates costs should not be charged for the period of secondment. No reductions should be made for shorter term absences.

Where the level of staff effort to be awarded is different to that requested, the RO will be required to re-calculate within 10 working days the estates and indirect costs, using the same costing basis and TRAC rates in force at time of application.

3.2.3.2 Other directly allocated costs

These comprise all other direct costs calculated on the basis of estimates, which are not included within the ROs estates or indirect cost rates.

Items that can be included within this heading are:

- Charge out costs for use of major facilities
- Charge out costs for use of existing equipment
- Charge out costs for 'pool staff', departmental technical and administrative services
- Animal costs – see section 3.2.2.3

Charge out costs will vary by RO and this will be taken into consideration during the review process.

3.2.4 Indirect costs

These include the costs of administration such as staff, finance, library and some departmental services.

Like estates, indirect costs will be calculated by the RO and a single figure is required for the application. Calculations should be made using eligible FTE in the same way as estates (see section 3.2.3.1).

3.2.5 Exceptions

Applicants should consult with the relevant programme manager about the scientific justification of their exceptional cost and in the case of overseas CoIs, be able to demonstrate that required expertise was not available in the UK. Applicants must also include in the proposal covering letter (to be uploaded as an attachment in their Je-S application) the name of the programme manager with whom they have discussed the proposed exceptional cost and briefly provide any further justification.

The ultimate decision will be made by the board or panel. Specific questions about MRC policy should be directed to RFPD@mrc.ukri.org

Applications submitted to any of the international calls or jointly-funded global initiatives are not required to do this as the vast majority of costs are likely to be exceptions.

3.3 Overseas costs

The costs for work undertaken at an overseas organisation are admissible and should be discussed with the programme manager before submission of the application. This excludes MRC overseas units who should follow the guidance in section 3.8. Similarly, applications submitted to any of the international calls or jointly-funded global initiatives are not required to do this.

Investigators at overseas organisations are generally not eligible to receive indirect and estates costs. However, where the research is being undertaken in a developing country the MRC may contribute towards indirect and estates costs at its discretion if it will assist in developing research capacity. Applicants should seek guidance from the MRC programme manager in advance of submitting the application.

Costs attributed to International Co-Investigators (Co-Is) from developed countries (those not on the *OECD DAC list*) and/or India and/or China must not exceed 30% of the FEC grant value. There is no cap on eligible funds going to international Co-I's from DAC list countries.

More than one International Co-I may be included on the proposal as long as the combined funding requested for International Co-Is does not exceed the caps stated.

100% of the direct costs will be paid to the International Co-Investigator for both DAC list and developed countries. However, a greater justification for inclusion of costs for international Co-Is in developed countries will be required.

Where allowed, indirect and estates costs associated with overseas locally employed staff should be included as exceptions. Although the MRC will not question the indirect costs and estates costs rates declared by overseas ROs, the full cost of the proposed research (including indirect and estates costs) will be taken into account in any assessment of value for money.

The following table summarises which costs are admissible and at what rate the MRC will pay these costs.

Description	Discuss with programme manager in advance	MRC FEC contribution (per cent)
Costs for overseas CoIs and any locally employed staff eg per cent of actual salary, travel and expenses. Must be entered as exceptions.	Yes	100
Costs charged by the overseas organisation and associated with the research eg consumables, field work etc. Must be entered as exceptions.	Yes	100
A contribution towards indirect and estates costs at the overseas organisation, where the research is being undertaken in a developing country, where it can be shown that it will assist in developing research capacity (calculated as 20 per cent of the overseas organisations' directly incurred costs). Must be entered as exceptions.	Yes	100
The costs of any service or product procured (for use in the UK) from an overseas supplier (eg mouse, antibody strains, cells lines, assays etc).	No	80
Travel and subsistence (including bench fees) for UK-based researchers going abroad to undertake work. This does not include costs incurred directly by the overseas organisation when the researcher is active in that country.	No	80

Overseas costs may not include:

- Overheads (estate or indirect costs) for an overseas Col in India or China, or any locally employed staff in a developed country.
- Overseas project partners costs – this may apply, for example, where a project partner provides guidance/advice in return for receipt of research benefit but where intellectual input is not sufficient for Col status.

3.4 Industrial partner costs

The level of contribution expected from the industrial partner depends on the intellectual property arrangements between the academic and industrial partners. Please refer to *MICAs* for further information including what can be included under industrial partner costs. Where IP arrangements have been pre-negotiated, the industrial partner is expected to contribute a minimum of 25 per cent for basic research or 50 per cent for applied research of the total project costs (ie total cost of project industry costs and academic costs).

Full details should be entered in section 4 of the MICA form and the sum entered as DI Other on the Je-S form.

Please note however that the general rule is that only the costs of the academic partner will be met if the grant is funded. This will be funded at the normal scheme FEC rate (usually 80 per cent).

3.5 NHS costs

Applications may be made for research costs associated with NHS studies. Costs included in these applications comprise of:

- Research costs
- NHS treatment costs
- NHS support costs

Research costs of a study. The MRC will only fund costs which fall under this heading. These are funded at the appropriate FEC rate (usually 80 per cent). The research award does not include NHS support and/or treatment costs, although the MRC will take NHS support and treatment costs into account when considering the value for money of the research.

Where a research study takes place in, or involves the NHS, Department of Health guidance on the responsibilities for meeting patient care costs associated with research and development in the NHS applies.

NHS support costs: These are the additional patient care costs associated with the research, which would end once the research and development activity in question has stopped, even if the patient care service involved continues to be provided. These might cover items such as extra patient tests, extra in-patient days and extra nursing attention. Researchers should contact their local NHS research and development department initially. If they are unable to help directly or if there is no local NHS research and development department, contact the local Comprehensive Local Research Network (CLRN) Senior Manager.

NHS treatment costs: These are the patient care costs that would continue to be incurred if the patient care service in question continued to be provided after the research and development activity has stopped. In determining NHS treatment costs the applicant must assume that the patient care service being assessed will continue even though there may be no plans for it to do so. Where patient care is being provided which differs from the normal, standard treatment for that condition (either an experimental treatment or a service in a different location from where it would normally be given), the difference between the total treatment costs and the costs of the 'usual standard care' (if any) constitutes excess treatment cost/saving, but is nonetheless part of the treatment cost, not an NHS support or research cost. These costs should be determined in conjunction with your NHS trust partner(s) and their commissioners.

3.5.1 Excess Treatment Costs of Studies Involving Human Participants

Researchers applying for research grants involving human participants will need to complete a Schedule of Events Cost Attribution Template (SoECAT) to be eligible for the National Institute for Health Research (NIHR) portfolio and the support it provides. This change came into effect on 1 October 2018.

Who needs to complete a SoECAT?

A SoECAT must be completed if a full application will be submitted for a funding scheme round that opened after 1 October 2018 and if any of the following apply:

- The proposed study is intended for the NIHR CRN portfolio, the route through which support and Excess Treatment Costs are provided in England. This may include studies that will take place in a social care or public health setting.
- The research requires HRA and HCRW Approval in England and/or Wales, and/or studies requiring NHS/HSC Management Permission in Northern Ireland and/or Scotland.
- The research will use NHS resources

A SoECAT **MUST** be completed even if you don't think your clinical research will involve excess treatment costs (ETCs).

A SoECAT is **NOT** required if:

- An Outline stage proposal is being submitted. However, if a Full proposal is invited, a SoECAT must be completed and submitted with the Full application
- A full application was submitted to a call that was announced before 1 October 2018.

When applying for a Programme Grant that includes a clinical study, but where the clinical study is not yet fully defined A SoECAT will need to be completed at the application stage and updated prior to requesting approval from HRA.

Completing a SoECAT form

When applying for MRC funding, the following steps need to be completed;

- Complete a new form called a 'Schedule of Events Cost Attribution Template (SoECAT)', which can be download from the [NIHR website](#).
- Once completed, this form needs to be reviewed and signed off by a Local Clinical Research Network (LCRN) AcoRD specialist. A list of LCRN specialists can be found

on the [NIHR website](#). Early engagement with the LCRN AcoRD specialist in the application process is recommended.

- Append the 'study information' and 'summary' pages of the signed off SoECAT form with your completed grant application. Please note that Je-S does not allow the upload of MS Excel files, therefore please convert the relevant pages to a PDF and upload it to the application as a 'Letter of Support'. Please detail the file's description as 'Schedule of Events Cost Attribution Tool'. The MRC reserve the right to request a copy of the complete original signed MS Excel form.

For further information, please see:

- Responsibility for meeting patient care costs
- Attributing the costs of health and social care research (AcoRD) (<https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research>.)
- EL(97)77: Meeting patient care costs associated with research and development in the NHS detailed guidance
- [NIHR](#) – latest information and updates on the new ETC arrangements, including the SoECAT form and guidance notes

Additional advice and guidance can be obtained from your local Trust's Research and Development Office or from the Department of Health Research and Development Finance team.

Website: www.info.doh.gov.uk/contactus.nsf/memo?openform

For research based in Scotland	Advice can be sought from the Chief Scientist's Office. For advice on NHS funding and policy, research ethics, IP, information and communication, please contact: Chief Scientist's Office, telephone: 0131 244 2246
For research based in Wales	Refer to NHS research and development in Wales
For research based in Northern Ireland	Refer to the NHS research and development in Northern Ireland.

3.6 Costs related to Biomedical Catalyst calls

- **Biomedical Catalyst: Developmental Pathway Funding Scheme (DPFS)**
- **Biomedical Catalyst: Regenerative Medicine Research Committee (RMRC)**

For the two schemes above supporting clinical evaluation, certain costs in excess of £50,000 for sub-contracts with contract ROs (CROs) may be paid at 100 per cent. This is limited to activities that meet all three of the criteria outlined below:

- Are required to be undertaken to regulatory standards by a competent authority to allow clinical evaluation
- Do not involve creativity/intellectual input to the development of the entity by the CRO

- Require access to skills and resources not available in academia, where this can be robustly justified.

Examples of eligible activities:

- Pre-clinical toxicology package carried out under Good Laboratory Practice (GLP)
- Synthesis/ manufacture of an entity carried out under Good Manufacturing Practice (GMP)

Examples of typically ineligible activities:

- Testing an intervention for efficacy in animal models
- Iterative development of an intervention (eg medicinal chemistry)
- Preparation of regulatory submission

If an applicant is considering applying for 100 per cent FEC for such activities they must discuss with the relevant programme manager before submitting. The programme manager will advise on suitability and the mechanism for inclusion of the exceptional costs.

Please note that the first £50,000 of aggregated eligible CRO costs should be included under the 'Directly incurred' heading. The remaining balance should be entered separately as 'Directly incurred' and then the "Exceptions" box must be ticked.

3.7 Open access publishing

Researchers need to comply with the MRC's policy on open access: (*Open access policy - Our research - Medical Research Council*)

Applicants should not include any costings for access publishing charges (APCs) or other types of publication in respect of peer reviewed research articles (including review articles not commissioned by publishers) and conference proceedings that acknowledge funding from the MRC.

The charges for APCs and other publication charges for all research papers resulting from work funded by the MRC (or one of the other research councils) that relate to grants with a start date of 1 April 2013 or beyond are supported through block grants to UK HEIs, approved independent research organisations and research council institutes. A RO can then access these funds to pay for APCs for any article resulting from research council funding.

3.8 Costing of applications involving MRC institutes (MRC Harwell, MRC London Institute of Medical Sciences and MRC Laboratory of Molecular Biology)

All MRC institute costs must be calculated using *FEC methodology*. Applicants must agree the costs of the proposed research with their Senior Finance Manager at an early stage before submission. Only the additional Directly Incurred costs for the institute are eligible and only these should be included in the proposal form. 100 per cent of the institute's Directly Incurred costs will be paid.

To allow the application to be assessed objectively and compared to others, existing support provided by MRC core funding to the institute e.g. Directly Allocated (including salaries for MRC staff), Estates and Indirect costs should not be entered on the proposal form but **MUST** be declared in the Justification of Resources.

The following variations from standard guidance apply to MRC institutes when applying for an MRC grant:

Directly Incurred costs	<ul style="list-style-type: none">• <u>Only</u> Directly Incurred costs are awarded to MRC institutes (as lead or co-investigator).• Directly Incurred costs should only be requested if additional to the institutes core funding and supporting work directly related to the research proposed.• 100 per cent of Directly Incurred costs for institutes will be paid; these should be included on the proposal form as an exception.
Directly Allocated costs	<ul style="list-style-type: none">• Are <u>not</u> awarded to MRC institutes.• MRC investigators/staff can be named and effort on the project indicated on the proposal form.• Salary costs for all MRC investigators and other staff involved (e.g. shared/pool staff supporting a range of facilities and projects) should be entered as <u>zero</u> on the proposal form.• Salary costs of all MRC staff should be included in the Justification of Resources.
Estates and Indirect costs	<ul style="list-style-type: none">• Are <u>not</u> awarded to MRC institutes and should not be included on the proposal form.• Estimates of MRC Estates and Indirect costs should be included in the Justification of Resources in line with FEC methodology.

3.8.1 Collaborative applications lead by an MRC institute involving other Research Organisations

Applications may be collaborative and involve costs for one or more ROs that are not MRC institutes, their costs should be calculated and entered on the proposal form in the usual way and will be paid at the standard FEC rate for the call (normally 80 per cent FEC).

Non-MRC ROs may be paid directly by MRC Head Office. If there are multiple non-MRC ROs involved, one of these must be willing to receive the funds and be responsible for distributing funds to other non-MRC ROs. This would typically be the RO receiving the largest proportion of the grant. If this is the case the PI must be provided with financial reports from the other ROs, as required by the grant conditions, allowing the collaborative research project to be managed in its entirety.

If the funding requested by non-MRC ROs is substantial it may be more appropriate for a non-MRC RO to lead the application.

3.8.2 MRC institute is a co-applicant

MRC institutes may be co-applicants for MRC grants, where another eligible RO is acting as the lead applicant.

Costs allowable for MRC institutes and guidance on how the lead RO should complete MRC institutes information in the proposal form and justification of resources is as explained in section 2.2.4.

If successful, the lead and any other non-MRC ROs will be funded at the standard FEC rate for the call (normally 80 per cent FEC), and the MRC institute will be funded based on Directly Incurred costs at 100 per cent. All payments will be made to the lead RO that will transfer the relevant Directly Incurred costs in full to the MRC institute.

3.8.3 MRC institute applying for other Research Council grants

MRC institutes may apply to opportunities operated by other Research Councils as a lead or a co-applicant. The application must be costed using FEC methodology and only additional costs not covered by MRC core support should be requested. If successful, the MRC institute will be funded at the standard FEC rate for the call (normally 80 per cent FEC) i.e. Directly Incurred, Directly Allocated, Estates, Indirect costs may all be awarded.

MRC institutes should contact MRC Head Office before applying for any grants over £1m from other funders.

3.9 MRC Units and Partnership Institutes

Eligible individuals from MRC Units and Partnership Institutes (Francis Crick Institute, Health Data Research UK, UK Dementia Research Institute) may apply for MRC grants as either a lead or co-applicant. These grants are intended to support research that is clearly additional to existing 'core' support.

Grants to Units and Partnership Institutes are awarded at the standard FEC rate for the call (normally 80% FEC) and all usual MRC funding rules, exclusions and expectations apply. Only funding related to new activity that does not duplicate existing core support can be requested. New grants should not be disruptive to the delivery of established core activity.

Unit/Partnership Institute applicants must contact the relevant MRC programme manager for advice before applying and address the specific requirements below in grant proposals.

Letters of Support	A core funding statement must be included as a letter of support attachment. The statement needs to clearly explain the relationship between the proposed work and core support. It must be signed by the Unit Director or equivalent.
Other Support	List core support and external funding awarded/applied for related to the grant in this section of the proposal form.
Directly Allocated costs	Investigators or staff receiving their full salary from core support cannot include salary costs on MRC grant proposals. Use the proposal form to indicate the time these individuals will work on the grant but enter salary costs as zero.

Indirect and Estates costs	Calculate these using only the FTE eligible to request salary from the grant.
Justification of Resources	Give particular attention to justifying any salaries requested and the method used to calculate Indirect and Estates costs. Aim to provide assurance no duplicative funding is being requested. For comparative purposes state the value of core supported salary contributions.

Unit core support is provided by MRC, Partnership Institute core support is provided by MRC and other funders

4. Proposals involving animal use

The elaboration of a compelling scientific case is an essential prerequisite for justifying the use of animals. Over the past few years there have been a number of important initiatives that have been aimed at raising the sometimes-inadequate standard of reporting of animal experiments in the scientific literature. The *NC3Rs' ARRIVE guidelines*, for example, lay out criteria that should be met in reporting animal studies in order that their results and conclusions can be properly evaluated by readers. These criteria address a range of issues relating to transparency and validity of experimental design, the avoidance or minimisation of bias and the adequacy of statistical aspects of the study including statistical power and appropriate statistical analysis.

In light of these initiatives MRC has revised and updated its guidelines on what information needs to be provided to allow proper evaluation of the scientific strengths and weaknesses of applications for funding involving animal use. In some cases, adherence to the principles defined in this section will require additional resources e.g. for animal identification such as 'microchipping', increased maintenance charges resulting from the randomisation procedure, or salary costs associated with obtaining statistical support. We recognise this and will support such costs where fully justified in the appropriate sections.

4.1 Replacement, reduction and refinement of animal experiments

Applicants are expected to have developed their proposals in accordance with the cross-funder guidance for the use of animals in research: *Responsibility in the Use of Animals in Bioscience Research and NC3Rs Guidelines: Primate Accommodation, Care and Use*.

Experiments using animals funded by the MRC must comply with the Animals (Scientific Procedures) Act 1986 (ASPA), amended 2012 and any further embodiments, in:

- Using the simplest possible, or least sentient, species of animal appropriate
- Ensuring that distress and pain are avoided wherever possible
- Employing an appropriate design and using the minimum number of animals consistent with ensuring that scientific objectives will be met.

Advice on opportunities and techniques for implementing these principles can be found on the *NC3Rs website*. This includes the [Experimental Design Assistant \(EDA\)](#), a free online tool from the NC3Rs to help optimise experimental design and ensure that the number of animals used is consistent with the scientific objectives.

4.2 Proposals involving animal use

Researchers are strongly advised to read the following section carefully before preparing a proposal to ensure all the relevant information required is included in the appropriate sections of their application. In particular, applicants should ensure their proposal clearly sets out and justifies the following:

- Research objectives and how the knowledge generated will advance the field
- The need to use animals and lack of realistic alternatives
- Choice of species of animals to be used
- Type of animal(s), for example, strain, pathogen free, genetically modified or mutant
- Planned experimental design and its justification
- Numbers of animals and frequency of measurements/interventions to be used
- Primary outcomes to be assessed
- Planned statistical analyses

4.3 Experimental design, avoidance of bias and statistical considerations

There is a wide range of designs and approaches to animal experimentation that are appropriate depending on the objectives of the research proposal. In all cases, the MRC expects that researchers provide well justified information in their applications concerning the experimental design and its suitability to answering the research questions posed.

While we recognise that there are ethical imperatives to reduce the number of animals used, it is also unethical to conduct a study that, because of its limited size, has inadequate statistical power to robustly answer a research question. Applicants should therefore provide adequate justification for their choice of design and numbers of animals and interventions. It is important that adequate information is given concerning methodological issues including (but not restricted to) the following:

- The avoidance of bias (for example blinding of observers assessing outcomes to the group allocation in a randomised design)
- How randomisation will be carried out (if used) or why it is not appropriate if it will not be used
- A clear definition of the experimental unit in the analysis and the implications thereof (that is, there is a difference between N samples from one animal, as distinct from one sample from each of N animals, or combining samples from multiple animals)
- A principled justification of the adequacy of the numbers of animals to be included so as to be able to minimise the likelihood of spurious results due to the play of chance alone
- Where animals are used in multiple types of experimental approaches within a single application (eg for tissue supply, pilot experiments or more defined preclinical studies), exemplars for these types of experiment should be provided

- The number of different time points at which measurements will be made on each animal
- A description of the statistical analysis methods that will be used, explaining how they relate to the experimental design and showing that they are appropriate for the types of data that will be collected
- An indication of the number of independent replications of each experiment to be performed with the objective of minimising the likelihood of spurious nonreplicable results. If there are no plans for studies to be independently replicated within the current proposal then this will need to be justified.

A number of examples of the level of detail and type of information required can be found *on our website*.

In addition, the NC3Rs have developed a free online tool to guide researchers through the design of their experiments, helping to ensure that they use the minimum number of animals consistent with their scientific objectives, methods to reduce subjective bias, and appropriate statistical analysis. The Experimental Design Assistant helps applicants build a machine-readable diagram representing their experimental plan, following capture of their methodology, and allows the applicant to then generate a PDF report which provides a transparent description of the experimental design in a standardised format. The NC3R's [Experimental Design Assistant](#) can be found on the *NC3R's website*. Applicants are encouraged to consider embedding the summary diagram of this tool into their one-page reproducibility and statistical design annex, where appropriate.

4.4 Peer review

Information relating to the use of animals will be subject to careful scrutiny, and will carry substantial weight when the scientific strength of the proposal is assessed. Guidance on where each aspect should be addressed in Je-S is given below.

This information must be provided for all proposals involving animals, regardless of whether or not the animal costs are requested as part of the proposal.

4.4.1 Je-S section on 'Animal research'

Within the 'Animal research' section, researchers must give details of any procedures categorised as moderate or severe (in accordance with the maximum prospective severity rating in the Home Office licence under which the work will be carried out) in order that the assessment of the proposal can balance the importance of the potential scientific advancement to the welfare of the animals.

4.4.2 Je-S section on 'Resources – Animal costs'

If applicants are contracting out animal research or proposing to undertake any animal experiments as part of collaborative programmes outside the UK, please see Section 4.5.

4.4.3 Je-S section on 'Animal species'

Sound scientific reasons for the use of animals and an explanation of why there are no realistic alternatives must be given, with an explanation of how the choice of species complies with ASPA (*see section 4.1.1*).

In this section please include the following information:

- Sound scientific rationale for the use of animals (see also Section 4.1)
- Explanation of why there are no realistic non-animal alternatives (see also Section 4.1.1.1)
- How the choice of species complies with the Animals (Scientific procedures) Act (1986). For knockout or transgenic lines briefly include information on the sources these may be obtained from and relevant information to demonstrate the verification of lines selected.
- Relevant information about the animals to be used (eg species, strain, sex, developmental stage, weight)

Applicants are encouraged to provide other 'supporting information' regarding experimental design, statistical analyses etc. in the 'Reproducibility and statistical design' annex to the case for support (see Section 2.2.3.4) and not in the Je-S application form. Please note that you are not required to duplicate information presented elsewhere in the application.

Section 4.1.4.3 provides more detail about the information required in the annex for proposals requesting the use of animals. A summary of where to put all required information regarding the use of animals in your proposal is at Section 4.1.8.

4.4.4 Case for support – Reproducibility and Statistical design annex

The scientific case underpinning the choice of animal model and the experimental plans should be detailed in the one-page annex to the case for support (entitled '*Reproducibility and statistical design*' annex) See Section 2.2.3.4 for more detail. There is no requirement to duplicate information.

The experimental design should be outlined, including a justification of the total numbers of animals to be used and, where appropriate, the frequency of measurements/interventions required on each animal. Planned procedures to minimise experimental bias (for example, randomisation protocols, blinding) should be outlined or an explanation included as to why such procedures are not appropriate. Each experiment does not need to be described in detail, but sufficient information must be included that reviewers are readily able to understand the experimental plan.

Researchers must provide a properly constructed justification of how the numbers of animals to be used were determined. In general, it would be expected that professional statistical advice will be sought in putting this section together.

In many instances this section will include statistical power calculations based on justifiable and explicit assumptions about the anticipated size of the experimental effects. If statistical power calculations are not given, applicants should provide a principled explanation of the choice of numbers. Power calculations can be used to calculate the minimum sample size required so that one can be reasonably likely to detect an effect of a given size, or to calculate the minimum effect size that is likely to be detected in a study using a given sample size. In general, explanations based solely in terms of 'usual practice' will not be considered adequate. An overview of the planned statistical analyses and their relation to the choice of sample size should be included.

An explanation should be provided of how and why the animal species and model being used can address the scientific objectives and the relevance to human biology. For knockout

or transgenic lines this should include information on the sources these may be obtained from and relevant information to demonstrate the verification of lines selected.

It is essential that the case is clearly made as to how the chosen design (with reference to the information regarding the numbers of animals and planned statistical analyses provided will enable the stated objectives of the study to be achieved. In addition to the usual background and specification of the primary and secondary objectives of the study, or specific hypotheses being tested, the primary and secondary experimental outcomes to be assessed should be clearly defined (eg cell death, molecular markers, behavioral changes). Each experiment does not need to be described in detail, but sufficient information must be included that reviewers are readily able to understand the design rationale and make robust judgements on the scientific case.

4.4.5 Je-S section on ‘Resources – Animal costs’

The costs of both the animals themselves and their maintenance may be requested and should be listed in the ‘Resources – Animal Costs’ section of the Je-S form. See *section 3.2.2.3* for additional information. Where experiments involve genetically altered animals, examples of the breeding strategies may be included in the justification of resources section to support total number of animals requested.

Applicants contemplating the use of animals purchased from commercial suppliers should, wherever possible, use UK suppliers, to minimise the risk of suffering during transport. For cats, dogs and primates, Home Office-approved suppliers must be used.

If applicants are contracting out animal research or proposing to undertake any animal experiments as part of collaborative programmes outside the UK, please see Section 4.1.5.

Applicants planning research using rhesus macaques should obtain animals from the *MRC Centre for Macaques*, who will advise on costs.

4.4.6 Proposal attachment ‘Justification of resources’

A detailed justification of the costs incurred should be given in the justification of resources attachment (see *section 2.2.4* for further information). This should detail the animal costs requested, and may outline breeding programmes if appropriate to support the number of animals required. No experimental or statistical details should be included in this section; these details must be included in the ‘Animal species’ section of the Je-S form and case for support.

4.4.7 Use of animals overseas

From 1 September 2017, if your project involves the use of animals overseas you must submit a signed statement (uploaded as a Letter of Support to the Je-S application) from both UK and overseas PIs that:

- they will adhere to all relevant national and local regulatory systems in the UK and overseas
- they will follow the guidelines laid out in the NC3Rs ‘Responsibility in the use of animals in bioscience research’ document (www.nc3rs.org.uk/responsibility-use-animals-bioscience-research) and ensure that work is carried out to UK standards
- before initiation of the proposed research work, appropriate approvals from Institutional and/or central animal ethics committees will be obtained for experimental

protocols to be adopted in their projects. Successful proposals may be expected to provide copies of these permissions before funding is released.

- Details on where the animal research will take place (UK or overseas) and through which funder the resources are being sought.

If the research involves the use of animals (rodents, rabbits, sheep, goats, pigs, cattle xenopus) overseas, rather than in the UK, please also complete the 'Additional questions on the use of [species] overseas' form, and attach as a letter of support in Je-S.

4.5 Ethical and welfare standards and review

Applicants must ensure that best practice in relation to animal husbandry and welfare is followed. Where the work proposed is not covered by an existing project licence under ASPA, applicants should put their proposals to the local Animal Welfare and Ethical Review Body for review prior to submission and ensure that ethical and welfare issues raised are addressed. Applicants should be aware that the NC3Rs will be involved in the review of any MRC applications proposing to use non-human primates, cats, dogs or equines, providing advice specifically on the 3Rs and animal welfare.

If applicants are contracting out animal research or proposing to undertake any animal experiments as part of collaborative programmes outside the UK, these experiments must be conducted in a way that conforms to the legal and ethical practices in that country, as well as conforming to the standards (including animal welfare) required in the UK. Where standards are different, the more rigorous guidelines will apply. Such applicants are strongly advised to view the 'Choosing contractors for animal research: expectations of the major UK public funders' presentation produced by the NC3Rs, which sets out the requirements of the MRC, and other major funding bodies, with regard to standards of animal welfare and study design, including for preclinical studies at contract research organisations. The presentation can be found *here*.

From 1 September 2017, if the research involves the use of rodents overseas, rather than in the UK, please also complete the "Additional questions on the use of rodents overseas" form, and attach as a letter of support in Je-S.

4.6 Home Office licences

It is the responsibility of all applicants to ensure that the appropriate Home Office licences are obtained. This will include the requirement that the research proposals are approved by the local ethical review process.

Home Office licences (or amendments to existing licences) do not have to be obtained before the application is submitted to the MRC, but if a grant is awarded, researchers must have the necessary licences in place before any animal experimentation begins.

4.7 Mouse strains

The MRC encourages the archiving and sharing of genetically altered mouse strains as a means of both reducing and refining animal use³. The MRC supports a central repository of mouse strains, the MRC Mouse Frozen Embryo and Sperm Archive (FESA) at MRC Harwell. FESA aims to ensure that valuable mouse strains are safeguarded, that the need to maintain colonies of live mice for long periods of time is reduced, and that the significant investment in engineering strains is capitalised upon fully.

Where there may be a need for the repeated creation of pre-existing genetically modified mouse strains, this must be fully justified. Applicants planning to produce genetically modified mouse strain(s) should investigate whether suitable strains are available via FESA or elsewhere before requesting resources for creating new strains.

Applicants planning on creating new genetically altered mouse strains as part of their work should actively consider archiving and sharing these strains via FESA. When archiving and sharing of genetically modified mice is not possible please clearly state in your application the reasons for this.

Contact: FESA

Email: fesa@har.mrc.ac.uk

4.8 Justification of animal use

Where a proposal involves multiple experiments (for example a pilot study, tissue supply or treatment comparison) the level of detail shown below should be included for each type of experiment.

Information	Details	Location and guidance section
Procedure severity	Confirmation of the use of animals (this should be ticked as yes even if the animal costs are not requested as part of the proposal) and details of any procedures categorised as moderate or severe in accordance with the maximum prospective severity rating in the Home Office licence under which the work will be carried out.	Animal research section of the Je-S form the proposal (Section 4.4.1)
The need to use animals and the choice of species	A sound scientific reason for the use of animals and an explanation why there are no realistic non-animal alternatives. An explanation of how the choice of species complies with ASPA. Relevant information about the animals to be used (eg species, strain, sex, developmental stage, weight)	Animals species section of the Je-S form under 'Supporting Information' for each species (Sections 4.1 and 4.4.2)
Experimental approach	The number of experimental and control groups, the total number of animals used in each experiment and the number of animals in each experimental group, and the number of times each animal will be measured; the number of independent replications of each experiment indicated; any steps taken to minimise the effects of bias when allocating animals to treatment (eg randomisation procedure) and when assessing results (eg blinding)	Reproducibility and statistical design annex (Sections 2.2.3.4 and 4.4.3)
Sample size	An explanation of how the number of animals was arrived at, including power calculations if appropriate or other supporting information to demonstrate that the findings will be robust. Details of any statistical advice sought/available.	Reproducibility and statistical design annex (Sections 2.2.3.4 and 4.4.3)
Planned statistical analyses	An overview of the planned statistical analyses in relation to the choice of sample size, along with details of any statistical advice available.	Reproducibility and statistical design annex (Sections 2.2.3.4 and 4.4.3)
Objectives and experimental outcomes	The primary and any secondary objectives of the study, or specific hypotheses being tested. The primary and secondary experimental outcomes to be assessed (eg cell death, molecular markers, behavioural changes)	Reproducibility and statistical design annex (Sections 2.2.3.4 and 4.4.3)
Justification of the choice of species/model	An explanation of how and why the animal species and model being used can address the scientific objectives and	Reproducibility and statistical design annex (Sections 2.2.3.4 and 4.4.3)

	the relevance to human biology. Relevant information about the animals to be used (eg species, strain, sex, developmental stage, weight)	
Justification of the experimental design and statistical framework	A scientific justification of why the numbers of animals to be used, the experimental design chosen, and planned statistical analyses are appropriate to enable the objectives of the study to be met.	Reproducibility and statistical design annex (Sections 2.2.3.4 and 4.4.3)
Funding requested	The total number of animals requested and the associated purchase and upkeep costs listed.	Animal costs section of the Je-S form (Sections 3.2.2.3 and 4.4.4)
Explanation of funding requested	Overview of how the figure for funding requested was reached. No experimental or statistical details should be included in this section, however a breeding plan may be included to demonstrate how the total number of animals requested was determined.	Animal costs section of the Je-S form (Sections 3.2.2.3 and 4.4.4) and Justification of Resources attachment (Section 4.4.5 and 2.2.4)

5. Ethics and approvals

5.1 Clinical staff

It is important that any clinically-trained individuals who intend to be employed through the grant to undertake research, and who remain interested in pursuing clinical careers, discuss their plans with their postgraduate medical dean, or equivalent, to ensure that where appropriate, one year of MRC-funded research counts towards the Certificate of Completion of Specialist Training.

5.2 Human participants in research

5.2.1 Regulations and guidance

The MRC expects all work involving human participants to be undertaken in accordance with its policies and guidance.

These include:

- Research regulation and ethics – MRC position (2005)
- 'MRC Guidelines for Management of Global Health Trials (2017) Good Research Practice: Principles and Guidelines (2012)
- Human Tissue and Biological Samples for Use in Medical Research (2001): Operational and Ethical Guidelines (2015)
- Human material derived from the nervous system (2003)
- Medical Research Involving Children (2004)
- Medical research involving adults who cannot consent (2007)
- Personal Information in Medical Research (2000)
- Research Involving Human Participants in Developing Societies (2004).

All these publications can be accessed in the publications section of our website.

The MRC Regulatory Support Centre (RSC) provides support and guidance for those conducting research with human participants, their tissues or data.

Adequate information should be included in each proposal to enable the MRC to evaluate any physical or psychological hazard to which participants may be exposed. Each proposal should specify the number, sex, age range and state of health of the human participants. Applicants will also need to indicate how informed consent will be obtained and whether the participants are, for example, patients, healthy volunteers or individuals in a control cohort.

Payments to healthy volunteers participating in research are allowable, provided that the payment is to reimburse expense, or compensate for time and inconvenience, and is not at a level that would constitute an inducement for people to take part in studies.

Independent ethics committee approval is required for research that involves human participants (whether patients or healthy volunteers); their data and/or tissues. There may be cases where this review must be made by an NHS Research Ethics Committee (NHS REC). For further guidance on when NHS REC approval is required please see go to the *Determine which review body approvals are required* opens in new window pages of the Health Research Authority (HRA) website. Proportionate review is also available for studies which present minimal risk or burden to participants.

If the study is testing the safety or efficacy of a medicinal product, it is likely that this will fall under the scope of the UK Medicines for Human Use (Clinical Trials) Regulations 2004, regulated by Medicines and Healthcare products Regulatory Agency (MHRA). More information on the types of studies that fall under these Regulations and practical help on implementing the requirements (including the requirements of a Clinical Trial Authorisation (CTA) application) can be found on the *Clinical Trials Toolkit*. Guidance on risk-proportionate approaches to the management and monitoring of clinical trials is provided in the MRC/DH/MHRA Joint Project document (see Appendix 2). For details of the risk-adapted approach to Clinical Trial Authorisations, please see Submitting a Notification for a trial on the MHRA website.

For investigations that involve NHS patients, their data, tissues or NHS resources; NHS R&D management permission is required from all relevant NHS organisations for research. For further guidance please see the *MRC Data and Tissues Tool Kit*.

If the investigation is to take place within an organisation such as a factory, school or service establishment, applicants may be asked to provide evidence of relevant approval(s) from the appropriate authorities.

Approval(s) for the research detailed in an MRC grant proposal must be granted by the appropriate bodies before any work can commence. Institutions, applicants and grant holders have absolute responsibility for ensuring that the necessary approvals are granted for the research considered by the MRC and that no research requiring approvals is initiated until they are in place.

The MRC reserves the right to refuse to make an award on ethical grounds alone, even if the agreement of an independent ethics committee has been obtained.

Applicants must ensure that the appropriate approval(s) are in place before that aspect of the research can start with the MRC.

5.2.2 Research involving human participants in lower and middle income countries (LMICs)

Applications involving research with human participants in lower and middle income countries (LMICs) may have additional ethical implications that should be considered in developing the research protocol. Any partnership between the UK and LMIC research organisations is expected to be fair and ethical (see J Dodson. (2017) Building Partnerships of Equals. UK Collaborative on Development Science).

Research involving human participants requires approval from an independent ethics committee in the UK; ethical review should also be sought from an independent ethics committee in any LMIC in which there are study participants.

In the 'ethical implications' section of the application form, applicants should describe any ethical implications relevant to their proposal and confirm that these are being addressed. The following is a list of ethical considerations that might arise when designing and conducting research in LMICs. If any of these are relevant to the research and not discussed elsewhere in the proposal, then confirm these issues are being addressed. It is not necessary to make a statement about issues that are not relevant to the proposal.

1. **Research approvals:** Applicants should confirm that they have sought or are seeking appropriate ethics review and any other relevant approvals, in the UK and in any other countries involved. For further information about the requirements for ethics review, please see *Research Involving Human Participants in Developing Societies* (Specific consideration 7).
2. **Vulnerable groups:** Applicants should state whether any participants will be from vulnerable groups, justify their involvement and briefly clarify how the study design takes account of their needs. Examples of vulnerable groups might include children, prisoners, victims of violence, military conscripts, individuals lacking capacity, or disadvantaged by poverty or gender.
3. **Informed consent:** Applicants should indicate if there are specific considerations in relation to consent influencing their proposal, for example, providing information to participants whose language has no written form, or seeking consent from community leaders as well as participants when this is expected.
4. **Managing participant care:** Applicants should state whether, in the design of the research, they have considered the risks of any intervention, the standard of care to be offered to participants (including controls) during the research, continuing care after the research ends, and/or ancillary care.
5. **Information Management:** Describe how participant confidentiality and data security will be managed, including transfer outside the LMIC or sharing data in a registry. All relevant information formats should be considered, including conversations, medical consultations, written data, images, sample analyses, and research outputs. Research data management should be described in the Data Management Plan, however specific issues can also be highlighted in the 'ethical implications' section of the application form.
6. **Management of biosamples/biobanks:** If a proposal involves the collection or use of biosamples, then applicants should confirm that they will comply with local LMIC (and/or UK) codes of practice or legal requirements. For example, this may influence arrangements for transfer of biosamples outside the LMIC for analysis.
7. **Adverse impacts of the research:** Applicants should consider the wider impact of the research, negative as well as positive, on participants and communities and state how this will be managed. For example, this may include engagement with local stakeholders to ensure that the outputs of the research are used to benefit the local population and reduce inequity or discrimination.
8. **Public / Community engagement (PCE in the LMIC):** Applicants are encouraged to involve community and patient advocate groups in designing and conducting the research to increase the acceptability of the study and its findings. If preliminary engagement work has been undertaken or there are plans for future engagement,

this should be stated. If all public engagement activities have taken (or will take) place *only* in the UK, then applicants should demonstrate that these are relevant to the LMIC participant population and that consideration has been given to capacity-building in LMICs.

5.2.3 Use of human tissue

Applicants whose proposed research involves the use of human tissue and/or use of human tissue to treat patients as specified in the relevant legislation must confirm in their proposal that they will comply with the appropriate legislation and follow the relevant Codes of Practice issued by the Human Tissue Authority (HTA).

For further guidance please see the *MRC Data and Tissues Tool Kit – Which approvals are needed?* and HTA licence.

Applicants whose proposed research involves the use of human foetal tissue, or non-foetal products of conception, (eg amniotic fluids, umbilical cord, placenta or membranes) should follow the guidance set out in relevant Codes of Practice issued by the HTA (in particular see paragraphs 157-161 in the Code of Practice on Consent).

Research involving gametes and embryos is subject to regulation by the Human Fertilisation and Embryology Authority (HFEA) and researchers must ensure that they adhere to the relevant guidance. For further details please see the *MRC Data and Tissues Tool Kit – HFEA licence*.

Cell lines and embryonic stem cell lines fall within the regulatory remit of the HTA by virtue of the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which regulates the processing, storage and distribution of stem cell lines for human application. Both the HFEA and the MHRA also have a regulatory remit in respect of cell lines and embryonic stem cell lines. A position statement on regulating human embryonic stem cell lines has been issued by the HTA, HFEA and MHRA which provides guidance on the relevant regulatory remits. More information on the regulatory routes for conducting human stem cell research in the UK can be found on the *UK Stem Cell Tool Kit*.

A letter of support must be attached to the application if human tissue will be sourced from a public or collaborator's resource eg brain bank (even if from the PI's RO), or from a separate RO.

The list of materials considered to be 'relevant material' under the Human Tissue Act 2004 can be found *here*.

5.2.4 Xenotransplantation

Applicants must therefore seek relevant approval(s) and confirm in their proposal that they will follow the DH guidance and, if applicable, comply with the ATMP regulations. For further guidance please see the *MRC Experimental Medicine Tool Kit – Xenotransplantation*.

5.2.5 Use of radioactive medicinal products in humans

Applicants, whose proposed research requires the administration of radioactive medicinal products (including in- vivo neutron activation analysis in humans), should follow the guidance issued by the Administration of Radioactive Substances Advisory Committee (ARSAC) and seek the relevant approval(s) as appropriate. Please note that ARSAC is

currently moving to a more integrated process with the Health Research Authority (HRA) that will remove the requirement for additional 'research certificate' applications. For further details please see the *HRA website*.

5.2.6 Genetic modification

The Genetically Modified Organisms (Contained Use) Regulations 2000 (GMO (CU)) as amended by the Genetically Modified Organisms (Contained Use) (Amendment) Regulations in 2002, 2005 and 2010 require laboratories that intend to carry out genetic modification to assess the risks of all activities and make sure that any necessary controls are put in place. Further information about the legislation and relevant approval(s) required is available on the Health and Safety Executive (HSE) website.

5.3 Dangerous pathogens

Institutions/departments proposing to accommodate projects involving the use of dangerous pathogens must comply with the safeguards recommended by the Advisory Committee on Dangerous Pathogens in their reports: Biological Agents; the principles, design and operation of containment in a level 4 facility (2006) and Biological Agents; managing the risks in laboratories and healthcare premises (2005).

5.4 Controlled drugs

Applicants whose proposed research requires the use of drugs controlled under the Misuse of Drugs Act, 1971, and its subsequent amendments, must seek a Home Office licence directly through the host institution's normal channels.

5.5 Development of software as part of a grant

In accordance with Government policy on Open Source Software (OSS), applicants whose proposed research aims to produce software outputs must specify a proposed software exploitation route in the case for support. When the project is completed, the software should be exploited either commercially, within an academic community or as OSS. Further information on OSS can be found at www.opensource.org

5.6 Bioterrorism and biomedical research

The MRC is aware that in light of global events, biomedical research that involves the use of potentially harmful pathogens and toxins has come under increased scrutiny, and that there are heightened concerns that the misuse of this research could increase the potential threat of bioterrorist attacks. Applicants are asked to take note of MRC's *policy statement* when preparing proposals.

5.7 Induced Pluripotent Stem Cell (iPSC) resources

Applicants whose proposed research involves the use of induced Pluripotent Stem Cells (iPSC) should make a strong case in support of the proposed iPSCs being able to appropriately recapitulate the natural state or diseased condition of interest versus other means of gaining similar insight.

Relevant UK regulations and guidelines must be adhered to. For guidance see the *Code of Practice for the use of Human Stem Cell lines*.

iPSC collections should ideally be based on well phenotyped cohorts with linked clinical and lifestyle data. Donations should be altruistic, anonymised and traceable. Appropriate consent must be secured for all proposed uses. To future proof derived lines, consideration should be given to seeking generic consent for a broad range of potential uses, given their pluripotent nature.

Depending on the specific project, consideration should be given to ensuring specific consent is sought for areas of particular interest including:

- Genetic analysis of derived cells
- Potential use in animal research, clinical transplantation or reproductive medicine; and
- Potential commercial applications of cell lines but without donors receiving personal financial benefit
- Consideration should also be given to the feedback of data from derived cell lines.
- The tissue source of cells from which the iPSC lines are derived should be documented and ideally banked for future reference.

Derivation and characterization

This is a fast moving field with numerous derivation approaches in use emerging. Comparable methods of iPSC generation should be used where possible, with full details of the reprogramming method provided.

Lines derived using novel methodologies should be calibrated against lines derived using established protocols and ideally human embryonic stem cell lines. Lines should be characterised to establish features including clonal purity, absence of expression of reprogramming factors, self-renewal capacity, genetic stability and pluripotency. Characterisation should take into account uncertainties regarding the degree of reprogramming and the extent and durability of epigenetic memory.

It is noted that fully characterizing lines may be costly and time consuming. The level of characterisation should be fit for purpose. Robust quality control systems should be put in place to ensure the identity and specification of banked and released cells.

Internationally agreed standards and guidance for stem cell line banking are available through the *International Stem Cell Banking Initiative*, and advice can be sought through MRC-funded resources such as the *UK Stem Cell Bank* and *Human iPSC Initiative*.

Access

Collections should detail how access will be provided to third parties in line with MRC *policy on data sharing* and cohort resource policy.

Material and Data Transfer Agreements (MDTAs), IP Licensing and Freedom to Operate should be considered, where appropriate, to ensure the broadest utility of derived lines.

MDTAs should control third party use and ensure UK guidelines and ethical procedures are followed, for example in relation to potential use in animals, clinical studies or reproductive science. Equivalent standards should be mandated if exported for overseas use.

6. Research Involving Existing Facilities and Resources

6.1 Research involving cohort resources

All applications for funding for new or existing **population** cohort studies are required to submit an outline for assessment by the Cohort Strategic Review Group (CSRG) prior to submission of a full application to a board. Applications for funding for **clinical** cohorts (usually set up around specific diseases or conditions) need not follow this process.

Outlines should be prepared following the MRC Cohort Outline Application Template and should be no more than 6 pages of A4 in length. Outline applications should be submitted via email to populationcohorts@mrc.ukri.org by 4pm on the day of the submission deadline. See the CSRG page for upcoming deadlines.

If invited by CSRG to submit a full proposal to an MRC Board, applicants will be expected to submit their full proposal within 3 months. Full applications should address any concerns raised by CSRG and also cover the points highlighted below.

It is important that all grant applications which include elements of infrastructure support for new or existing cohorts make clear what new health research questions or hypotheses it will be possible to answer over the next five to ten years using the cohort resource. This is required regardless of whether or not the grant application is requesting funding towards investigating any of these specific research questions.

For existing resources, grant applications must contain an explicit statement on what research has been done using the cohort, including publications, and what the impacts have been.

Applications must also detail:

- Why can this science be addressed using this cohort above other resources?
- What does this cohort offer that other cohorts do not (nationally and internationally) and how does it relate to other relevant cohorts? Applicants should either list the assets (measures, specimens, population group) as an Annex or reference the cohort website.
- What are the plans for establishing the cohort as a resource – how is it/will it be used by the wider research community?

The grant application must make clear what new activities, including new data sweeps or new analysis of existing cohort data, will be carried out as part of the grant. Applicants must be clear which costs relate to de novo data collection, analysis of new data and/or maintenance or use of existing data.

There should be complete transparency in the funding being requested, particularly when resources are funded by more than one funder. Applicants must make clear which elements of the cohort resource and studies are funded by whom and over what period.

Data sharing and preservation

In line with MRC policy on data sharing and preservation, applicants must specify the proposed arrangements for data access, data sharing and curation. Appropriate costs to support these elements of the work must be included in the funding requested and applicants should take care to clarify exactly which costs are associated with data sharing, data curation and/or data access.

Applications should also outline:

- Governance arrangements for data sharing and data access by the wider research community. This should include the process by which third parties apply to use the cohort and how and by whom proposals are assessed.
- Where and how the cohort meta-data will be made available.
- The time-frame under which any new data obtained will be added to the cohort resource. Renewals must also demonstrate that previous funding for data sweeps has enriched the cohort.

6.2 Access to facilities provided by other organisations, such as synchrotron radiation facilities

While in general charges may be levied by other organisations for access to these facilities and the costs must be included by applicants in their proposals, there are some special agreements and funding arrangements in existence, in particular for access to synchrotron facilities.

Applicants whose proposed research involves the use of the Diamond Light Source or European Synchrotron Radiation Facility (ESRF) should indicate this in the case for support section of the application form. Requests for beam time should not be included in the proposal to the MRC, although travel costs associated with beam time usage may be sought through the grant proposal where they are not recoverable elsewhere.

Proposals for beam time are made directly through Diamond Light Source or the Science and Technology Facilities Council (STFC) through whom access can also be booked to the Institut Laue-Langevin (ILL) and the ESRF.

Applicants wishing to use other STFC facilities should first discuss with the STFC and the MRC the basis for charging before submitting a grant proposal to the MRC. Applicants wishing to use facilities at Grenoble (ESRF and ILL) should note that UK access is provided through STFC.

6.3 High performance computing facilities

Applicants wishing to use the high performance computing resources of EPSRC, whether or not MRC financial support is required, should submit a Je-S application. For further information see EPSRC *high performance computing and support* and ARCHER.

6.4 Data, tools and facilities of Genomics England

The MRC is keen to receive applications for funding from eligible UK researchers seeking to utilise the 100,000 Genomes Project data, tools and facilities. Applications can come through any of our standard response-mode schemes or relevant targeted initiatives. Researchers will need to be members of the Genomics England Clinical Interpretation Partnership (GeCIP) to access the dataset and associated tools – please refer to the *Genomics England website* for further information.

Applications submitted to the MRC will need to provide assurance in a number of key areas:

1. A letter of support from the host institution (Head of Department or equivalent) confirming that they have completed the GeCIP Participation Agreement, including subscribing to the Genomics England Intellectual Property Policy;

2. A letter of support from the Principal Investigator that confirms that they are a member of a GeCIP and their research application has been formally approved by the Genomics England Access Review Committee and identifies which Intellectual Property Scenario has been agreed. The MRC is willing to consider an application where these matters are under consideration but the applicant should provide the timing for an expected decision. An MRC award will not be allowed to proceed unless these agreements have been finalised.

As part of the scientific case for support in the application, the applicants will need to confirm that the data available through Genomics England (and elsewhere) is sufficient to fully deliver the scientific objectives, including appropriately powered findings. If the full data is not available at the time of writing the application, then the applicant must confirm when it will be available within the timeframe of work.

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