MRC Medical Research Council

Guidance for Applicants

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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

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 Higher Education Funding Council for England (HEFCE), Higher Education Funding Council for Wales (HEFCW), Scottish Funding Council (SFC) and Department for Employment and Learning Northern Ireland (DEL).
- **Independent research organisations (IROs)**
  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 RCUK website*.
- **Government-funded organisations (other than MRC-funded units and institutes)**
  Government-funded organisations such as PHE or the Met Office can apply for MRC funding only as a co-applicant. The PI can apply for 80 per cent of full economic costs in the same way as all other co-investigators (CoIs). 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.
- **MRC units/institutes**
  Applications to the Research Boards can only be made with prior agreement between the Unit/Institute Director and MRC Head of Theme.
- **University units (former MRC units)**
  University units can apply as an HEI. However, any core programmes in a similar area of science to that covered in the proposal must be listed in the 'Other support' section of the proposal form.

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 *RCUK terms and conditions*, 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 and Technicians to be involved see section 3.1.

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 3.1.2.1* 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 (CoIs). A CoI assists the PI in the management and leadership of the research. CoIs should normally be able to meet the eligibility criteria for PIs and be based in the UK at an eligible RO. All CoIs must have a verified Je-S account.

Researchers from overseas research organisations may be a CoI if they provide expertise not available in the UK. Inclusion of an overseas CoI 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 3.1.5.*

1.3.3 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 2.4.3), 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 2.8).

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 2.4, 2.5 and 3.1.1.4).

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 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.

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 3.4.1). 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 and partnership grants, but 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 UK.

Email: JeSHelp@rcuk.ac.uk

Phone: +44 (0) 1793 44 4164*

The Je-S Helpdesk is staffed Monday to Friday 8.30am - 5pm (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 call or board round

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

A frequent cause of error when submitting an application arises from the applicant not ensuring that the call selected on the first page of Je-S (when creating the document), corresponds to the selection made further in the application under 'Board' to allow the proposal to be directed to the correct board/panel/committee scheme (see Je-S guidance).

A detailed list of *science areas* covered by each of the board or panels is available. For a research grant to a board, the applicant will need to choose the following options on Je-S:

- Standard proposal (not fellowship or studentship)
- Research grant (scheme)
- The relevant board eg MCMB Aug (call)

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.

Each board will only have one call so it is no longer necessary to choose the type of grant as a call in its own right. To select the type of grant applied for, please select the grant under the heading 'Grant type' which includes the following options:

- Centre grant
- Methodology research panel
- New Investigator Research Grant
- 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*"

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 RCUK Grants Team who will then process the submission for the MRC.

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 (accessible from the top right of the Je-S home page).

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 for proposal submissions at their RO to confirm how much time they will need to process the application and complete the submission process. All applications must be submitted to the MRC via the RCUK Je-S system by 4pm on the advertised closing date.

Applications received after the deadline will not be considered.

2. The Application

2.1 The proposal form

The proposal form provides a summary of the whole project. Some of the sections overlap with mandatory attachments, such as pathways to impact, as the attachments provide the detail required for decision-making purposes.

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: • The context of the aims and objectives of the research • The potential applications and benefits

Technical summary*	A more in-depth summary aimed at reviewers who have some knowledge of the area of science involved.
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.
Impact summary*	To prevent duplication, applicants should make reference to the 'Impact Summary' from the Pathways to Impact document rather than re-stating this information. The Impact Summary should address the following two questions: **1. Who will benefit from this research?** List any beneficiaries from the research, for example those who are likely to be interested in, or to benefit from, the proposed research both directly or indirectly. It may be useful to think of beneficiaries as 'users' of the research outputs, both immediately, and in the longer term. Beneficiaries must consist of a wider group than that of the investigators' immediate professional circle carrying out similar research. For example: • Are there any beneficiaries within the commercial private sector who will benefit from the research? • Is there anyone, including policy-makers, within international, national, local or devolved government and government agencies or regulators who would benefit from this research? • Are there any beneficiaries within the public sector, third sector or any others who might use the results to their advantage? Examples include museums, galleries and charities. • Are there any beneficiaries within the wider

	public? **2. How will they benefit from this research?** Describe the relevance of the research to these beneficiaries, identifying the potential for impacts arising from the proposed work. Please consider the following when framing your response: • Explain how the research has the potential to contribute to the nation's health, wealth or culture. For example: Fostering global economic performance, and specifically the economic competitiveness of the United Kingdom? Increasing the effectiveness of public services and policy? Enhancing quality of life, health and creative output? • What are the potential impacts likely to be, and what is their importance? • What are the realistic timescales for the benefits to be realised, and how will this research contribute? • What research and professional skills will staff working on the project develop which they could apply in all employment sectors?
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.
Project co-funders	A project co-funder is an organisation which is jointly funding a project with the MRC. The relationship can be directly with the MRC or the RO. This could include charities, industrial or commercial companies and government organisations. The terms of the co-funding should be detailed in a memorandum of agreement/understanding. Contributions from project co-funders should be detailed in the 'Project co-funders' section of the

	JeS application form
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.

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.

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 *case for support* table for more information
Justification of resources	A maximum of two sides of A4
Pathways to impact	A maximum of two sides of A4
Data management plan	Length varies, see section 2.9 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 *MRC*

	Industry Collaboration Agreement (MICA)
Heads of terms	For more information see *MRC Industry Collaboration Agreement (MICA)*
Additional costs proforma: NHS support and treatment costs	For more information see section 3.1.7 NHS costs
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 2.10 Research Council facilities
Final/Interim Report	Programme Grant renewals only. For more information see *Programme Grant renewals: additional requirements*
Gantt Chart/Work Plan	A maximum of one side of A4 Only allowed as a separate attachment on certain calls eg DPFS/DCS.

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 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. This will come into effect with applications **submitted to closing dates on or after 1 April 2017**. For more information please see '*MRC supports preprints*'.

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.

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.

Any 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) and font size of 11pt
- Use 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
- Extra detail on ethical, risk or patient safety data issues
- The only annexes which will be accepted are:
    - NHS support and treatment costs proforma, see section 3.1.7
    - Project partners letters of support, see *section 2.8*
    - Limited additional annexes may be allowed **in exceptional circumstances** for proposals addressing large population studies, including clinical trials
    - Applicants who are MRC staff can submit a progress report on previous MRC grants held
    - Methodology and experimental design, see section 2.4.3
- 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
- We only require copies of letters of support where project partners are involved or where provision of human tissue or access to patients is essential for the study
- When uploading PDF documents, please ensure they are given a logical file name and description so that information can be found easily
- Ensure all pages of each document are numbered
- Set out the scientific case under each of the headings specified in the guidance notes for the specific funding scheme
- All the points in the generic guidance must be addressed as well as those in call-specific guidance

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

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 *Case for Support Form* 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.
- RCUK also requires information on public engagement in science. To prevent duplication, applicants should make reference to the 'Impact summary' from the pathways to impact document, rather than re-stating this information.

- 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	Explain the need for research in this area, and the rationale for the particular lines of research planned. • 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	*People and track record* • 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. • 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.

Environment

- 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.

Research plans

- Give details of the general experimental approaches, study designs, and techniques that will be used (the one-page annex 'Methodology and experimental design' annex should be used to supplement information in this section, where necessary and as appropriate. See below for further details). It is not necessary to describe each experiment, but give enough detail to show why the research is likely to be competitive in its field. For example:
    - Highlight plans which are particularly original or unique
    - Describe plans to reduce bias such as blinding or randomisation (or a justification of why such measures are not possible/appropriate). A justification of the proposed sample size must be given (where appropriate) along with details of the planned statistical analyses.
    - 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
- 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
Ethics and research governance	• 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.
Exploitation and dissemination	• 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.
Project partners (see also section 2.8)	• 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.

Additional requirements for New Investigator Research Grants:
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 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.

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'.

2.2.3.4 Methodology and experimental design (optional annex) resources

A one-page annex may be included, in addition to the page limits in Section 2.3.3.2, to provide additional detail of the methodology and experimental design aspects of the proposal (beyond that contained in the main case for support). This information must be provided as a clearly marked annex at the end of the main case for support, entitled 'Methodology and experimental design annex'. Please note that you are not required to duplicate information presented elsewhere in the application.

The use of this annex is **strongly advised** where the proposal includes the use of animals and/or human participants, or where the methodology/experimental design proposed is particularly novel. Other applicants are encouraged to use this annex to provide any important information relating to reproducibility, methodology and experimental design. In addition to the above and Section 4.1.4, please also refer to the summary for key methodological & experimental design considerations during peer review (below) for a summary of key points you may wish to include in the annex. Where appropriate, the use of figures, tables and/or diagrams is encouraged.

In many instances this section may include statistical power calculations based on justifiable and explicit assumptions about the anticipated size and variability 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.

This annex is solely for the provision of information pertaining to the methodology and experimental design of the proposed research and is not to be used as a continuation of the main body of the case for support. It may not exceed one page in length and standard formatting guidance applies. Applications not adhering to these conditions will be returned unprocessed.

Robust methodology and experimental design should be at the centre of any proposal to aid reproducibility of research findings. In this regards, provided below is a summary of key considerations during the peer review of applications. This summary is not exhaustive and should be used in conjunction with the information provided in the Guidance for applicants.

Applicants are encouraged to seek input from those with the relevant statistical and/or methodological expertise to review their proposed experimental design and analysis plan.

Summary of key methodological & experimental design considerations during peer review:

Has the applicant **clearly set out** and **justified** the following:

- Measures for avoidance of bias (e.g. blinding, randomisation)
- Number of experimental and control groups and sample size per group
- How the sample size was calculated, showing power calculations and including justification of effect size (the applicant should provide sufficient information such that sample size/power calculations *could* be replicated)
- Overview of the planned statistical analyses in relation to the primary outcomes to be assessed
- Frequency of measurements/interventions to be used
- Circumstances in which power calculations are not appropriate to determine sample
  size

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
Staff – directly incurred posts Researcher/technician	Justify why a researcher/technician is needed for the proposed work and why the proposed time input is appropriate.	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?
Staff – directly allocated posts Principal investigator (PI), co-investigator (CoI) and research co-investigator time (unless working 100 per cent of their hours on the grant eg fellows)	Justify the time that the PI and CoI spend on the grant. A PI or CoI cannot request time for supervising postgraduate research students, writing publications after the end of the project, writing grant applications or peer review.	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 CoIs 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?
Travel and subsistence	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?	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. Travel costs incurred when using facilities should be included where necessary.
Other directly incurred costs	Give a description of what has been requested and why?	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 CoIs and other research staff on continuing contracts. You must provide a breakdown of any costs which are incurred for bulk items.
Directly incurred equipment	Why is the item needed?	Why can the item not be used/borrowed from elsewhere
Impact	Justify any resources requested to support the impact plan. For example: • staff time, travel and subsistence • consultancy fees	Full justification (what it is and why you need it) of each item requested. **Please note: patent costs and other IP costs are not eligible; Universities already receive funding for these from HEIF.** Also estate and indirect costs should not be requested for Technology Transfer Officers (TTOs). These are project-specific resources.
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 partnership or centre grants.
Exceptions	Please see Section 3.1.4	

2.2.5 Pathways to impact

This should be a maximum of two A4 pages and is primarily for detailing the activities which will promote potential economic and societal benefits. Only use as much space as needed; it is not necessary to fill two pages.

To prevent duplication, applicants should make reference to the 'Impact Summary' from the Pathways to Impact document rather than re-stating this information.

Our primary criterion is research excellence. RCUK introduced 'Pathways to Impact' to encourage you to think about what can be done to ensure your research makes a difference. Through pathways to impact we want to encourage you to explore, from the outset, throughout the life of your project and beyond who could potentially benefit from your research and what you can do to facilitate this.

2.2.5.1 Pathways to impact statement

You should upload your statement as an attachment on Je-S and describe what specific actions will be taken to ensure that the potential beneficiaries identified in the impact summary (on the proposal form) have the opportunity to benefit from the research.

A clearly thought through and acceptable pathways to impact statement should:

- Identify and actively engage relevant users of research and stakeholders at appropriate stages
- Articulate a clear understanding of the content and needs of users and consider ways for the proposed research to meet these needs or impact upon understandings of these needs
- Be specific – what is going to be done throughout the lifetime of the grant to facilitate maximum impact of the research?
- Outline the planning and management of associated activities including timing, personnel, skills, budget, deliverables and feasibility. Ensure that planned activities are appropriate to the research that will be undertaken. We would expect all investigators to be able to undertake activities beyond scientific presentation. However we are aware that the pathways to impact for basic research are likely to be different to those for translational research. Examples of the variety of short and long-term impacts realised from different types of MRC funding are available and through the evaluation reports of the latest available MRC Researchfish data.
- Include evidence of any existing engagement with relevant end users.

Describing pathways to impact will apply for the vast majority of proposals. In the few exceptions where this is not the case, the pathways to impact statement should fully justify the reasons why this is not possible.

Research council guidance for completing the sections on pathways to impact is available.

Top tips for articulating potential impact:

- Draft the impact summary very early in your preparation, so that it informs the design of your research.
- Remember to consider and include project-specific costs relating to proposed impact activities eg engagement workshops or marketing materials.
- Do not cut and paste the text provided within the impact summary into pathways to impact. The purpose of the impact summary is to provide a short description of the beneficiaries and potential impacts, which could be used in the public domain. Pathways to impact should set out what you will do to realise the potential impacts.
- Public engagement is a popular form of impact activity. For such activities to be as effective as possible, try to think of your research in the context of two-way engagement, not just outreach.

In completing both the impact summary and pathways to impact statement, bear in mind the broad range of impacts that your research may have, spanning the advancement of scientific knowledge, health and wellbeing, economic competitiveness, policy development and the provision of skilled people to the workforce. We will use pathways to impact in the assessment of grant applications, but the primary route for capturing the impact of the science that we fund will continue to be through Researchfish.

2.2.5.2 Definition of impact

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 may be included as one element of your pathway to impact. 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.

2.2.5.3 Assessment

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

- Contribution to achieving the MRC's strategic aims
- Potential for improving medical science
- Value for money

The impact summary and academic beneficiaries sections of the Je-S form, and the pathways to impact statement, will be used in the assessment of the proposal throughout the peer review process. Reviewers and board/panel members will be asked to consider the following points in their assessment of the proposal:

Identification of potential impact:

- Are all potential beneficiaries appropriately identified?
- Are the key areas where impact could be explored during the course of the grant appropriately identified and clearly articulated?
- Are the key areas where impact could be explored realistic?

Approach to delivering impact:

- Are the activities outlined by the applicant feasible and appropriate?
- Are the activities likely to deliver the impacts the applicant has identified?
- Does the applicant have the right team and people engaged to undertake the activities proposed?

2.2.5.4 Further information

Further information regarding all aspects of RCUK's approach to impact in research, including further guidance on completing your 'Pathways to Impact' statement is available on the RCUK website: www.rcuk.ac.uk/ke/impacts/

2.2.6 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 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.

For conflicted experts the following information must be provided in the covering letter:

- The name of the person not to approach
- The RO(s) they are based at
- A reason why they should not be approached

2.2.7 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 2.4.3). Detail of how this support relates to the proposal as a whole should be included in the case for support and in the pathways to impact attachment.
- 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

2.2.8 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.

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 MRCdatasharing@headoffice.mrc.ac.uk.

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

2.3 Research Council Facilities

Should they be required as part of the research project, applicants can choose one of two RCUK 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, Pathways to Impact)
- 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 - 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. 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 2.7).

2.5.2 Applicants' response to reviewers' comments

When an 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.

- 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 eg because of further later peer review comments, the existing copy will need to be removed and a new version uploaded

3. Resourcing

All research grant proposals and post-doctoral fellowship applications will be costed on the basis of full economic costs (FEC). If a grant is awarded, the MRC will provide funding at 80 per cent of the FEC and the RO(s) must agree to find the balance of FEC for the project from other resources.

Please note some calls have different FEC rates to the standard 80 per cent eg global health. Refer to call guidance for further information.

Universities and other HEIs will use transparent approach to costing (TRAC) methodology to calculate FEC. Other ROs can apply for FEC, provided that the methodology they adopt has been validated by the RCUK Funding Assurance as appropriate and robust.

3.1 Fund type

The application form requires that all costs are identified under the following four fund types:

Fund type	Description	Fund headings
Directly incurred costs	Costs that are explicitly identifiable as arising from the conduct of a project are charged as the cash value actually spent and are supported by an auditable record.	Staff Travel and subsistence Equipment Other costs
Directly allocated costs	Costs of resources used by a project that are shared by other activities. They are charged to projects on the basis of estimates rather than actual costs and do not represent actual costs on a project-by-project basis.	Investigators' salary costs* Estates Other directly allocated
Indirect costs	These are RO overhead costs They include the costs of the RO's administration such as staff, finance, library and some departmental services.	Indirect costs
Exceptional costs	Costs that research councils fund at 100 per cent of FEC. The two most common examples are studentships on centre grants, and costs directly incurred by overseas organisations. Capital items cannot be registered as exceptions under any circumstances.	Exceptional costs

* Where the investigator's time is not committed 100% on the grant

3.1.1 Directly incurred costs

3.1.1.1 Staff

The payroll costs of all staff, full or part-time, who work on the project, and whose time can be supported by a full audit trail may be included. When a person is contracted to work 100 per cent of their time on a single project (whether they are working full- or part-time) timesheets are not necessary. In all other cases, timesheets or project records are required. The need for such staff should be justified in the case for support.

Research assistants, whether named or unnamed should be requested at a salary level commensurate with the skills, responsibilities and expertise necessary to carry out the proposed research activity. Where an application includes provision for a named fellow, researcher, technician or support staff,

we will normally expect to award funds at the level requested; this should reflect their current salary.

Salary increments over the period of the project should be taken into account but not anticipated in future pay awards.

The RO, as the employer, is responsible for the contracts of employment of the staff concerned and consequently for any redundancy or other compensatory payments that may be required. Work permits, if required, are a matter for direct negotiation between the RO and the relevant government departments.

For any one investigator, the maximum amount of time that research councils will fund across all the projects they support is a maximum of 1650 hours a year (equivalent to 37.5 hours a week, 44 weeks a year). All staff fields throughout the proposal should be entered using this formula when answering questions regarding percentage of time worked.

The total salary costs for any individual on all research council grants and fellowships must not exceed 100 per cent FTE. Where the proposal is to be submitted before the RO has agreed details of the any pending new pay scale revisions, the research councils expect that the proposal will be costed on the basis of the organisations present pay structure.

Researchers supported on open-ended or fixed-term contracts may apply for grants and request funds for their own salary, providing they have a contract of employment with the RO for the duration of the grant. Where a PI is due to retire before the grant has ended, then the grant must also include details of a replacement for the remaining period and costs included for them for the required period. The research councils' conditions for grant awards do not include a requirement to appoint staff on a fixed-term basis. This is a matter for the employer to determine and is not related to eligibility for funding.

Please note that investigators, researchers and technicians may be included as either directly incurred, directly allocated or exceptions. 'Other staff' can only be included as directly incurred.

- **PIs and CoIs:** Proposals will need to show the costs of time to be charged to the project by investigators. This will be derived from hours on the project and relevant salary rate (which could be based on an average or pool rate). Research councils will not require time sheets to be completed as long as the individual is contracted to work 100 per cent on the project. Where a project outlasts a post, the expectation is that their current involvement in the proposal will be covered by a contract with the RO and that there are suitable arrangements in place to manage and take responsibility for an outgoing investigator.
- **Additional staff:** Salaries may be sought for research technical or other staff required to, work full- or part- time on the research.

Research staff can comprise postgraduate and post-doctoral scientists (including social scientists), statisticians, research nurses etc.

Please note however that costs for PhD studentships cannot be requested within MRC research or programme grants.

Salaries may be sought at a level appropriate to the research or the experience of a known individual, where this is in accordance with the salary scales and terms and conditions of service applying at the prospective host institution, and is justified in the proposal. For posts requiring recruitment, the salaries may be sought at an appropriate level using the salary rate pool banding. Salary levels should take account of the previous experience and professional contribution of a named individual, as well as their research responsibilities.

- **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 calculated in relation to paid staff of equivalent status in the host RO, and the request should be net of any contributions from other sources which themselves must be declared in the justification of resources section.
- **Infrastructure technicians:** Those whose costs are not included in the estates or indirect costs and whose time is shared across several projects or activities and will not be supported by an auditable record should be applied for under 'Other directly allocated costs' as 'Infrastructure technicians'. The costs need to be added as a single figure for the duration of the proposed research project as stated in the application. The infrastructure technician costs do not need to be justified in the 'Justification of Resources' section.

3.1.1.2 Travel and subsistence

A proposal may include funds for travel and subsistence for use by investigators and staff assigned to the project and 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.

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.

Please note that alcohol can only be included if accompanying a meal.

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.

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.

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

3.1.1.3 Equipment

This heading should be used for any equipment bought or leased for the project which costs £10,000 (inc VAT) or above. 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.

Please note the £10,000 includes all component parts of the equipment requested.

Single items of equipment costing less than £10,000 (inc VAT) should be included under the other directly incurred costs heading. Where the call is a capital call, costings over £10,000 such as refurbishment should also be included as equipment.

All fields must be completed for each entry when making an application and costings should be at current prices with no allowance for inflation.

Applicants are advised that all research councils have had extensive cuts in the amounts of capital they can award. Accordingly 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.

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 for more information on meeting this cross-council requirement.

Please note where it is not possible to provide 3 quotes eg 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.

The equipment section in the costings should be completed as outlined below:

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)

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 CoI.

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

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.

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.

Please note that the guidance 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.

3.1.1.4 Other costs

Costs sought should be specified as far as possible in the proposal and justified in terms of requirement for the research proposed.

Please note publication costs should not be included.

Costs should include:

- Consumables
- Recruitment and advertising costs for staff directly employed on the project
- Scanning/surveys
- Sub-contracting

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. For example if the ROs involved in the research do not have the required technology, such as specialist scanners to carry out a specific area of the project, they may decide to contract this work to another organisation. 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). Gene sequencing can be requested at 100 per cent.

RO collaboration, CoIs 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.

3.1.2 Directly allocated costs

It is the responsibility of the RO to have a process in place to monitor the time claimed by any investigator to ensure that no more than 100 per cent FTE (37.5 hours per week) of their time is claimed over all grants on which that individual is named. They should also ensure that estates costs for any individual do not exceed 100 per cent FTE across all grants by all research councils.

3.1.2.1 Investigators

PIs and CoIs should be included under this heading if their time charged on the grant is based on estimates, rather than actual costs. Where costs are actual, auditable and verifiable they should be included under directly incurred costs. Investigator time, not cost, must be justified in the case for support.

PIs and CoIs 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. If a PI or CoI 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 costed (up to a maximum equivalent of 37.5 hours a week) on the grant, usually under directly incurred staffing costs. Estates and Indirect costs can be requested regardless of whether they are getting a salary/payment or not.

PIs, CoIs and fellows, whose time and salaries have already been wholly (100 per cent) awarded in the FEC of previous research grant proposals or a single separate fellowship provided by the research councils, must make this clear in the application and request a zero salary.

Salary increments should be taken into account, but possible future pay awards should not be anticipated.

3.1.2.2 Estates

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. They will be calculated by the RO and a single figure will be required at time of application.

Please note estates cannot be included for technicians and research support staff.

Estate costs provide a share of the cost of providing the physical infrastructure for research. They will be calculated by each RO using TRAC methodology, so will vary between ROs and also between departments within ROs.

Where any named individual will be working away from the RO on long-term secondment for a period in excess of 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 applied to the original application to include the TRAC rates which were applicable at time of application.

3.1.2.3 Animal costs

These costs may be shown as either directly incurred costs or directly allocated. 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 eg 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.

3.1.2.4 Other directly allocated costs

These comprise all other direct costs calculated on the basis of estimates. Items that can be included within this heading are:

- Research and technical staff whose time is shared across several projects (such as pooled technicians) and no audit record of time is required, only an estimate
- Charge out costs for use of major facilities
- Charge out costs for use of existing equipment

  Charge out costs for departmental technical and administrative services

Please note that contributions from project co-funders should not be entered here. They should be detailed in the 'Project co-funders' section.

3.1.3 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. Information about the derivation or justification of indirect costs is not required.

Please note indirect costs cannot be claimed for technicians or research support staff.

It is the responsibility of the RO to have a process in place to monitor the time claimed by any investigator to ensure than no more than 100 per cent of FTE is claimed as indirect costs for any individual across all grants funded by all research councils.

They will largely be based on the research staff effort assigned to the project. The MRC and peer reviewers will not scrutinise them and will in general accept the values charged by the RO. They will need to be re-calculated by the RO if there are changes in the amount of investigator and/or other research effort awarded.

Where a MRC unit/institute is the lead applicant, any award will be made on the basis of 100 per cent directly incurred costs only and will not include indirect or estates costs.

3.1.3.1 Overseas staff

Investigators or project partners at overseas organisations are generally not eligible to apply for or receive indirect and/or estates costs.

However, applicants requiring overseas staff who are locally employed in a developing country should seek guidance from the MRC programme manager

in advance of submitting the application. The MRC may contribute to estates and indirect costs at its discretion.

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 ROs, the full cost of the proposed research (including indirect costs and estates costs) will be taken into account in any assessment of its value for money.

Please see the relevant Je-S help page for further details.

3.1.4 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

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.

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:

3.1.5 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 3.2.

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, is permissible 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).	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 CoI, 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 CoI status.

3.1.6 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).

3.1.7 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. CLRN contacts are available.

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.

If applying for NHS support costs or treatment costs, applicants should complete an NHS Costs proforma/template, which is available to *download from the MRC website (XLSX, 60KB)*. Please note that Je-S does not allow the upload of MS Excel files, therefore please convert the completed template to a PDF and upload it to the application as a 'Letter of Support'. Please detail the file's description as 'NHS support and treatment costs' .

A 'Letter of Support' must also be included with the application from the lead NHS provider acknowledging the amount requested and confirming that these are the likely costs.

For further information, please see:

- Responsibility for meeting patient care costs
- Attributing revenue costs of externally funded non-commercial research in the NHS (ARCO)
- EL(97)77: Meeting patient care costs associated with research and development in the NHS detailed guidance

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:

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.

3.1.8 Costs related to specific calls

- **Biomedical Catalyst: Developmental Pathway Funding Scheme (DPFS)**
- **Developmental Pathway & Clinical Studies (DCS) 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.

3.1.9 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.

3.2 Costing of applications involving MRC units and institutes (NOT university units)

MRC Units/Institutes may apply as lead applicant for MRC grants relating to their mission, applications to the Research Boards can only be made exceptionally with prior agreement between the Unit/Institute Director and MRC Head of Theme.

All MRC Unit/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 Directly Incurred costs for the Unit/Institute are eligible and only these should be included in the proposal form. 100 per cent of the unit/institute 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 Unit/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 units/institutes when applying for an MRC grant:

Directly Incurred costs	• Only Directly Incurred costs are awarded to MRC Units/Institutes (as lead or co-applicant). • Directly Incurred costs should only be requested if additional to the MRC Units/Institutes core funding and supporting work directly related to the research proposed. • 100 per cent of Directly Incurred costs for units/institutes will be paid; these should be included on the proposal form as an exception.
Directly Allocated costs	• Are not awarded to MRC units/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 (eg shared/pool staff supporting a range of facilities and projects) should be entered as zero on the proposal form. • Salary costs of all MRC staff should be included in the Justification of Resources.
Estates and Indirect costs	• Are not awarded to MRC units/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.

3.2.1 Collaborative applications lead by an MRC unit/institute involving other Research Organisations

Applications may be collaborative and involve costs for one or more ROs that are not MRC Units/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.

3.2.2 MRC Unit/Institute is a co-applicant

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

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

3.2.3 External Scientific Staff (ESS)

These are investigators and other scientific staff that receive a salary from MRC but are located outside of an MRC unit/institute. If ESS are involved in an application enter zero salary on the proposal form and ensure the ESS box is ticked. The salary should be included in the Justification of Resources. Estates and Indirect costs relating to ESS can be requested at the normal rate for the RO where they are located.

3.2.4 MRC institute/units applying for other Research Council grants

MRC units/institutes may apply to other Research Councils as a lead or a co-applicant. The application must be costed using FEC methodology. If

successful, the MRC unit/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 units/institutes should contact MRC Head Office before applying for any grants over £1m from other funders.

3.3 University units and the Francis Crick Institute

Eligible individuals from MRC University Units (UUs) and the Francis Crick Institute (Crick) may apply for MRC grants as either a lead or co-applicant. These grants are intended to support research relevant to Unit mission that is clearly additional to existing 'core' support. UUs apply as a department of the University.

Core supported Programme/Group Leaders may only apply for MRC Programme Grants in exceptional circumstances with prior agreement from MRC Head Office.

Grants to UUs and Crick 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.

UU/Crick 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.

UU core support is provided by MRC, Crick core support is provided by MRC, CRUK and Wellcome Trust

3.4 Support from other sources

3.4.1 Support on current projects

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 on their proposal form in the section 'Other support' 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.

3.4.2 Project co-funders

A project co-funder is an organisation which is jointly funding a project with the MRC. The relationship can be directly with the MRC or the RO. This could include charities, industrial or commercial companies and government organisations. The terms of the co-funding should be detailed in a memorandum of agreement/understanding.

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.

3.4.3 Project joint-funders

A joint funder is another research council that is jointly funding the grant with the MRC.

The MRC may enter into a jointly-funded call with another research council where the area of science falls across both remits. In this instance, the specific guidance for the call will clearly state to which research council the applicant should apply.

Where the proposal potentially falls within the remit of more than one research council, the applicant must contact the relevant MRC programme manager to seek further advice.

When an application is received by the MRC which falls within both the remit of the MRC and the remit of another research council, the MRC may enter into an arrangement with the other research council to jointly fund the project should it be awarded.

3.5 Research involving cohort resources

In addition to the general criteria for assessment, applicants should take account of the following factors:

Scientific potential and importance

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 also 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?
-

Resources requested

The grant application must make clear what new activities, including new data sweeps or new analysis of existing cohort data, will be carried out a

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.

4. Proposals involving animal use

4.1 Use of animals

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 *RCUK 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 eg 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.

4.1.1 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.

4.1.2 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

4.1.3 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 NC3R's *Experimental Design Assistant* can be found on the *NC3R's website*.

4.1.4 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.

4.1.4.1 Je-S section on 'Animal research'

Within the 'Animal research' section, researchers must give details of any procedures categorised as moderate or severe in order that the assessment of the proposal can balance the importance of the potential scientific advancement to the welfare of the animals.

4.1.4.2 Je-S section on 'Animal species'

Applicants are encouraged to provide the 'supporting information' as detailed below in the case for support 'methodology and experimental design' annex and not in the Je-S application form. In the narrative text field in Je-S, under 'Supporting information', please state the information is found at 'methodology and experimental design' annex. More information on the use of this annex can be found at Section 2.4.3. Please note that you are not required to duplicate information presented elsewhere in the application.

Under 'Supporting information', 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*).

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.

The scientific rationale for the experimental design should be explained in the case for support (*see section 4.1.4.3*).

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.

4.1.4.3 Proposal attachment 'Case for support'

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 '*methodology and experimental design*' annex) See Section 2.4.3 for more detail. There is no requirement to duplicate information.

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 in the animal species section of the form, see *section 4.1.4.2* above) 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.

4.1.4.4 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 3.1.2* 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.

Applicants planning research using rhesus macaques should obtain animals from the Centre for Macaques.

4.1.4.5 Proposal attachment 'Justification of resources'

A detailed justification of the costs incurred should be given in the justification of resources attachment (see *section 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.

4.1.5 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 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, ethical and normal 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.

4.1.6 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.

4.1.7 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

4.1.8 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.	Animal research section of the Je-S form the proposal (Section 4.1.4.1)
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.	Animals species section of the Je-S form under 'Supporting Information' for each species (Sections 4.1.1 and 4.1.4.2)
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)	Animals species section of the Je-S form under 'Supporting Information' for each species (Sections 4.1.1 and 4.1.4.2)
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.	Animals species section of the Je-S form under 'Supporting Information' for each species (Sections 4.1.1 and 4.1.4.2)
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.	Animals species section of the Je-S form under 'Supporting Information' for each species (Sections4.1.1 and 4.1.4.2
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,	Case for support attachment (Sections 2.3 and 4.1.4.3)

	behavioural changes)	
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 the relevance to human biology. Relevant information about the animals to be used (eg species, strain, sex, developmental stage, weight)	Case for support attachment (Sections 2.3 and 4.1.4.3)
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.	Case for support attachment (Sections 2.3 and 4.1.4.3
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 3.1.2 and 4.1.4.4)
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 3.1.2 and 4.1.4.4

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)
- Guidelines for Good Clinical Practice in Clinical Trials (1998)
- 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 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 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*.

If human tissue is being supplied by a third party, a letter of support from the third party must be attached to the application.

5.2.3 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.

5.2.4 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*.

5.2.5 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 High throughput sequencing hubs (accessing next generation sequencing)

The MRC has established four high-throughput sequencing (HTS) hubs with associated technical and bioinformatics support. The hubs are designed to support small and medium-sized projects by providing scientific, technical and bioinformatics expertise and capacity in the application of high-throughput DNA sequencing.

The MRC's preferred organisations for sequencing research are the MRC hubs. Where local facilities are not available, we expect researchers seeking MRC support to access services through the hubs in the first instance. Whilst there may be cheaper alternatives for next generation sequencing (NGS) services, the hubs are positioned to provide a higher-end service that justifies potentially higher premiums (eg expert input at the project development stage and analysis stage) and ultimately provide better value for money.

There is no special MRC fund or assessment procedure for applicants who wish to utilise the HTS facilities within the Hubs. Applicants requesting MRC grant support to use the hub resource should have liaised with the relevant hub manager in advance and be able to confirm within the application that the necessary access and support will be available. For contact details and further information please visit the MRC HTS resources page.

5.6 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.

5.7 National supercomputing facilities

Applicants wishing to use the national supercomputing resources of EPSRC, whether or not MRC financial support is required, should submit a Je-S application. For further information see EPSRC Supercomputers and HECToR.

5.8 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*

Please note: The policy on exploiting research and development software does not apply to software developed in the areas of defence, national security or law enforcement. Neither does it apply to software developed by Trading Funds.

5.9 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.

5.10 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 (PDF, 487KB)*.

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.

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