

# Research Management: a guide for medical research charities

Revised Spring 2014

## Guide to research management

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## Foreword

Medical research charities aim to make the most effective use of their resources through supporting the best science, and the best scientists. Setting strong research strategies, managing the research application and peer review processes and evaluating the outputs and impact of research are all key elements that research funders need to consider.

Over the years AMRC has worked with our members to develop principles of peer review which allow funders of all sizes to carry out high quality peer review of all their research funding. Membership of AMRC is recognised as a quality mark demonstrating that vigorous peer review processes are in place ensuring that only the highest quality of research is supported.

This document looks at how funders manage their grant management processes, and defines areas where AMRC's policies or the principles of peer review apply, or where there are examples of good practice or other case studies that charities might wish to consider.

Research funding mechanisms evolve, taking in new technology and ways of working. Research managers need to be kept aware of these changes, and we hope that this guide will be useful to those new to research management in charities and to those who are more experienced.

## 1 Introduction

#### 1.1 What is peer review and why should charities use it

Peer review is a way of assessing the quality of scientific ideas by subjecting them to independent scrutiny by qualified experts (peers). Funders use peer review when choosing what research to support. These experts are usually researchers or clinicians, but some funders also ask patients to provide advice on the feasibility or importance of the research. Both sets of people are 'experts', but have different areas of expertise.

Medical research charities receive many complex applications from biomedical, clinical and social scientists and, even in the largest charities, the staff and trustees are not usually sufficiently expert in all fields to be able to judge the quality of the research. Peer review therefore enables charity trustees to seek appropriate, independent, expert advice and remains widely accepted, both within the research community and outside it,

Properly conducted, peer review can and does provide a relatively unbiased view about which research should be supported. There are some challenges around peer review processes being not transparent, focusing on negatives and being overly bureaucratic,

#### 1.2 The principles of peer review

AMRC has developed 5 principles of peer review (see annex 1) to help medical research charities ensure that their peer review processes are of high quality.

**Accountability:** Charities are open and transparent about their peer review procedures and publish details, including the names of members of scientific advisory committees or other decision making bodies.

Balance: Scientific advisory committees reflect a fair balance of experience and scientific disciplines.

*Independent decision making:* The scientific advisory committee is independent of the charity's administrative staff and trustees.

*Rotation of scientific advisers:* Scientific advisory committee members have a fixed term of office and do not have tenure.

*Impartiality:* Scientific advisory committees include a significant number of non-beneficiaries (those who don't hold active grants from the charity) in addition to any lay representatives. There is a conflict of interest policy and potential beneficiaries are not present when decisions are made.

These principles are used to assess all new AMRC members, and to <u>audit all AMRC members every 5</u> <u>years</u><sup>1</sup>.

The principles of peer review can be implemented in a number of ways, reflecting the scale of the charity funding, so that regardless of their size, charities that fund using the AMRC principles of peer review can be assured that they are following best practice. The full principles are included in annex 1.

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<sup>1</sup> http://www.amrc.org.uk/our-work/peer-review/peer-review-audit

#### 1.3 AMRC policies

All AMRC members agree to abide by our policies. Our policy on <u>supporting research in universities</u><sup>2</sup> focuses on the role of a charitable funder to support the direct costs of research. Our policy on <u>animals in research</u><sup>3</sup> outlines the role of medical research funders in supporting the principle of using animals in research when it is necessary to advance understanding of serious health conditions to develop better treatments and there is no alternative. These policies are modified as circumstances change.

#### 1.4 How to use this guide:

This guide covers all aspects of grant management. Each section identifies the relevant policy or 'principle' of peer review, highlighting what is *mandatory* for AMRC membership and what is *good practice* that members may wish to consider. These advisory statuses have been taken from our <u>Principles of Peer</u> <u>Review</u><sup>4</sup> so that both documents complement each other.

We've included some new topics in this guide including changes in our policy on animal research and consideration of the replacement, refinement and reduction of animal use (3Rs). We have also covered areas of developing importance, such as open access, open data and research integrity. This document is not meant to be exhaustive and will be reviewed periodically and updated to reflect changing best practice. If you would like to share your good practice, please <u>get in touch</u><sup>5</sup>.

http://www.amrc.org.uk/contact-us

<sup>&</sup>lt;sup>2</sup> <u>http://www.amrc.org.uk/publications/statement-supporting-research-universities</u>

<sup>&</sup>lt;sup>3</sup> <u>http://www.amrc.org.uk/publications/statement-on-the-use-of-animals-in-research</u>

<sup>&</sup>lt;sup>4</sup> <u>http://www.amrc.org.uk/publications/principles-peer-review</u>

## 2 Research strategy

A published research strategy needs to clearly and comprehensively set out priorities for the broad areas of research a charity wishes to fund and why, and detail how funding will be used to meet these aims over the length of the strategy (usually 3-5 years).

A good research strategy links funding activities with the charity's mission and objectives, the wider research environment and patient need, and allows trustees, donors and beneficiaries to see how research funding will make a difference to the charity and its wider goals. It also helps charity staff, external peer reviewers and the scientific advisory committee assess whether an application for funding falls within the charity's remit.

The strategy should be regularly reviewed to make sure it is fit for purpose and maintains the charity's position within the research landscape, preventing overlap with other research and potentially bridging gaps where research may be lacking.

#### Mandatory

Accountability

Funders must have a published research strategy in place on their websites. Single institution charities need to have a research strategy that sets out the context for the competition for funding.

#### Good practice

Advice from the scientific advisory committee and wider network of advisers should be a major component of research strategy development. Charities should also set their research strategies in relation to the wider funding environment, and where appropriate, the needs of the patient groups they serve.

For more information see AMRC's Developing a Research Strategy<sup>6</sup>

Below are two examples where charities have used different methods to develop their research strategies. These give a flavour of how funders have focussed their strategy on the areas where research is needed.

#### Case Study: Gap Analysis – Breast Cancer Campaign

Breast Cancer Campaign periodically undertakes an analysis of the gaps in current breast cancer investigations to ensure they are supporting the most vital areas of research. The first analysis, published in 2008, led to the creation of the <u>Breast Cancer Campaign Tissue Bank</u><sup>7</sup> - the first of its kind in the UK and Ireland, which has given access to scientists across the country to the exact tissues they need to conduct their investigations. In 2013, the analysis was repeated and 9 speciality areas were identified for in depth evaluation. Over 100 experts worked to review the literature and met to identify the gaps. The results were collated, edited by an editorial board and published in a paper 'Critical research gaps and translational priorities for the successful prevention and treatment of breast cancer'<sup>8</sup>. This Gap Analysis allows Breast Cancer Campaign to work out where the scientific gaps are, and thereby develop their research strategy to support researchers to fill these 'gaps'. Alongside the Gap Analysis, a publication action plan 'Help us find the cures'<sup>9</sup> was launched outlining what Campaign and others need to do to tackle the gaps in order to overcome breast cancer by 2050.

#### Case Study: Priority Setting Partnerships – Parkinson's Disease

Parkinson's UK, Cure Parkinson's Trust and three academic partners have formed a <u>James Lind Alliance</u> <u>Parkinson's Diseases Priority Setting Partnership</u><sup>10</sup> that aims to work with people with Parkinson's disease, their carers and former carers, and with health and social care professionals. The partnership aims to identify and prioritise the most important research questions about the treatment and care of Parkinson's disease, including its symptoms and its impact on day-to-day living. This will help to guide Parkinson's research and make sure that researchers are addressing the most urgent needs of people living with the condition. Further information can be found here<sup>11</sup>.

<sup>&</sup>lt;sup>6</sup> http://www.amrc.org.uk/sites/default/files/doc\_lib/2013\_07\_developing\_a%20\_research\_strategy.pdf

<sup>7</sup> http://breastcancertissuebank.org/about-tissue-bank.php

<sup>&</sup>lt;sup>8</sup> <u>http://breast-cancer-research.com/content/15/5/R92</u> <sup>9</sup> <u>http://unww.broast-cancer-research.com/content/15/5/R92</u>

http://www.breastcancercampaign.org/documents/ga-2013/help-us-find-the-cures.pdf

<sup>&</sup>lt;sup>10</sup> <u>http://www.lindalliance.org/ParkinsonsPSP.asp</u>

<sup>&</sup>lt;sup>11</sup> http://www.parkinsons.org.uk/content/what-questions-should-parkinsons-research-answer

## 3 Application procedures

#### 3.1 Advertising awards

Funders should ensure that all grant schemes are advertised to a wide range of potential applicants, The advertisement should contain all the necessary information that researchers might need to complete their application such as:

- the remit and themes of the call (from very specific to wide ranging)
- the deadline for submission of applications
- links to the application forms and details of how to submit (including whether applicants need to complete an outline application)
- the maximum amount of funding that can be applied for (if applicable) or similar guidance
- the maximum duration of the project
- links to the grant terms and conditions and other relevant policies (intellectual property, animal research, patient data for instance)
- contact details for an appropriate member of staff to answer queries

Funders that support research at single institutes should ensure that all eligible researchers are aware of the call for applications.

#### **Good practice**

Funders should ensure that the process for application, strategic context and terms and conditions of award are easily accessible on their websites and to have a set calendar of deadlines, to allow researchers to plan their applications.

#### Example information for applicants and details of the peer review process

- Meningitis Research Foundation: information for applicants<sup>12</sup>
- Wellcome Trust: grant making process<sup>13</sup>
- The Motor Neuron Disease Association: peer review processes<sup>14</sup>

#### 3.2 Informal approaches by applicants

#### Mandatory

Independent decision making

Charities should be clear that decisions on scientific quality are made by impendent peer reviewers and not charity administrative staff

Applicants sometimes contact charities to ask informally about the appropriateness of their application and seek advice about the charity's remit. This can be really useful as it allows you to anticipate what applicants might come in as well as developing contacts in your research field.

#### **Good practice**

Funders should give accurate advice and information about research schemes on offer, whether they are eligible to apply and if their research would be appropriate. Charity staff should only decide if an application isn't suitable for funding when it is clearly outside the charity's remit – in which case you might, if appropriate, point them towards alternative sources of funding (see <u>RDInfo</u><sup>15</sup> for information about other funders). If you are unsure, it's good practice to ask your scientific advisory committee for confirmation.

Although preliminary or informal approaches should be welcomed, it's worth pointing out that they aren't a substitute for clear guidelines on the scope of funding schemes and eligibility. You might however find it helpful to point potential applicants towards examples of research that has been funded in the past.

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<sup>&</sup>lt;sup>12</sup> <u>http://www.meningitis.org/research/information-for-applicant/guidance-for-applicants</u>

<sup>&</sup>lt;sup>13</sup> http://www.wellcome.ac.uk/Funding/Biomedical-science/Application-information/WTD004051.htm

<sup>&</sup>lt;sup>14</sup> http://www.mndassociation.org/Resources/MNDA/Research/Documents/BRAP%20Governance%20overview%20-

<sup>%20</sup>version%201.5%20Nov2013.pdf

<sup>&</sup>lt;sup>15</sup> http://www.rdinfo.org.uk/

#### 3.3 Application forms

Application forms will vary from charity to charity but some common things that should be included are:

- applicant and co-applicants' names, position and experience (a brief CV) and the research institution where the research will be undertaken
- project title
- proposed starting date and duration
- brief abstracts of research in both scientific and lay terms
- details of project including purpose, background, methodology and citing existing literature
- financial details (salaries, superannuation, running expenses and consumables, equipment costs and other direct support costs)
- justification of support requested
- signed statement from head of department responsible for supervision of the research and the appropriate officers of the employing authority responsible for administering the grant;
- information about the use of animals, ethical approvals or animal home office licenses

Application forms may also include:

- details of previous grants and applications to other bodies
- additional details, specific to the research e.g. agreement to abide by good practice guidelines; disclosure of research outcomes which may result in intellectual property rights etc.

#### Example application forms

Some example application forms can be viewed here:

- The Stroke Association: <u>application form for projects</u><sup>16</sup>
- The AICR: <u>handbook for project grant applications</u><sup>17</sup>

#### 3.4 Lay abstracts

Although it's not mandatory for funders to ask for lay abstracts, they can help to put the research into context and be useful for developing information for fundraisers, donors and the general public. For charities that ask for lay opinions on the research as part of their decision making, a clear lay summary can make the difference between funding and rejection.

Lay abstracts should describe the planned research in an accessible language for a general audience. Some funders have a lay summary in a form of 'questions someone may ask' in order acquire the appropriate information.

#### **Good practice**

If the charity uses the lay summary as part of the decision making process, funders need to be explicit about what information should be included so that researchers can understand what is required. It's best practice to include this information on your website and in any guidance documents.

#### Example lay summary guidance

- Marie Curie Cancer Care: lay summary application form<sup>18</sup>
- British Heart Foundation: what to include in lay summaries<sup>19</sup>
- The Stroke Association: how to write a lay summary<sup>20</sup>

- programme/?utm\_source=CSmarketing&utm\_medium=offline&utm\_campaign=Research
- <sup>19</sup> <u>http://www.bhf.org.uk/research/research-grants-1/how-to-apply/lay-summaries.aspx</u>
   <sup>20</sup> <u>http://www.stroke.org.uk/research/how-write-lay-summary</u>

<sup>&</sup>lt;sup>16</sup> <u>http://www.stroke.org.uk/research/apply-project-grant</u>

<sup>&</sup>lt;sup>17</sup> http://www.aicr.org.uk/Docs/Applicant%20Handbook%20Oct13%20FINAL.pdf

<sup>18</sup> http://www.mariecurie.org.uk/en-gb/research/funding-for-palliative-end-life-research/marie-curie-research-

#### 3.5 Allowed costs

Universities cost research according to full Economic Cost (fEC) which identifies directly incurred costs, directly allocated costs and indirect costs.

#### Mandatory requirement

All AMRC members agree with our statement on <u>supporting research in universities</u><sup>21</sup>. Charitable funding of research relies on public donation and philanthropy and as such donors expect their money to be spent on research to develop treatments. Funders should therefore only support the directly incurred costs of research and shouldn't pay indirect or directly allocated costs.

#### Directly incurred costs are the direct costs of research and include:

- research staff (e.g. research assistant salaries, junior researchers at post-doctoral level). Charities
  paying salaries of staff working part time should check that their total FTE doesn't exceed 100% (i.e.
  if a researchers is already employed on a 75% contract, the maximum a charity should pay under a
  new grant would be 25% FTE)
- consumables and other costs directly attributable to the project
- the cost equipment specific to the needs of the project
- travel and subsistence

*Directly allocated costs* are shared costs based on estimates and do not represent actual costs on a project-by-project basis. Directly allocated costs may include:

- research investigators: the proportion of time spent by the senior researchers such as the principal investigator and co-investigators on a research project. Some charities specify that 'senior staff' are those who completed their PhD more than 10 years ago, and as such expect them to be employed by the university or fully funded from elsewhere so do not require funding for their own salaries
- other directly allocated costs: these include the costs of shared resources such as clerical and administrative staff, nurses, lab technicians, supervisors and collaborators who are already employed. Equipment not specific to the research such as lab supplies and lab equipment are also classed as directly allocated costs
- estates: the space used by researchers

Some charities may accept some directly allocated costs for specialised staff such as highly skilled technicians in specific techniques, statisticians and economists. However, this is normally dependent on receipt of strong justification by the research team and approval from the scientific advisory committee.

*Indirect costs:* these costs are necessary for underpinning research but cannot be allocated to individual projects, and cover computing and information support, central services, general maintenance, lighting, heating and other infrastructure costs.

Sometimes, universities ask funders to cover a proportion of the directly allocated and indirect costs of research. Charities need to make it clear that you do not pay towards these costs and that the government has established the <u>Charity Research Support Fund</u><sup>22</sup> to help universities to cover these. In England, the Charity Research Support Fund provides universities with up to a 28% uplift on the funds they receive from charities. This fund is distributed as part of the block grant, allowing charity money to be spent directly on research. HEFCE publishes <u>annual data</u><sup>23</sup> on the amount of CRSF awarded to each university department.

<sup>22</sup> http://www.amrc.org.uk/our-work/working-with-others/working-with-universities/charity-research-support-fund

<sup>&</sup>lt;sup>21</sup> http://www.amrc.org.uk/publications/statement-supporting-research-universities

 <sup>&</sup>lt;sup>23</sup> http://www.hefce.ac.uk/data/year/2014/201415qr/#d.en.86840

#### 3.6 Attributing costs in clinical research

AMRC members funding in open completion are eligible for additional government support towards the <u>costs</u> associated with undertaking research in the NHS<sup>24</sup>. Funders should ask for research applications to be costed using the Department of Health's <u>AcoRD</u><sup>25</sup> framework which defines the clinical research into three cost categories:

- NHS treatment costs: the patient care costs, which would continue to be incurred if the patient care service in question continued to be provided after the R&D study had stopped. These are met through the normal NHS commissioning process
- NHS support costs: the additional patient care costs associated with the research, which would end once the R&D study had stopped, even if the patient care involved continued to be provided. These are met by the R&D budget of the Health Departments of the UK.
- Research costs: the costs of the activities being undertaken to answer the research questions. These costs end when the research ends and are usually met by grant funders.

There are four types of research infrastructure cost that AMRC funders do not have to pay as these activities are covered by the Department of Health:

- o local study trial co-ordination and management
- data collection needed to answer the questions that the research study is addressing (including collecting data for and completing the report)
- regulatory preparation and compliance including obtaining ethical approval and complying with the Medicine for Human Use (Clinical Trials) Regulations 2004
- the time taken by chief and principal investigators (CI and PI) to explain the study to professional colleagues, and to understand, the research elements of a study

Under AcoRD, AMRC charities that fund in open competition don't have to pay these costs as they are indirect costs or related to the pre-existing research infrastructure within the English National Institute for Health Research Clinical Research Network (NIHR CRN) or equivalent networks throughout the UK.

The NIHR CRN have produced some guidance and <u>pre-application support</u><sup>26</sup> and <u>FAQ's on AcoRD</u><sup>27</sup> that you should point researchers towards if they are having difficulties completing their AcoRD finances. They are also developing a new service designed to help researchers and funders in England and Wales identify and attribute the activities in research studies. The tool and advice service will be piloted during 2014 and we will update this document when we have further information.

#### Good practice

Funders should be clear about the costs they are willing to pay, and the kind of justification that is required in exceptional circumstances. Application forms and supporting guidance should remind researchers that they need to work with their finance offices, clinical trials units, local NHS trusts and the local NIHR CRN network to ensure that all costs of research have been identified and appropriately paid for.

#### Examples costing guidance

- British Heart Foundation: <u>costing non-clinical research guidance salaries and stipends</u><sup>28</sup>
- The Wellcome Trust: <u>AcoRD guidance and allowable costs</u><sup>29</sup>

#### 3.7 *Ethical approvals*

All studies involving human participants need to have the appropriate ethical agreements in place. Research Ethics Committees (RECs) will not consider applications in advance of funding approval, so REC approval should always be a condition of granting an award and applicants must indicate that they are aware of this at the time of submission.

<sup>&</sup>lt;sup>24</sup> http://www.amrc.org.uk/our-work/funding-clinical-studies/acord-costing-research-in-the-nhs

<sup>&</sup>lt;sup>25</sup> https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

<sup>&</sup>lt;sup>26</sup> http://www.crncc.nihr.ac.uk/researchers/planning\_your\_study/AcoRD

<sup>&</sup>lt;sup>27</sup> https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/260709/AcoRD - FAQs\_updated.pdf

http://www.bhf.org.uk/research/information-for-researchers/how-to-apply/costing-salaries-and-stipends.aspx
 http://www.wellcome.ac.uk/funding/biomedical-science/application-information/wtd004084.htm

Studies taking place in the NHS also require approval from the host NHS organisation, using the Coordinated system for NHS permission (CSP), which is requested after funding has been approved. CSP looks at how the research will be carried out, who will act as sponsor and whether all the necessary resources are available to allow the study to progress.

The <u>Health Research Authority</u><sup>30</sup> manages the National Research Ethics Service. It has recently been granted funding from the Department of Health to streamline assessment and approvals by incorporating assessments by NHS staff alongside independent REC opinion. This will mean researchers will be able to submit one application, have one assessment and one approval for research in the NHS in England.

#### **Good practice**

Many funders require copies of approval letters before they will activate the grant, and allow funds to be paid to the researcher. For grants where approval is sought later in the grant, funders should monitor the progress of the grant and may use milestones/deliverables to ensure that the grant progresses as expected.

#### Information sources

- <u>Stem cells tool kit</u><sup>31</sup>
- <u>Clinical trials tool kit<sup>32</sup></u>

#### 3.8 Electronic application systems

Most funders require electronic versions of grant applications as this allows them to easily transfer information between systems and to peer reviewers. Some funders still ask for a paper copy with signatures as this forms part of their record of award whereas larger funders often use online application products that are tied into their research management systems.

Choosing an online application system can be complicated and it depends on the specific needs of the charity. If you are thinking about which system to choose, it is important to weight up the pros and cons and try to speak to other funders who are using them. These systems can be expensive to develop so might not suit funders with a smaller portfolio. Below are three examples where charities are using these online systems - these might be helpful starting points if you are considering looking into this.

#### Case Study: Electronic Grant Management System (eGMS) – Cancer Research UK

Cancer Research UK use a bespoke online application process to reduce the administrative burden of peer review. This system is called <u>eGMS</u><sup>33</sup> and guidance on how to use it is available <u>here</u><sup>34</sup>. Researchers can log into the system and prepare applications online. Once submitted, these can be made available to external peer reviewers (providing they agree to undertake peer review) and the scientific advisory committee. eGMS is also used to monitor live grants through the annual reporting process.

#### Case Study: CC Grant Tracker – Multiple Sclerosis Society

The Multiple Sclerosis (MS) Society uses an online application system called <u>CC Grant Tracker</u><sup>35</sup> for all funding applications. As with other systems, researchers register and log in to CC Grant Tracker to apply for funding and manage existing grants. For the MS Society, this system has replaced the submission of hard copies of applications and electronic versions sent in via email.

#### Case Study: Benefactor – Tenovus

Tenovus uses a grant management tool called <u>Benefactor</u><sup>36</sup> which has been designed specifically for grant giving organisations. Benefactor can be configured to meet an individual charity's processes and you can change the terminology so it matches your own. It also has some financial tracking capability.

<sup>&</sup>lt;sup>30</sup> http://www.hra.nhs.uk/

<sup>&</sup>lt;sup>31</sup> http://www.sc-toolkit.ac.uk/home.cfm

<sup>&</sup>lt;sup>32</sup> http://www.ct-toolkit.ac.uk/

<sup>&</sup>lt;sup>33</sup> https://egms.cancerresearchuk.org/egms/Implementation/Modules/Login/LoginModuleContent.aspx?Config=LoginModuleConfig& Page=Login

<sup>&</sup>lt;sup>34</sup> http://www.cancerresearchuk.org/science/manage-grant/egms/

<sup>&</sup>lt;sup>35</sup> <u>http://www.cctracker.co.uk/index.stm</u>

<sup>&</sup>lt;sup>36</sup> http://www.gallerypartnership.co.uk/grant-management

#### 3.9 Terms and conditions

The terms and conditions of award make up the contractual side of a research grant. Application forms often include a statement that applicants and their institutions agree to abide by terms and conditions so it is important that they are easily accessible on your website. Typical areas that terms and conditions cover are:

- research integrity and good conduct
- employment, administration of the grant and reporting
- audit
- availability of equipment
- publications and publicity
- intellectual property
- liability limitation
- variation and termination
- governing law

Some funders also include terms covering ethical approval, open access publication and Europe PubMed Central, data sharing, the 3Rs and sponsorship of clinical trials.

#### Example terms and conditions

The MS Society: <u>terms and conditions</u><sup>37</sup>

#### 3.10 Open access

Research papers that are 'open access' (OA) are available online and can be viewed by everyone, not just academics that have access via their libraries. A growing number of AMRC members require the researchers they fund to publish in open access journals by including it in their terms and conditions. For clinical research, AMRC and many of our member charities support the <u>All Trials Registered</u>, <u>All Trials Reported</u> campaign<sup>38</sup> which pushes for all clinical trials to be published, even if the results are unclear. There are two 'types' of open access that funders might consider:

*Gold OA:* allows the research paper to be made open immediately, but most publishers charge for this. *Green OA:* allows researchers to make a copy of the paper available after an embargo period (the time when the paper is published and available to academics, but not openly available) at no extra cost.

#### **Good practice**

If you mandate that research papers must be open access, your terms and conditions should be clear on what the maximum embargo period is and whether you will allow researchers to charge any additional fees directly to you, or use existing grant money to pay for them.

In 2012, the UK government <u>agreed</u><sup>39</sup> that all papers arising from research they fund (through the Research Council and government departments) should be open access. With this change in policy, many charities are concerned that there will be additional costs that will be borne by funders, particularly as there seems to be a growing push for immediate 'gold' OA rather than delayed 'green' OA. <u>AMRC's Open Access Working</u> <u>Group</u><sup>40</sup> is developing a position statement for all AMRC charities and is investigating ways of reducing the burden of administering open access. You may wish to nominate a member of your research team to learn more about open access, so they can advise researchers and field questions. Below are two case studies from our members who have policies on open access. These might be helpful if you are thinking about developing your own policy or if you are looking for guidance on how to handle any queries relating to this.

#### Case Study: Open Access – British Heart Foundation

The British Heart Foundation has an open access publication policy stating that the research it funds should be made freely available to the broader scientific community and the public. It asks that an electronic copy of each primary publication is made freely available in <u>Europe PubMed Central</u><sup>41</sup> as soon as possible and no later than 6 months after publication, and this is part of their <u>Condition of Grant</u><sup>42</sup>. They support immediate, unrestricted ('Gold') open access to primary research articles and will cover the costs of these fees.

- <sup>39</sup> http://www.researchinfonet.org/publish/finch/
- 40 http://www.amrc.org.uk/our-work/open-access-and-open-data/open-access
- <sup>41</sup> <u>http://europepmc.org/</u>

<sup>&</sup>lt;sup>37</sup> http://www.mssociety.org.uk/sites/default/files/Research%20grant%20award%20conditions.pdf

<sup>&</sup>lt;sup>38</sup> http://www.amrc.org.uk/blog/amrc-supports-campaign-all-trials-be-registered-and-results-reported

<sup>&</sup>lt;sup>42</sup> http://www.bhf.org.uk/research/information-for-researchers/how-to-apply/standard-conditions-of-grant.aspx

#### Case Study: Making Funds Available for Open Access – Marie Curie Cancer Care

Marie Curie Cancer Care allows the costs of open access publication fees on grant applicants as indicated in their terms and conditions<sup>43</sup> of grant. They also allow applicants to use any under spend on a grant to support open access fees. Researchers working at Marie Curie Centres can apply for open access fees for publications from research that is fully or part-funded by Marie Curie directly and costs might be met in full of partly. This has the added benefit of highlighting upcoming publications at the point of acceptance and gives an opportunity to ensure the funder is adequately acknowledged.

#### 3.11 **Open data**

It is very common for medical research projects to include large data sets that are developed as part of the project. These data sets can be as important as a peer reviewed publication, as they allow other researchers to understand what has happened and compare it with their own information sources. Open data are available freely and are usually held in separate data repositories. Many funders ask that researchers develop a data sharing plan as part of their funding application to show how data will be made 'open'.

#### Good practice

Funders that want to encourage open data should make this clear in their terms and conditions, and define what types of research projects need a data sharing /management plan. Examples of this are shown in the case studies below.

#### Case Study: Open Data – The Wellcome Trust

The Wellcome Trust aims to make research data widely available to the research community in a timely and responsible manner to maximise public benefit. Their <u>data sharing policy</u><sup>44</sup> explains that researchers, research institutions, providers, funders and publishers all have a role to play in creating an environment where integrity and transparency are a central part of managing, using and sharing research data. The Wellcome Trust expects all of its funded researchers to maximise the availability of research data with as few restrictions as possible. They also ask that applicants detail their approach for managing and sharing data in their applications so that these plans can be assessed during the funding decision process.

#### Case Study: Policy on Data Management and Sharing – Parkinson's UK

Parkinson's UK is committed to ensuring that the outputs of the research it funds, including research data, are managed and used in ways that maximise patient benefit. Making research data readily available to the research community ensures they can be verified, built upon and used to advance knowledge and its application to generate improvements in health. This is detailed in their <u>policy statement</u><sup>45</sup>.

#### 3.12 Animals in research

Although not all AMRC members fund or have funded research involving animals, all AMRC charities support the principle of using animals in research when it is necessary to better understand health conditions and diseases and develop new and better treatments, only when there are no alternatives. AMRC members only fund research which complies with the law and support the principle of the <u>3Rs</u><sup>46</sup> - to refine, reduce and replace the use of animals in research. Many funders already ask for evidence of consideration of the 3Rs in research applications and we are working with our members to share good practice and ensure they can exceed the regulatory requirements to improve animal welfare and science.

#### **Good practice**

AMRC has signed the <u>Concordat on openness on animal research</u><sup>47</sup> and we encourage funders to be open about research they fund that involves animals. It is good practice to do this in the scientific context of what the research has or hopes to achieve and it should be backed up with supporting material explaining why it's required (e.g. there are no suitable non-animal alternatives). This helps to reassure supporters that this work is not undertaken lightly, and is only done when there are no alternatives. Further information to help you to talk to the public about animal research can be found <u>here</u><sup>48</sup>.

- 44 http://www.wellcome.ac.uk/about-us/policy/policy-and-position-statements/wtx035043.htm
- 45 http://www.parkinsons.org.uk/sites/default/files/researchpolicy\_datamanagement\_6.pdf
- <sup>46</sup> http://www.amrc.org.uk/our-work/animal-research/what-are-3rs

<sup>&</sup>lt;sup>43</sup> <u>http://www.mariecurie.org.uk/Documents/Research/funding-research/2014\_Programme/Terms-and-Conditions-21Nov2013.pdf</u>

<sup>&</sup>lt;sup>47</sup> http://www.understandinganimalresearch.org.uk/policy/concordat-on-openness-on-animal-research

<sup>&</sup>lt;sup>48</sup> http://www.amrc.org.uk/sites/default/files/doc\_lib/Talking-to-the-public-about-animal-research.pdf

#### 3.13 AMRC policies on animal research and consideration of the 3Rs

Guided by our <u>Animal Research Working Group</u><sup>49</sup>, AMRC has developed a number of <u>policies</u><sup>50</sup> on animal research, three of which will become mandatory requirements for all members over the coming years.

#### Mandatory

1. Publicly support our statement on the use of animals in research

All AMRC funders must support our position <u>statement</u><sup>51</sup> on the use of animals in research and must indicate so on their own websites. The statement sets out our support for research using animals where there is no alternative and where there is a clear link between the research and advancing the understanding of disease, preventing disease or developing potential treatments. We have provided some <u>suggested wording</u><sup>50</sup> to do this and although you don't have to use these words specifically, they do offer one way to capture the essence of the message of our sector. If you wish, you could of course reproduce the statement directly on your website. This will be mandatory by November 2014.

2. Consider the 3Rs (replacement, refinement and reduction of animals in research) in peer review

We've made it clear that charities funding animal research should consider the 3Rs in their peer review processes. This means that you need to include <u>questions on the 3Rs</u><sup>50</sup> in your funding application forms and ask <u>peer reviewers</u><sup>50</sup> to consider the 3Rs as well as making sure they are briefed on the report 'Responsibility in the use of animals in bioscience research: Expectations of the major research council and charitable funding bodies'<sup>52</sup>. You should also refer grant applications using animals under special protection (non-human primates, cats, dogs, equines) or raising any particular concerns to NC3Rs for additional peer review<sup>50</sup>. These processes should be in place for the 2015 peer review audit and will be mandatory by 2017.

3. Provide us with details on the use of animals in our annual data collection

It's important that we have a good understanding of animal research funding practices across the sector so we have asked all AMRC members to provide three additional pieces of data for each grant reported annually:

- 1. Are animals protected under UK law used in this project?
- 2. Which animal species is used?
- 3. Are any of these animals genetically modified?

These data should be included in grants awarded in 2014 (reported in February 2015) and mandatory for grants awarded in 2015 (reported in February 2016.)

#### **Best Practice**

You should consider updating your <u>grant terms and conditions</u><sup>50</sup> to promote the consideration of the 3Rs by potential applications. In doing so, you should also include reference to the <u>ARRIVE guidelines</u><sup>53</sup> and the report '<u>Responsibility in the use of animals in bioscience research: Expectations of the major research</u> <u>council and charitable funding bodies</u><sup>52</sup> for reporting research using animals.

#### Information sources

- Cancer Research UK's public facing <u>leaflet</u><sup>54</sup> explains the use of animals in research
- <u>Parkinson's UK policy statement on the use of animals in research</u><sup>55</sup> and example <u>terms and</u> <u>conditions</u><sup>56</sup> talk about research involving animals

- <sup>51</sup> http://www.amrc.org.uk/publications/statement-on-the-use-of-animals-in-research
- <sup>52</sup> http://www.nc3rs.org.uk/page.asp?Id=871 <sup>53</sup> http://www.nc3rs.org.uk/page.asp?id=1357

- <sup>55</sup> http://www.parkinsons.org.uk/sites/default/files/policystatement\_animalsinresearch.pdf
- <sup>56</sup> http://www.parkinsons.org.uk/sites/default/files/researchgranttermsconditions.pdf

<sup>&</sup>lt;sup>49</sup> http://www.amrc.org.uk/our-work/working-with-our-members/animal-research-working-group

<sup>&</sup>lt;sup>50</sup> http://www.amrc.org.uk/our-work/animal-research/amrc-policies-on-animal-research

<sup>&</sup>lt;sup>54</sup> http://publications.cancerresearchuk.org/downloads/product/CRUK\_Animal\_Research\_Leaflet.pdf

## 4 Outline applications and triage

#### 4.1 **Outline applications**

Some charities ask applicants to submit an outline of the proposed research before they complete a full application. This helps the charity to assess whether the proposal falls within its remit and whether it can offer the most appropriate funding scheme for the applicant. Outline applications are often reviewed by a subset of the scientific advisory committee, or by charity research management staff. Applicants that are approved at this stage are then invited to submit a full application. The process is described in the flowchart below and a case study below.



#### Case Study: Outline Applications – Action Medical Research

Action Medical Research request all applicants to first <u>submit an outline application</u><sup>57</sup> before a full application is invited. The charity's scientific advisers determine whether the proposed work is within remit and that the work is also of sufficient quality to be recommended for further assessment. Successful applicants from the outline stage are invited to make a full application. Awards are made following peer review.

<sup>&</sup>lt;sup>57</sup> <u>http://www.action.org.uk/our\_research/apply\_research\_grant/outline\_proposal</u> Guide to research management – Spring 2014

#### 4.2 Triage

Mandatory	independent decision making			
AMRC charities that use triage must ensure it is fair and transparent to researchers.				

Triage can be used to reduce the number of applications that are sent for external review by taking out applications that do not fit with the research strategy (this can be decided by charity staff) or are of too poor quality (to be decided by the chair or other members of the scientific advisory committee). Triage can occur at the outline or full application stage and it helps to focus efforts on only the best applications.

Triage is often done by the scientific advisory committee or a sub-set of members. They are asked to consider whether applications merit further consideration and if they should be sent to external reviewers. Those that are not considered to be of sufficient quality are removed from the application process at this stage.

Triage should be done fairly and independently and it's important that funders explain the decision-making process to all potential applicants and for unsuccessful applicants to be informed at the earliest opportunity. Below is an example of how one of our members handles the triage process that might be useful starting point if you are thinking of introducing a this process.

#### Case Study: Triage – Breast Cancer Campaign

Breast Cancer Campaign has a scientific advisory board (SAB) to review all the submitted applications. The SAB use a triage system to identify at an early stage any proposals which are unlikely to be funded. Each application is reviewed and scored by two members of the SAB from 1 to 10. Applications scoring under 6 by both reviewers are not considered further. Final triage decisions are made by the Chair and Deputy Chair of the SAB, based on the reviews provided by the two members of the SAB. The SAB reviewers' comments are fed back (verbatim but unattributed) to all applicants afterwards. The benefit of doing triage is that it reduces the number of applications that require external peer review thereby freeing up the research manager's time.

## 5 External reviewers

#### 5.1 Why use external reviewers as well as an internal committee?

#### Mandatory

All AMRC members must use external peer review for grants over £25,000 per annum or for smaller grants where the panel lacks the relevant scientific expertise.

All AMRC members must use external peer review in conjunction with committee assessment for all grants over £25,000 per annum. At least two external reviewers should be obtained. However applications that cover a wide range of techniques, or are complex and multi-disciplinary or very expensive (such as programme grants) will need more. This may mean that several reviewers need to be approached to secure the requisite number of reviews.

Charities should also use external reviewers:

- for any grant that represents a significant proportion of the charity's grant giving and for all awards of more than a year's funding;
- for all applications from members of the advisory committee and for applications from researchers associated with them or their departments;
- where up-to-date expertise in the field in question is not available on the advisory committee.

For some types of funding schemes and where a quick decision is needed, external review may be unnecessarily cumbersome. A number of charities offer a 'fast-track' system for awards under £25,000 per annum which might include:

- pump-priming grants for less than one year's funding
- travel awards

#### Good practice

Charities should seek the opinion of experts where they do not have that expertise on their scientific advisory committee, for example clinical trials or animal research. Larger grants (e.g. rolling programmes, units, core funding) require more extensive assessment and usually a site visit, involving appropriate experts from the review panel, as well as external experts, sometimes from overseas.

#### 5.2 Selecting external reviewers

#### Mandatory

Balance & independent decision making

AMRC charities must use a variety of methods to select external peel reviewers, and not rely on a single person/small group to nominate peer reviewers. The process used to assign reviewers to applications must be fair.

Selecting appropriate external reviewers is vital to the success of the peer review process. An external reviewer may be a scientist but may include other professionals, as well as lay people, if their expertise is appropriate to the application.

#### **Good practice**

Charities should seek to have a wide pool of reviewers from diverse institutions, covering the full range of research interests of the charity. Research administrators and managers may wish to build a list of reviewers covering the breadth of expertise in particular areas. Charities should consider using scientists based overseas to supplement UK-based peer reviewers and the same reviewer shouldn't be used more than once in any grant round.

Reviewers should be expert in the particular field or closely related field of the application. They should be based at an academic institution or hospital, be relatively senior and have a strong publication record. Reviewers from industry should be avoided unless they bring specific expertise, as this may lead to conflicts of interest, particularly if industry is funding or supporting a similar project.

Some charities invite applicants to suggest external referees. If you do, you should check for conflicts of interest and there should be no commitment to use those who are nominated. Some funders also ask applicants to tell them who they do not want to review their application but this should be accompanied with strong justification as to why (for example, a known competitor in the field or perhaps a continued disagreement between competitors that may result in an biased review). You may wish to discuss with the committee chair if you are unsure whether the justification is valid.

Difficulties of overuse of external reviewers can be problem (particularly in small research fields) and you should avoid sending more than 3 or 4 requests to the same reviewer each year. Seeking overseas reviewers can help to overcome this problem but it is advisable to ask them to comment on the scientific merit of applications rather than the financial aspects due to wide international variations in the costs of undertaking research.

Smaller charities without specialised research grants administrators may find it difficult for the committee chair to carry sole responsibility for selecting reviewers. In this situation, charities might invite the entire committee to discuss the choice of reviewers or appoint another member of the committee to assist the chair.

A variety of mechanisms may be used to select reviewers. For example, the committee chair can work with the research administrator, the research administrator can work alone or the most appropriately qualified member of the advisory committee can suggest names. A database of reviewers may be drawn up using a range of resources including:

- suggestions from committee members;
- publication databases (e.g. Europe PMC);
- other charities; professional bodies, or the MRC.

#### 5.3 Contacting external reviewers

Funders normally ask external referees to undertake a review by email and send a copy of the application abstract. They may refuse either due to lack of time or conflict of interests but might suggest other people to approach or nominate a colleague. You should check these names as they may not have the experience of expertise needed to do a fair and balanced review.

When you are contacting external reviewers, a personal approach can be helpful and you may need to be flexible on deadlines.

#### 5.4 Payment

Charities are often concerned about the challenge of finding external reviewers and wonder whether payment might make the process easier. Most researchers consider taking part in peer review an important and valuable part of their overall academic role. They do not require payment to act as external referees but would value feedback and some acknowledgement. Telling external reviewers the outcome of an application they have reviewed and formally thanking them for their work in annual reviews or reports helps to demonstrate their contribution.

In our 2010-11, peer review audit, only 6 charities out of 116 made payments for external peer review (2 paid honoraria and 4 paid between £30-100).

#### 5.5 External reviewers' comments

It is important to allow external reviewers sufficient time to complete a review: at least two weeks is recommended for reviewers to read and comment on an application, remembering that they will have many other demands on their time. Charities need to be aware that there are certain times of year where delays might be expected, for example, the university examination periods, the summer holiday period and over Christmas. Dates of the main conferences for specific disease areas should also be noted.

An invitation to suggest other experts in the field can also assist in expanding the database of reviewers.

#### Mandatory

#### External referees need to confirm that they do not have a conflict of interest.

#### **Good practice**

A standard form, which enables reviewers to provide comments on the key aspects of the application and allows them to indicate where he/she does not have the appropriate expertise to comment, is recommended. The form should include sections for anonymised comments that will be shared with applicants as well as named comments that will be shared with the scientific advisory committee.

External reviewers' reports should be available to chair and the committee member(s) who will 'lead' the discussion about the application at the committee meeting. All members, taking into account any potential conflicts of interest, should see the reviewers' written reports.

#### 5.6 Applicants responding to external reviewer comments

Some funders send anonymised peer review comments (minus any scores) to the applicants before the committee meeting and invite them to respond, identifying any changes they may want to make or to defend their ideas. Although this practice increases the workload, it may help funders that are keen to develop areas of research where the number or quality of applications is poor or highly variable.

Applications, external peer review comments and any responses should then be sent to the scientific advisory committee for review before the committee meeting.

## 6 The Committee

#### 6.1 Choosing a chair for the scientific advisory committee

Your committee will contain a group of experts from fields related to your research strategy. For charities with a broad remit, the fields will range across diseases, types of research and different methodologies. It is vital that the chair of the committee is able to manage such a diverse group, as the committee has difficult decisions to make in the limited time of the meeting. The chair should be a well respected expert, who has a clear idea of the charity's mission and research strategy, and the particular aims of the funding stream under review.

#### Mandatory

#### Independence, rotation & impartiality

The chair may apply for grants, but if they do so, they shouldn't attend the whole meeting, and committees must have a nominated vice chair. As with all committee members, the chair should have a fixed term of office and should operate under the charity's conflicts of interest policy. The chair can be a trustee of the charity, however they must only vote on whether applications should be funded in either the committee meeting or the trustee's meeting – they shouldn't have the opportunity to vote twice as this unbalances the nature by which funding decisions are made.

For some charities, particularly those working in a narrow field or a single disease, a 'disinterested' chair from a related scientific or other appropriate area, or someone who has recently retired, could be very helpful in providing impartial guidance to the committee.

As with all members, the chair should have a 3 year term of office, with the possibility of renewing for a second 3 year term.

#### **Good practice**

Charities often ask the previous chair or committee members to suggest a successor, who trustees invite to undertake the role. To allow a smooth transition, charities often ask the new chair to join as a committee member for the chair's last year.

#### 6.2 Committee members

Your scientific advisory committee should be made up of experts from fields related to your research strategy, and from a wide range of institutions. For charities with a broad remit, the fields will range across diseases, types of research and different methodologies. You may also wish to include statistical expertise on your committee, particularly if the applications you receive are likely to contain information on sample sizes and statistically significant end points, or if you are funding clinical research.

#### Mandatory

Accountability, impartiality, balance & independence

Charities must have an advisory committee of more than 3 members including the chair and they should publish the names of their committee members on their website as part of the information about the peer review process. No more than 50% of the members of the committee should be actively in receipt of grants from the charity. All committee members should be appointed for a fixed term of office and should operate under the charity's conflicts of interest policy

Committee members should be appointed for a fixed term of office of 3 years, with the possibility of renewing for a second 3 year term. Charities should attempt to stagger terms of office so that there is overlap between members with different amounts of service on the committee. Committee members may apply for grants, but charities should ensure that all awards are approved subject to their conflict of interest policy (see 6.5).

#### **Good practice**

We recommend the committee should be of at least 5 people including the chair, meet face-to-face, though teleconferences and video conferencing can be effective at allowing international members to participate. New committee members should have an induction about the aims and research strategy of the charity and how the committee evaluates applications.

A single individual shouldn't be responsible for nominating all members of a committee and membership should represent a fair balance of experience, scientific disciplines, institutions, age, gender, ethnicity and geographical location.

Advisory committees should also have a significant number of non-beneficiaries (i.e. members whose institution doesn't benefit significantly from funding or other charity support, whose department or research group isn't in receipt of a grant, and those who themselves are not grant holders). Charities should be aware of any possible conflicts of interest that may arise in light of committee members being beneficiaries and this should be covered in a conflict of interest policy (see 6.5).

Scientific advisory committee members shouldn't discuss applications with applicants outside of the committee meeting and, similarly, applicants should not approach committee members either before or after the committee meeting - all correspondence should be made via the charity.

#### 6.3 Lay members

#### **Good practice**

Charities should consider incorporating lay opinion in peer review.

Many funders include lay members on their scientific advisory committee, or on separate committees, to incorporate the views of patients or carers. These members often have direct experience of a particular condition or disease so bring a valuable and unique perspective over what research should be funded. Lay members can also help to provide a strategic or practical challenge to grant applications, asking 'how does this research fit with our strategy' or 'is this research important to people with our condition'. For clinical projects, lay members can also assess the feasibility of doing a study for a particular patient group.

Feedback from AMRC members indicates that if lay reviewers are invited to sit on the main committee, it is preferable that at least two attend to ensure that a lone lay reviewer does not feel isolated or uncomfortable in their role. Lay experts shouldn't comment on the scientific aspects of applications, so it is important that applicants write a clear lay summary of their research proposal for lay readers. They can also be helpful for the charity in disseminating knowledge about the way it allocates funds for research.

Other factors that charities may wish to consider when using lay reviewers include:

- clarity from the outset about why the charity is involving lay reviewers;
- allocating sufficient resources to supporting lay reviewers, including additional time that may be required from administrative staff;
- lay reviewers must also be able to devote time to the process and should already have demonstrated commitment to the charity and understand its mission and aims;
- the selection process for lay reviewers should be transparent and, like scientific reviewers, they should serve a set term of office;

There should be an induction process for lay reviewers and, if possible, they should attend a meeting of the scientific advisory committee or the lay review panel before they commit to serving.

#### Case Study: Service User Panel – The Stroke Association

Applications that are supported by the Stroke Association's scientific advisory committee are sent out for additional review by their <u>Service User Panel</u><sup>58</sup>. This panel involves stroke survivors, family members and carers in the decision making process. Applicants applying for funding are asked to fill in a plain English summary form which asks questions that stroke survivors feel are most important. The panel then ranks each application from highest to lowest in terms of priority for funding. Although panel members do not need a medical background, they must have a personal link to stroke and an interest in research.

#### Information sources

• The <u>Natural Ground report</u><sup>59</sup> shows how some medical research charities are developing and incorporating patient and public involvement (PPI) methods into their grant giving activities.

<sup>58</sup> http://www.stroke.org.uk/research/help-us-choose-what-research-fund

<sup>&</sup>lt;sup>59</sup> http://www.amrc.org.uk/publications/natural-ground-paths-patient-and-public-involvement-medical-research-charities

#### 6.4 Committee meetings

#### Good practice

Scientific advisory committee meetings run differently depending on the charity but there are some commonalities that should be considered:

- one to three (normally two) the committee members should lead discussions on each application. These members need to do a thorough review so should have copies of all the external reviewers' reports and any lay panel comments well before the committee meets.
- if a committee member is unable to attend a meeting, it's good practice to ask them to send in written comments before the meeting so that these can be shared with the rest of the committee and included in the discussions.
- circulating the external reviewers' reports to members before the committee meeting can be more useful than tabling reviews on the day or asking staff to summarise them.

The maximum number of applications that can be discussed in a full-day meeting can vary considerably and will depend, in part, upon whether all applications will be discussed in detail and how quickly the committee reaches agreement. It's helpful to try and strike a good balance between the number of applications that can be considered and the time for discussion and decision-making during the course of a day-long meeting. Talking through the timings with the committee chair can be helpful in steering how the meeting might run.

Scoring the applications by all panel members before the meeting can save valuable time on the day, particularly if they are collated by the grant management staff and the results provided to the committee. Either a numerical score (e.g. marks out of 10) or descriptive grading system (e.g. A = accept, B = consider further or C = reject) can be used. Where there is agreement amongst members, attention can be focussed on applications where detailed discussion is required (see 6.7).

The order in which applications will be discussed may vary and can be based on different factors. Applications may be listed by institution, by disease or technique, or by scientific area or could be ordered on the basis of when they were received.

A mechanism for sifting out poor quality applications that don't need in-depth discussion by the committee can be really helpful to save time for the other applications. This can be done at the beginning of the meeting or as the agenda is worked through.

#### 6.5 Conflict of interest

#### Mandatory

Impartiality

AMRC members must have a published <u>conflict of interest policy</u><sup>60</sup> describing how potential conflicts are managed fairly and consistently. Committee members can apply for funding, but must leave the room if:

- they declare a conflict of interest upfront (e.g. if the applicant is a close friend or relative or if there are other circumstances which prevent them giving an impartial view of the application)
- their application is being discussed
- they are named as a co-investigator, collaborator or other named research staff on the application
- an application is being discussed from the same institution (particularly for small institutions) or at the very least, from the same department
- the committee member has co-authored with the applicant or joint lead applicant in the last five years. This may require further discussion with the committee member and chair.
- the chair applies for funding, they should absent themselves for the entire meeting, and a vice chair should take on their role.

Your conflict of interest policy should also extend to any trustees serving on your committees in line with recent updated <u>guidance from the charity commission</u><sup>61</sup>.

#### Good practice

The applicant should not see the reviewers' reports on their application and committee member(s) with a conflict shouldn't receive external reviewers' reports on applications; this will entail removing certain papers where these are circulated in advance.

<sup>61</sup> http://www.charitycommission.gov.uk/detailed-guidance/trustees-staff-and-volunteers/conflicts-of-interest-in-charities/

<sup>&</sup>lt;sup>60</sup> http://www.amrc.org.uk/sites/default/files/doc\_lib/2013\_07-developing-a-conflicts-of-interest-policy.pdf

The peer review process depends on the individual's honesty in declaring any interest and committee members should be asked to do so at the beginning of the meeting. The committee should satisfy itself that all conflicts of interest have been declared and, if necessary, the committee may wish to debate and decide who should or shouldn't take part in the discussion. The research administrator should be aware of conflicts of interest and this area is also an important responsibility for the chair. You may wish for each committee member to sign of declaration of their conflicts of interest on an annual basis.

Many charities also take steps to ensure that external referees do not have a conflict of interest as part of the review process. Potential referees should receive the grant abstract when they are invited to review so that they are not able to see the full application if a conflict is apparent.

#### Example conflict of interest policies

- Cancer Research UK: <u>conflicts of interest policy</u><sup>62</sup>
- Action for A-T: <u>conflicts of interest policy</u><sup>63</sup>

#### 6.6 Blinding

Although some charities try to reduce bias by 'blinding' applications so that reviewers aren't aware of the applicant's name or institution, we advise that this isn't best practice. Although it allows a reviewer to focus on the science of the grant, blinding prevents an assessment of the expertise of the researchers and appropriateness and quality of the departmental and institutional environment. Also in small fields, blinding is often ineffective and given the expertise of the peer reviewers, it can be relatively easy to identify applicants from the research proposals.

#### 6.7 Scoring system

Committees are usually clear about which projects should not be funded, but can have great difficulty arises in deciding which applications to support. Many charities use a scoring system, where committee members score each application based on a defined scale to support decision making.

#### **Good practice**

Where committees are asked to use a scoring system, the charity needs to clearly explain this and give examples that are relevant to the reviewer. Scoring systems for lay reviewers might focus on the importance of the research to people with the condition, the practicalities of doing the work and likelihood of make a difference. For academic reviewers, the focus is normally on originality, scientific quality, expertise of the researchers and access to the relevant infrastructure.

#### Case Study: Scoring Systems – Arthritis Research UK

Arthritis Research UK ask their expert reviewers *to* score applications as excellent, good, moderate or poor on the basis of a range of quality indicators including the importance and originality of the hypothesis, the scientific and/or clinical impact and the appropriateness of the costs for the work to be undertaken. This helps to identify which studies should be funded with high priority (internationally competitive work of high relevance), fund if money is available (nationally competitive), low funding priority (lacking originality, feasibility or relevance) or not to fund (scientifically or technically flawed or not relevant).

#### 6.8 Interviewing

As well as seeking external reviewer comments on applications for fellowships and other senior personal awards, some charities interview candidates, particularly for more senior awards. Interviewing is normally carried out by the scientific advisory committee or a sub-set of members and could involve lay reviewers. Meeting the potential candidate allows the committee to ask questions about the proposed research and to assess other factors such as the applicant's future career plans that may influence decision-making.

Charities should be aware of the additional administrative burden of interviewing candidates and the practical arrangements that will be required. The committee chair should also have experience in conducting interviews and be able to guide the committee regarding what questions are appropriate.

63 http://www.actionforat.org/COI.pdf

<sup>&</sup>lt;sup>62</sup> http://www.cancerresearchuk.org/science/funding/terms-conditions/funding-policies/policy-conflict-interest/

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#### 6.9 Committees of single institute charities

Charities that fund at a single institute or group of linked organisations are not funding in open competition, so their trustees need to be assured that the research applications are of a high quality and not needlessly replicating work being done elsewhere.

#### Mandatory

#### Impartiality & independence

Funders that award to a single institute must follow additional principles of peer review to ensure that funds are being put to best use:

- ask for written proposals of what the block grant will cover
- seek independent reviews of the proposal
- set up an external review committee, where two thirds of members have no connection or interests in the unit or programme being assessed. One member should be a member of the internal scientific advisory committee and no more than 50% of the panel should be grant holders from the charity
- the peer review committee must contain a majority of members that are not grant holders: 70% is best practice, but 50% plus the chair is essential.
- undertake site reviews of the quality, strategy and direction of research activity at least every 5 years
- ensure the site review process is transparent; the process and timetable should be agreed with relevant parties well in advance
- request progress reports from researchers at least every 2 years to be reviewed by the scientific advisory committee
- feed the assessment back to the institute and ensure there is a system in place to check that the findings are recommendations of the review are acted upon. This may require the charity to have written procedures to manage negative feedback and instigate disinvestment of funding

As well as the requirements outlined above, committees advising charities that fund at a single institute must contain two thirds of members from outside the institution to ensure independent, impartial advice. Involving international experts or researchers who have recently retired can also improve independence. AMRC's principles of peer review<sup>64</sup> – long term funding can offer further guidance.

#### Case Study: Supporting UCL Institute of Neurology – Brain Research Trust

Brain Research Trust<sup>65</sup> supports UCL Institute of Neurology (IoN) by awarding grants for PhD studentships and by funding equipment and research. The IoN, based in Queen Square, London, was established in 1950 and together with the National Hospital for Neurology and Neurosurgery (NHNN), constitutes a national and international centre for teaching, training and research in neurology and allied clinical and basic neurosciences. Funding at a single institute has enabled Brain Research Trust to focus efforts on supporting a world leading medical research centre for neurology for more than 40 years.

#### 6.10 Decision making - committee or trustees

#### Mandatory

Independent decision making

There should be a clear line of communication between the scientific advisory committee and the charity's board of trustees,

The decision to recommend funding must be based on the scientific merit of the application within the context of the charity's research strategy. The formal decision to fund and the responsibility for this decision is that of the trustees. It may be helpful for the scientific advisory committee to know the budget available for the meeting and whether this is for the whole project/programme or for the first year of the award. This enables them to take an overall view of the applications and fit them within the charity's strategy. Some charities delegate a budget to particular meetings, enabling the committee to make the funding allocation within this sum and report to the trustees.

#### **Good practice**

The chair of the committee or a senior member of charity staff should attend trustee meetings to report on the recommendations. This helps to maintain good communication between the committee and the trustees and can be a good platform to update the committee on any changes to the charity's mission and policies.

<sup>64</sup> <u>http://www.amrc.org.uk/sites/default/files/doc\_lib/2013\_08\_principles\_of\_peer\_peview.pdf</u> <sup>65</sup> <u>http://www.brt.org.uk/</u>\_\_\_\_\_\_

## 7 Communicating the outcome

#### 7.1 To applicants and their institutions

#### **Good practice**

Applicants should be informed of the outcome of their application as quickly as possible. It can be helpful if you let applicants know at the time of the application when they should expect to receive feedback.

If trustees have delegated a budget to a meeting of the advisory committee, the applicant may be contacted before the trustee meeting. In situations where it is clear that the application will not be recommended for funding, but there is appreciable delay between the meeting of the advisory committee and trustees, it may be appropriate tell them informally of the outcome. However, although staff in the charity may communicate in various ways with applicants, they shouldn't become involved in discussion of the decision-making process.

Although formal acceptance by the host institution of the terms and conditions of the award prior to application is usually required, this should be reconfirmed once the award has been agreed. It is important to ensure that the terms and conditions issued with the application form are consistent with the formal agreement required at acceptance. Some additional signatures may be required at this final stage especially if the application has been modified in any way or where there were collaborating institutions. This stage also provides a further opportunity to explain the financial arrangements and to confirm that ethical or legal approvals have been given. Formal acceptance might take several forms but common methods include requiring a signed second copy of the award letter or a short formal acknowledgement form.

#### 7.2 Feedback to applicants

#### **Good practice**

Comments should, where possible, be fed back to applicants as it may help them improve for their next application. This applies to both external reviewer and scientific advisory committee comments.

Feedback can enable unsuccessful applicants to improve sections of their research proposals which were unclear or perhaps underdeveloped for the future. However, charities should be very clear to applicants regarding their policy on resubmission of applications as some applicants may interpret feedback as an invitation to rewrite and try again.

Providing feedback contributes towards openness and accountability of peer review system and emphasises the need for reviewers to be honest and fair in their comments. When, on occasion, there is discordance between the reviewers' comments and a decision is made not to fund, further explanation to the applicant may be required and this should be drafted by the research administrator or scientific advisory committee chair. For smaller charities, the chair or specific member of the advisory committee may assume responsibility for providing feedback.

If you are feeding back external reviewer comments to the applicant, you should check that all identifiable information concerning the reviewer is removed (for instance if the reviewer repeatedly references their own work or names themselves). If you feel that a reviewer is being unprofessional throughout their report (for instance overly critical or inappropriate tone), you may wish to discuss this with your committee chair and make small edits to their wording. When doing do, care should be taken to ensure that the points of criticism remain clear and edits are kept to a minimum.

#### 7.3 To reviewers

External reviewers should be thanked for their work and told of the outcome of the application. This helps to build positive relationships that might be useful if you approach this reviewer in the future. You might also wish to explain if the committee's feedback complemented or contrasted with their comments and the reasons why. In doing so, try to be careful not to be drawn into disagreements but remain neutral in the process.

External referees who provide exceptional reviews may also be considered suitable for the scientific advisory committee when members are rotated off so it's important to keep positive dialogue with them.

#### 7.4 To supporters and the public

#### **Good practice**

The public and supporters should be kept informed regularly about new projects that have been supported by the charity. Funders usually ask applicants to provide lay summaries in the application process which can be useful to writing content for websites or other correspondence with supporters. Where possible, funders should also publish the success rate of funding applications on their website to be fully transparent with both the public and potential applicants.

Keeping the public informed is really important as it creates a link between the donations received and research funded, helping to demonstrate how their money is being spent and the potential impact that it could have (see 7.6 for more information on this). It also allows people to see how their money is being spent on research that matters most to patients. Below is a case study detailing how one of our members communicates the outcomes of a committee meeting to the public. This might help you decide what information you could share.

#### Case Study: Communication with Applicants and the Public – Spinal Research

Spinal Research <u>publishes</u><sup>66</sup> details about all of their current, collaborative and completed research projects. Pain English summaries are available online along with the project duration and costs. Additionally, Spinal Research publishes percentage <u>success rates</u><sup>67</sup> for grant rounds, increasing transparency in their public facing information.

#### 7.5 To the rest of the charity

It's important to remember that the charity staff should also be kept up to date over what's research is being funded, particularly if they are working in fundraising or marketing as they often don't have strong links with the scientific advisory committee. Writing up an internal communication explaining what research is underway as well as any new projects that have been funded can help to bring everyone up to speed. It also reinforces that research is part of the charity's aims and might be useful for members of staff speaking with potential donors.

#### 7.6 Demonstrating impact

It's more important than ever that charities show the impact of the work they are supporting to the public and wider supporters. This can help to show how you are fulfilling your research strategy and demonstrate that you are clear about the impact you want to have on improving health and increasing treatment options. It's also important to articulate the potential practical benefit that these projects might bring as this could help to justify future investment. Demonstrating impact should also be part of the charity's wider goals in reaching out to the public and informing them how the money they have donated is being spent. You can do this through a number of ways, but perhaps most commonly is through your website as shown in the case study below.

**Case Study: Communicating Research with the Public and Impact – Marie Curie Cancer Care** Marie Curie <u>publishes</u><sup>68</sup> short lay summaries of the research projects it supports through their annual research programme. This also includes video clips of the principal investigators talking about their research and the potential impact of their work, helping to bridge the gap between the researcher and the public. Charities have a great opportunity to show the importance of the research they fund and potential benefits it can bring so it's important to maximise these opportunities of engaging with the public. Marie Curie also publishes blogs written in lay language about publications that have arisen from Marie Curie funding. Once a year, it runs a Research Conference, which is attended by researchers, Marie Curie employees and service user representatives. Marie Curie funded research features strongly, though not exclusively, at this annual event.

<sup>67</sup> http://www.spinal-research.org/research-matters/grants-awards/success-rates/

<sup>&</sup>lt;sup>66</sup> http://www.spinal-research.org/research-matters/what-we-do/our-projects/current-projects/

<sup>&</sup>lt;sup>68</sup> http://www.mariecurie.org.uk/en-gb/research/funding-for-palliative-end-life-research/marie-curie-research-programme/?Tab=3

#### 7.7 Research integrity

For funders, research integrity is essential to ensure that public donations are put to best use in increasing understanding of health and diseases leading to new treatments and better standards of care. Without it, we would have little control over the quality and scientific merit of research. This is important for everyone, in particular medical research charities who often rely on public donations to fund research.

Research has come under scrutiny recently with concerns raised about reproducibility and verification of research findings, animal use in medical research, open data, transparency and reporting of results. Many of these issues require careful consideration – not just from funders, but the researchers and employers of researchers. It's important that we take a coordinated approach to recognise where improvements can be made and to make changes to ensure that only the highest standards of research conduct are upheld.

AMRC is a supporter of the <u>concordat to support research integrity</u><sup>69</sup> - a cross-disciplinary national framework for good research conduct and its governance. The concordat sets out a framework for funders, researchers and their employers to follow. It ensures that research is carried out to high standards, and that any issues around the integrity of research are dealt with systematically. Importantly, the concordat recognises that research in the UK is already subject to rigorous safeguards such as ethical review and standards of professional practice. It is therefore designed to strengthen research integrity through existing frameworks, rather than introducing any new or additional regulatory mechanisms.

The concordat is seen as a quality benchmark and you can <u>sign up as a supporter</u><sup>70</sup> in your own right. This isn't an AMRC mandatory requirement but supporting it will help to ensure that the UK research community has the highest standards of rigour and integrity. For funders, this may also help to provide assurance to their supporters that the research they support is well governed.

 <sup>&</sup>lt;sup>69</sup> <u>http://www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx#.UzGJxs7n3To</u>
 <sup>70</sup> <u>http://www.universitiesuk.ac.uk/aboutus/AssociatedOrganisations/Partnerships/Pages/ResearchIntegrity.aspx</u>

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## 8 Managing the grant

#### 8.1 Annual reports

As well as receiving quarterly invoices, funders also need to know how the project is progressing. Many charities use a standard annual reporting form to find out what has happened and whether there has been any substantial findings or changes to the project plan. Some charities are using the <u>Researchfish</u><sup>71</sup> evaluation system to collect progress reports from their researchers (see 9.2).

When reports are received, they should be read by members of the grant team or reviewed by a member of the scientific advisory committee who can provide an expert point of contact with the charity and enable it to assist with any difficulties which may arise.

#### 8.2 Final reports

Final reports should be detailed and include copies of publications and other forms of dissemination, a lay summary and a longer narrative report of the research. More information is usually required for programme grants. Final reports should be received within three months of the end of the project and many funders withhold payment until the final report has been received.

For both annual and final reports, you may wish to update members of the public on the progress or findings of research projects. This can be helpful in 'telling the story' of the research and what the implications might be. It can also be a useful fundraising tool but you may wish to work with the researchers to agree appropriate lay wording for reporting these updates. Funders using Researchfish may find it particularly useful to use this system as information is collected into a single repository.

#### 8.3 Site visits

#### Mandatory

Where a charity funds research in one centre only, they should undertake an overall strategic review of the work of the unit every 5 years. The review should be led by internationally recognised researchers and will allow the charity to be sure that the research they have funded is of a high standard.

#### **Good practice**

For large awards or rolling grants, site visits should be made to learn more about progress on the research being undertaken. The timing of visits will vary but they should be carried out at an appropriate time in the planning cycle for both the charity and the research team. Quinquennial reviews are the norm and these are discussed in more detail in 6.9.

Although details of the review process vary between charities and depends upon the size of the team to be reviewed and the extent of the charity's commitment, some general principles should be followed:

- the review process should be discussed at the time of award and the principle investigator or unit head should be notified well in advance of the proposed date of a site visit.
- the format of the review should be agreed beforehand. A report, including publications and future plans might be required, as well as presentation(s) on the day of the visit;
- a team of reviewers, (three to five is reasonable, with at least one member of the scientific advisory committee), and who have no direct interest in the unit or programme should participate in the visit. Care should be taken in the selection of external assessors to ensure impartiality and appropriate expertise.
- the review team should comprise senior figures in the area of research being reviewed and their agreement to participate should be sought well in advance of the proposed date of the review. It can be helpful if the team is able to meet beforehand to discuss any issues raised by the report, publications or external reviewers' comments.

Senior staff from the charity should be involved to answer any administrative questions and ensure that all relevant information is available to the review team.

<sup>&</sup>lt;sup>71</sup> <u>http://www.amrc.org.uk/our-work/showing-impact/using-researchfish-track-impact-charity-research-funding</u> Guide to research management – Spring 2014

The charity must be clear about the issues that it wishes the reviewers to cover and feedback should be considered carefully. A report should be prepared for the trustees to make final recommendations. Feedback should also be provided to the unit director or principle investigator(s). If there are a number of issues to discuss, a further meeting between the charity research managers and/or chief executive and the research team may be required.

#### 8.4 Managing intellectual property

Many research projects have the potential to develop intellectual property (IP), which can be protected by copyright or patents. Charities expect researchers to tell them when IP has been developed, but some charities also proactively manage their research portfolio, identifying projects that have the potential to develop IP, and working with the research team to help support the development.

"<u>Benefiting from Innovation</u>"<sup>72</sup> provides more information on how charities can support the development of IP. We have also produced some <u>guidelines</u><sup>73</sup> on IP for funders who are developing or reviewing their terms and conditions. Below are two case studies showing how funders can deal with IP that might give some useful information if you are new to this area.

**Case Study: Dealing with Intellectual Property – Association for International Cancer Research** The Association for International Cancer Research (AICR) takes an active approach to managing intellectual property. This is done through a close partnership with <u>MRC Technology</u><sup>74</sup>, which has really helped them to develop their understanding of tackling IP head-on, and involves:

- Assessing IP potential at the outset of each grant
- Regular close monitoring of 'high IP' grants
- Facilitating commercial development if necessary/where possible
- Actively pursuing revenue share agreements when patents are filed

#### Case Study: Terms and Conditions – Multiple Sclerosis Society

In 2008 the MS Society went through an exercise of rationalising their terms and conditions of award. At the time the document stretched over 30 pages and was unclear. Some award holders found the document confusing and key IP clauses were diluted. The charity engaged an IP lawyer, who condensed the terms and conditions to just six pages. This made them a more intuitive read, removed repetition and provided clarity on matters relating to IP, leaving no doubt about the charity's expectations of grant holders and host institutions.

The MS Society's new terms and conditions<sup>75</sup> state that the onus for identification, protection and management of IP is on the grant holder and host institution. The charity must be notified at each step of the process and provide written consent before any agreements are signed or major decisions made in relation to IP. They also ask for a non-exclusive license for use of the IP. At any point during this process the charity also reserves the right to request that the IP is transferred to them; this is not something they do unless absolutely necessary – only when they believe the IP will not be managed appropriately and not to the potential benefit of people affected by multiple sclerosis. The terms and conditions contain to-the-point clauses that are legally binding.

The MS Society also developed an <u>IP policy</u><sup>76</sup>, putting their position into context for grant holders and host institutions. The policy clearly states their reasons for expecting appropriate management of IP, which is first and foremost to ensure that all IP arising from their research programme will be managed in a way to maximise the potential benefit to people affected by MS.

<sup>&</sup>lt;sup>72</sup> http://www.amrc.org.uk/publications/benefiting-innovation-intellectual-property-advice-medical-research-charities

<sup>&</sup>lt;sup>73</sup>http://www.amrc.org.uk/publications/guidelines-ip-terms-and-conditions

<sup>74</sup> http://www.mrctechnology.org/

<sup>75</sup> http://www.mssociety.org.uk/sites/default/files/Research%20grant%20conditions%20and%20policies.pdf \

<sup>&</sup>lt;sup>76</sup> http://www.mssociety.org.uk/sites/default/files/MS%20Society%20Intellectual%20Property%20%28IP%29%20Policy\_0.pdf

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## 9 Evaluating the outputs

The outputs of research - publications, patents or impacts on policy - often occur after the research funding has ended, and the final report has been submitted. Charities need to demonstrate public benefit, and as such showing that the research they fund has an impact for people with the condition. But it can take many years and many research groups to translate a research idea into a new treatment or therapy. Funders need to have mechanisms to collect this information..

#### 9.1 Retrospective review

As well as checking how a project is progressing and its final results, funders can also take a retrospective view of parts or all of their completed research.

Surveying researchers that held grants that were completed in the previous 5-20 years can allow charities to find out how the research was progressed. Charities can also arrange to interview holders of significant programme grants, to see how the research grants they funded fitted into the wider research programme. But this takes a lot of time, and can be seen as 'cherry picking' the best examples, rather than giving a true picture of the impact of a research programme. The case study below shows how one of our members reviews the research they have supported over a longer period of time - it may help you decide how best to communicate these points to the public.

#### Case Study: 20 Year Review – The Stroke Association

The Stroke Association have produced a report<sup>77</sup> reviewing 20 years of investment in stroke research. They show how much money has been spent on research in terms of project grants, programme grants, fellowships, professorships and research centres. Research spend is also broken down by region as well as specific research themes such as surgery, drug development and rehabilitation. The report also shows how the association has expanded stroke research in the UK and how this has contributed to a decline in stroke mortality over the last two decades. Challenges for the future are also highlighted including new emergency treatments, brain remodelling and tackling emotional wellbeing and unmet needs after stroke.

#### 9.2 Continual collection of outputs

Many of our members are now using <u>Researchfish</u><sup>78</sup>, an online evaluation system for collecting information on outputs, outcomes and impacts of research. Researchers are asked to link their outputs to the different grants that they hold from funders who are using the system. Because impacts are added prospectively, funders are able to assess the impact of a whole funding stream as well as from individual grants.

Researchfish funders are developing a data sharing policy that will link to the AMRC's <u>data sharing</u> <u>agreement</u><sup>79</sup> with our members. The overarching principle is that anonymised sector-wide data can be released, but no data that can be attributed to a particular funder will be produced without permission. Below is a case study from MRC who have been using Researchfish for a number of years - it shows the types of analyses that can be done and may be helpful if you are considering using Researchfish as part of your plans for evaluating your research portfolio.

#### Case Study: Researchfish – MRC

MRC have been using the Researchfish system for 4 years. In a <u>2012 analysis</u><sup>80</sup> of their portfolio, Researchfish was able to stratify outputs across a range of criteria including publications, collaborations, further funding and policy influences. This has given rise to a number of interesting findings including:

- papers arising from MRC-supported research have over twice the world average citation impact than papers resulting from other UK health-related or biological sciences research
- 61% of MRC grantees started new collaborations between 2006 and 2012
- 23% of awards influenced a policy-setting process or received citation in a policy document
- 50% of MRC awards have either received an award or recognition for their research, highlighting the significant contribution UK researchers make to science and society internationally

<sup>&</sup>lt;sup>77</sup> http://www.stroke.org.uk/sites/default/files/files/Research%20Report\_Web\_June%202013.pdf

<sup>78</sup> https://www.researchfish.com/

<sup>&</sup>lt;sup>79</sup> http://www.amrc.org.uk/publications/amrc-data-policy

<sup>&</sup>lt;sup>80</sup> http://www.mrc.ac.uk/Achievementsimpact/Outputsoutcomes/Researchfish2012/index.htm

#### 9.3 Long term evaluation

In reviewing longer term awards or collective programmes of work, you may wish to show what highlights have been achieved in the wider research landscape such as improvements in survival rates, speed of recovery or gains in quality of life. You could consider publishing these impacts in your annual review, helping to demonstrate the value of donations and support from the general public. This may also help you to define new challenges and research opportunities as part of your research strategy.

#### Information sources

• The Cystic Fibrosis Trust published details of research successes in their <u>annual review</u><sup>81</sup>.

<sup>&</sup>lt;sup>81</sup> <u>https://www.cysticfibrosis.org.uk/who-we-are/about-us/annual-review-and-accounts.aspx</u>

## 10 Concluding words

Managing research grant funding is a challenging area, and in all but the largest charities is carried out by very small teams. This guide outlines the key points of grant management and shows how charities can carry them out in compliance with AMRC policies and principles. It also provides case studies showing how AMRC members and other medical research funders are approaching these areas.

As we approach the next AMRC peer review audit, we are keen to capture more of these examples, and to expand this guide to cover emerging topics. Please get in touch if you think we have missed something.

#### Annex 1 – Principles of peer review

Medical research funders aim to make the most effective use of their resources through supporting the good science, and the best scientists. Peer review is an accepted means of assessing the quality of academic research, and AMRC believe that it is the best way for medical research charities to decide what research to fund. These principles of peer review have been developed to maximise the benefits of peer review, while addressing the criticisms and minimising the weaknesses of the system.

We recognise that our membership is diverse and charities will have many different ways of carrying out peer review in practice. This document outlines the **mandatory standards** to which all AMRC member charities operate, and highlights **good practice** that we encourage our members to adopt or work towards. We also recognise the challenges in implementing these principles in 'single-institute' charities, and offer supplementary guidance. If you are unsure of how these principles should be applied to your charity please contact us to discuss your circumstances in more detail.

#### Summary

#### External and internal reviewers

External and internal reviewers are both mandatory for deciding the scientific quality of research applications. Applications for grants worth over £25,000 per annum must be assessed by external peer reviewers with appropriate experience and expertise. All applications must be reviewed by a scientific advisory committee (sometimes called an internal peer review panel or similar).

Peer review within all AMRC member charities is carried out according to the following principles:

**Accountability**: Charities are open and transparent about their peer review procedures and publish details, including the names of the members of scientific advisory committees or other decision making bodies.

Balance: Scientific advisory committees reflect a fair balance of experience and scientific disciplines.

**Independent decision making:** The scientific advisory committee is independent of the charity's administrative staff and trustees.

Rotation of scientific advisers: Scientific advisory committee members have a fixed term of office and do not have tenure.

**Impartiality**: Scientific advisory committees include a significant number of non-beneficiaries. There is a conflict of interest policy and potential beneficiaries are not present when decisions are made.

This document is a summary guide. For full guidance please see the resources available on the AMRC website <a href="https://www.amrc.org.uk/our-work/peer-review">www.amrc.org.uk/our-work/peer-review</a>

#### Mandatory standards and good practice

External and internal reviewers Mandatory standards:

- Bring together a scientific advisory committee, made up of independent experts, who meet on behalf of the charity to assess applications and make recommendations for funding to the charity's trustees.
- Identify appropriate external experts to give detailed written feedback on research applications for all grants of over £25,000 per annum. These reports must be used by the scientific advisory committee to enrich their assessment of the applications.
- Use the scientific advisory committee and at least two external reviewers for all research grants worth over £25,000 per annum. It is important that the extent of peer review is in proportion to the amount of funding to be awarded. Larger grants may require more than two external reviewers. Grants worth between £10,000 and £25,000 per annum must be reviewed by the scientific advisory committee and under £10,000 per annum grants must be reviewed by the committee chair as a minimum.

We have provided further guidance on what constitutes proportionate peer review.

#### Accountability

Mandatory standards:

- Have a research strategy and information about what type of research the charity funds available online.
- Publish scientific advisory committee members' names and details of the peer review process online.
- Assess the replacement, refinement and reduction (the 3Rs) of animals in research applications. This includes ensuring all panel members are aware of the 3Rs and have suitable resources to consider them and referring all applications involving non-human primates, cats, dogs and equines to the National Centre for the 3Rs for special review.

At the 2013 AGM, AMRC members agreed to ensure that the 3Rs must be part of the peer review process when reviewing grant applications involving animals. This must be implemented by all members in time for the 2015 Peer Review Audit.

Good practice:

- Make calls for applications accessible to a wide range of potential applicants.
- Publish the charity's conflict of interest policy online.
- Provide feedback to applicants.
- Publish success rates online and feed them back to applicants.
- Publish information on research that has been funded by the charity, such as about the disease areas covered or individual project summaries.

To improve transparency we have recommended that conflict of interest policies and information on the grants awarded by the charity are made available online.

#### Balance

Mandatory standards:

- Ensure scientific advisory committees reflect a fair balance of experience and scientific disciplines. Panels should reflect the remit of the charity and the funding stream, such that there is no overrepresentation of discipline. Attention should also be paid to the need to avoid discrimination against members on the grounds of age, gender, ethnicity or geographical location. Charities that have difficulty recruiting panel members in a specific disease area should seek scientists with expertise in overlapping research fields or who are familiar with relevant techniques.
- Use a variety of methods to select internal and external peer reviewers, so that charities do not rely on a single person or small group of people to nominate reviewers. All appointments to the scientific advisory committee must be approved by the charity's trustees.

We have clarified that all appointments to the scientific advisory committee must be approved by the charity's trustees.

Good practice:

- Have a scientific advisory committee composed of at least five members, including the chair.
- Consider the use of lay reviewers. Natural ground: Paths to patient and public involvement for medical research charities<sup>82</sup> sets out key questions that charities can use to facilitate this process. Charities that involve lay reviewers should be clear about its purpose, and make this clear to applicants.

We have provided further guidance on how many members a scientific advisory committee should have.

#### Independent decision making

Mandatory standards:

- Ensure decisions on scientific quality are made by independent peer reviewers and not the charity's administrative staff.
- Ensure any preliminary screening process (triage) is fair and transparent.
- Ensure the procedure for assigning reviewers to applications is fair.
- Have no more than two trustees on the scientific advisory committee; they must not constitute more than 25% of the panel. For committees of over 20 people, 20% may be trustees. Trustees may chair the panel but this is strongly discouraged if they are eligible to apply for funding from the charity
- Have a quorum for the scientific advisory committee of at least three members.
- Ensure there is a clear line of communication between the scientific advisory committee and the charity's board of trustees, and that the chair is able to communicate decisions to the trustees.

We have clarified the number of trustees permitted to be active members of a scientific advisory committee. We have added new guidance that trustees may chair the committee. We have added guidance on how many members of a scientific advisory committee are required for the meeting to be guorate.

Good practice:

• Allow the chair of the scientific advisory committee to attend trustee meetings to report on the activity of the panel.

#### Rotation of members of the scientific advisory committee

Mandatory standards:

• Appoint committee members, including the chair, for a fixed term of office. Members must serve no longer than eight years and must not re-join for three years after retiring from the committee. This must be made clear to those on the committee at the time they join.

We have provided further guidance on how long committee members may serve for.

Good practice:

- Set an initial term for scientific advisory committee members of three years, with the option of renewing for a further two or three years.
- Stagger the appointment of new members to maintain a balance of experience during transition.

#### Impartiality

Mandatory standards:

- Allow no more than 50% of the scientific advisory committee to be active grant holders (beneficiaries). Ensure that scientific advisory committee members sign the conflict of interest policy, so they are aware of their responsibilities. External reviewers should be given an opportunity to declare a conflict of interest before committing to review applications.
- Ensure would-be beneficiaries are not present when their applications are discussed or when funding decisions are made. If a committee member has an involvement in an application, e.g. works in the same department or institution as an applicant, they must declare a conflict of interest, and the situation should be managed according to the conflict of interest policy.
- The chair should not normally apply for funding, but if they do, they should not attend the meeting or appoint reviewers. If they do attend the meeting, they must not be present for the discussion of their own application or score any applications. They may act only as an impartial mediator in the

<sup>&</sup>lt;sup>82</sup> <u>http://www.amrc.org.uk/publications/natural-ground-paths-patient-and-public-involvement-medical-research-charities</u>

meeting. Where the chair is required to be absent, it is the responsibility of the vice-chair or nominated person to facilitate the meetings and report to the trustees the outcome of the meeting.

Good practice:

- Devise an induction process for new scientific advisory committee members.
- Allow no more than 30% of the scientific advisory committee to be active grant holders (beneficiaries).

We have clarified that it is good practice to have a low percentage of scientific advisory committee members that are also grant holders.

#### Long-term funding and block grants

This funding may be in the form of a core grant, centre funding, research programmes or linked research projects. These block grants are incredibly valuable to the institution, as they fund important research as well as providing researchers with 'protected' time where they can develop pilot research and apply for funding from additional sources. Some charities are setup to raise funds solely to support research at a single institution.

For these types of funding, additional mandatory standards apply:

- Request progress reports from researchers to be reviewed by the scientific advisory committee or external reviewers at least every 2 years.
- Undertake a regular site review of the quality, strategy and direction of research activity at least every five years. AMRC recommend every three to five years. This should be done by an external review committee, whose members have no connection with or interest in the unit or programme being assessed. One of the members should be a member of the charity's scientific advisory committee.
- Ensure the review process is transparent and the process and timetable is agreed with relevant parties well in advance.
- Feed the assessment back to the institute and ensure there is a system in place to check that the findings and recommendations of the review are acted upon. This may require the charities to have written procedures to manage negative feedback and instigate disinvestment of funding.

We have provided clarity that the Principles of Peer Review apply to all research funding provided by AMRC members and that members providing block grants must also follow additional standards. We have added a requirement that progress reports must be assessed at least every two years.

#### **Further information**

All AMRC's resources on how to follow these principles, including more detailed guidance, are available on the AMRC website<sup>83</sup>.

If you have any queries about this document, please contact:

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