

confidential. The application form and any associated papers forwarded to referees and Board/Panel members by MRC are sent 'In Confidence'. Referees and Board/Panel members involved in assessing proposals may need to consult in confidence, with colleagues about individual applications.

Scientific Contacts

Program Managers for MCMB(Molecular and Cellular Medicine Board)

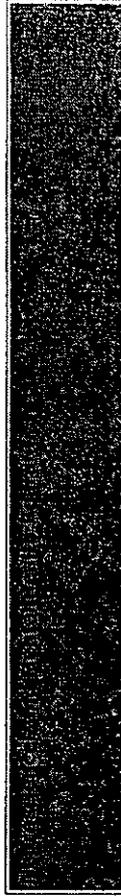
Name	Role	Scientific Area	Contact
Dr Ian Viney	Board Programme Manager	N/A	ian.viney@headoffice.mrc.ac.uk
Dr Graham Cadwallader	Programme Manager for Cancer Biology	Laboratory based studies related to basic cancer cell and molecular biology and cancer therapy; radiobiology; radiological protection; genome stability; DNA damage and repair.	graham.cadwallader@headoffice.mrc.ac.uk
Dr Louise Kellert	Programme Manager for Structural Studies	Structural biology (protein, nucleic acid and carbohydrate structure); protein engineering; NMR; mass spectrometry; x-ray diffraction; cryo-EM; Synchrotron Radiation; chemical biology; biophysics; basic technology; Discipline Hopping Awards.	louise.kellert@headoffice.mrc.ac.uk
Dr Fiona Russell	Programme Manager for Immunology	Cellular and molecular immunology; allergy; inflammation and the inflammatory process (excluding asthma); auto-immune disease; cell biology; biochemistry; Computational Biology.	fiona.russell@headoffice.mrc.ac.uk
Dr Kevin Moreton	Programme Manager for Genetics	Genetics; gene mapping and sequencing; gene regulation and expression; gene targeting and transfer; gene therapy (including delivery system development); genome evolution. Bio-informatics and E-Science.	kevin.moreton@headoffice.mrc.ac.uk
Dr Heike Weber	Programme Manager for Developmental Biology	Developmental Biology; developmental genetics; stem cell biology; transplantation.	heike.weber@headoffice.mrc.ac.uk

Programme Managers for PMIB(Physiological Medicine and Infections Board)

Name	Role	Scientific Area	Contact
Dr Declan Mulkeen	Board Programme Manager	N/A	declan.mulkeen@headoffice.mrc.ac.uk
Dr Catherine Moody	Deputy Board Programme Manager and Programme Manager for Metabolism and Reproduction	Reproductive biology; metabolic biochemistry and clinical endocrinology - including diabetes; paediatrics; fetal origins of adult disease; trauma and intensive care; muscle system. MRC contact for MoD joint grants scheme.	catherine.moody@headoffice.mrc.ac.uk
Dr Morvan Roberts	Programme Manager for Cardiovascular, Kidney, Respiratory	Cardiovascular research, including: vascular biology, lipoprotein metabolism, atherosclerosis, thrombosis, cardiac electrophysiology, heart failure.	morvan.roberts@headoffice.mrc.ac.uk

Dr Mark Palmer	(including asthma) and Bone Research	hypertension. Haematology; thalassemias; sickle cell disease. Kidney disease; renal medicine. Respiratory medicine including asthma. Skin/bone/joints research; osteoporosis, rheumatoid arthritis.	mark.palmer@headoffice.mrc.ac.uk
Dr Matthew Wakelin	Programme Manager for Nutrition and the Environment	AIDS; HIV vaccine development; anti-HIV drug discovery; trials and basic science related to HIV and AIDS; pathogenesis of AIDS; topical virucids development; parasitology, tropical medicine, and other research relevant to the health of developing societies.	matthew.wakelin@headoffice.mrc.ac.uk
Dr Angela Williams	Programme Manager for Research on Infections	Bacterial and viral infection and immunity; clinical infectious disease; infectious disease immunology; vaccine research; bacteriology and virology (excluding HIV and AIDS).	angela.williams@headoffice.mrc.ac.uk

Programme Managers for NMHB(Neurosciences and Mental Health Board)



Name	Role	Scientific Area	Contact
Dr Rob Bennett	Board Programme Manager	N/A	robert.bennett@headoffice.mrc.ac.uk
Dr Karen Finney	Deputy Board Programme Manager and Programme Manager for Research on	Dementias; Transmissible Spongiform Encephalopathies (TSE's); brain banking; psychoneuro-immunology.	karen.finney@headoffice.mrc.ac.uk
Dr Rachel Curran	Programme Manager for Cognitive and Behavioural Neuroscience	Cognitive and behavioural neuroscience, sensory neuroscience (including vision, hearing, movement); Psychology.	rachel.curran@headoffice.mrc.ac.uk
Dr Delyth Morgan	Programme Manager for Clinical Neurology and Imaging	Clinical neurology (stroke, epilepsy, brain repair, head injury (cognitive and rehabilitation aspects)); Imaging.	delyth.morgan@headoffice.mrc.ac.uk
Dr Mark Pitman	Programme Manager with special responsibility for liaison with DR on TSEs	Aspects of Transmissible Spongiform Encephalopathies (TSEs) specific to Department of Health.	mark.pitman@headoffice.mrc.ac.uk

Dr Chris Watkins	Programme Manager for Research on Mental Illness and Drug Addiction	Mental Health (including clinical, genetic, and neuropharmacological aspects); clinical psychology; treatment of mental health; addiction.	chris.watkins@headoffice.mrc.ac.uk
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Programme Managers for HSPHRB(Health Services and Public Health Research Board)

Name	Role	Scientific Area	
Dr George Sarna	Board Programme Manager	N/A	george.sarna@headoffice.mrc.ac.uk
Dr Caroline Stone	Programme Manager for Health of the Public	Health services research related to molecular and cellular medicine, public health research; longitudinal studies; medical sociology; epidemiology - design, methodology; statistics; telemedicine; training in health services and public health research.	caroline.stone@headoffice.mrc.ac.uk
Dr Claire Newland	Programme Manager for Health Services Research	Health services research - general and related to neurosciences and mental health; physiological medicine and infections; research related to primary health care; elderly people; back pain; surgery.	claire.newland@headoffice.mrc.ac.uk
Dr Angela Cooper	Programme Manager for Cancer Trials	Clinical Trials on Cancer.	angela.cooper@headoffice.mrc.ac.uk
Dr Joe McNamara	Trials Manager	Initial point of contact for clinical trials; policy development in relation to clinical trials; management of trials procedures; managing the MRC clinical trials portfolio; liaison with NHS Health Technology Assessment Programme.	jo.mcnamara@headoffice.mrc.ac.uk

Programme Managers for SLG(Strategy and Liaison Group)

Dr Joan Box	Clinical Research Liaison Manager	Liaison with clinical community, medical Royal Colleges, medical charities, other Research Councils and consumers.	joan.box@headoffice.mrc.ac.uk
Dr Peter Dukess	Strategy Manager for DH	DH/NHS partnership including research governance, support for science and scientific reviews; <small>technology, data solutions</small>	peter.dukess@headoffice.mrc.ac.uk
Dr Imogen Evans	Strategy Manager for Clinical Sciences	Training; ethics (national and international); scientific misconduct, complementary medicine.	imogen.evans@headoffice.mrc.ac.uk

Dr Imogen Evans	Strategy Manager for Clinical Sciences	Training; ethics (national and international); scientific misconduct, complementary medicine.	imogen.evans@headoffice.mrc.ac.uk
Dr Barbara McFarlane	Strategic Projects Manager	Development of strategy relating to stem cell banking, health informatics, vaccine guidelines and nanotechnology.	barbara.mcfarlane@headoffice.mrc.ac.uk
Dr Frances Rawle	Strategic Projects Manager	Development and coordination of strategy related to DNA collections	frances.rawle@headoffice.mrc.ac.uk

IN CONFIDENCE

SCIENTIFIC RESEARCH GRANT REPORT FORM

A COPY OF THIS FORM AND GUIDANCE NOTES IS ALSO AVAILABLE ON THE WWW @
<http://www.mrc.ac.uk>

This form should be completed in typescript or black ink. The submission of a Scientific Report is regarded by the Council as an essential requirement of their Grant Schemes. Parts 1-5 should correspond with the information contained in the award letter. Any changes must be clearly identified and explained in the text of the report. Send this form and your detailed report (see Section 17) with (two) copies of each to reach the MRC within 3 months of the end of the research grant. Failure to do so will result in financial penalties. This report may be used as part of a Progress report or when requesting a Renewal or Extension. Investigators are asked to restrict their comments to the spaces provided on this form.

<p>1. GRANT NUMBER: G _____</p> <p>TYPE OF GRANT:</p>	<p>2. GRANT PERIOD: START DATE: ____/____/____ END DATE: ____/____/____</p>	<p>3. TYPE OF REPORT: PROGRESS RENEWAL EXTENSION FINAL</p>
<p>4. INVESTIGATOR(S):</p>		<p>INSTITUTION(S) / AUTHORITY</p> <p>DEPARTMENT WHERE WORK DONE</p>
<p>5. TITLE OF INVESTIGATION:</p>		

6. OBJECTIVES OF THE RESEARCH:
 List the main objectives as stated in the original proposal in order of priority

PROMPT
 Scientific aims & any plans for the application / exploitation as stated when funding originally sought

7. ACHIEVEMENTS OF THE RESEARCH:
 Describe the extent to which the objectives of the research have been achieved and relate the significance of the scientific advances/insights achieved to recent work in the field.

Identify important results and relate to general developments of the field. Please explain any changes in objectives during the study.

8. PROGRESS OF THE RESEARCH:
 (i) Outline the methodology used in the research.

Examples (design) issues/cells, techniques/ approaches, measurements/outcomes.

(ii) Was there any significant change in the research work or programme of work compared with the original proposal.

YES/NO
 If YES give reasons for changes, i.e. Did the research proceed as expected and on time? If NO give details. Were there any circumstances which aided or impeded the progress of the research? If YES, explain the steps you took to overcome them. Examples of problems could include difficulties in recruitment of staff, late delivery of equipment and malfunction of equipment.

<p>15. PUBLICATION AND DISSEMINATION OF RESULTS: (i) List titles of papers and internal reports etc. arising from the research (including items in preparation) and did you refer to MRC support.</p>	<p>List publications, (in referred journals and others) detailing authors, underlining the names of authors funded by this grant, date, title, journal volume, page no., (where known), conference proceedings, book chapters etc. Include publications which have arisen through these collaborations. Please detail any significant publicity.</p> <p>IF YES, give details.</p>
<p>(ii) Has any data been lodged in a public access database.</p>	<p>YES/NO</p>
<p>16. EXPLOITATION OF RESULTS:</p>	
<p>(i) Who are the likely beneficiaries of the research and have you disseminated any of the results to the User Communities (NHS, Industry etc.)</p>	<p>E.g. other researchers, business and commerce, local or central government and other users.</p>
<p>(ii) Record anything patentable / commercially exploitable arising from the research, in the short, medium or long term?</p>	<p>Give details and describe what arrangements have been made or are planned for exploitation of the results.</p>
<p>(iii) What are the implications for improving health and health care or quality of life in the short, medium or long term and what progress is being made towards exploiting these opportunities.</p>	<p>Refer to any actual or potential application or exploitation of research or relevance to Government Department priorities.</p>
<p>(iv) Record any increased collaboration with existing or new industrial commercial partners and any new sponsorship, funding for basic/strategic research.</p>	<p>This part of the report is particularly relevant to holders of ROPAs.</p>

17. DETAILED REPORT ATTACHED:
 You may also attach:

(i) a report of not more than six sides* of a A4 typescript (point size 12) with a list of references. It should outline the scientific and / or technological achievements of the research expanding as necessary on the answers provided above.

(ii) a separate summary (maximum of one A4 page) suitable for publication describing the achievements made on the Research Grant.

Do not submit lengthy internal reports or PhD theses. Copies of key publications arising directly from the investigation should be appended, but are not acceptable as a substitute for any part of this report.

Include title, investigator, institutions and the name of a person whom readers should contact.

18. SIGNATURES

INVESTIGATOR(S):

HEAD(S) OF DEPARTMENT(S):

ADMINISTRATIVE AUTHORITY:

POSITION HELD:

SIGNATURES AND DATES

PURPOSE AND AIMS OF SCIENTIFIC REPORTS ON RESEARCH SUPPORTED THROUGH MRC RESEARCH GRANT SCHEMES

The Council takes very seriously its responsibility for ensuring that its resources are used cost effectively; we must be able to demonstrate to the Government and the public at large that we support high quality work and that, where appropriate, the findings are applicable and/or exploitable. The Scientific Report the Council receives on the work it has supported through the grants system is an important element in assuring such accountability.

Two types of reports are required on each terminating grant:-

- a) A Scientific Report on the work undertaken;
 - b) A Financial Statement of actual expenditure incurred against the grant, along with an explanation of any significant variances between sums awarded and actual expenditure under particular cost heads. This note describes the procedure for submitting the Scientific Report.
- 1.1 It is a condition of an MRC research grant that a report of the work carried out is submitted within three months from the end of the research grant. Where the longer term utility of the work undertaken has still to be assessed, it remains open to grantholders to submit a second report, at a later stage, after the research team has had the opportunity to address some of the more long-term issues.
 - 1.2 Assessment at "one point in time", we appreciate, will not always be appropriate as the significance of work supported under any MRC funding mechanism may not be apparent shortly after completion.
 - 1.3.1 MRC support may lead to instances where project objectives are not

achieved and therefore any assessment may be considered inappropriate. On the other hand, if no attempt at assessment is made until several years after the end of the project, the trail may have gone cold.

What the MRC needs is a timely identification of the overall success if its funding schemes in delivering scientific advances. However, the MRC will give serious consideration to assessment mechanisms for "re-visiting" outcomes some time after completion, where the effort seems mutually beneficial and justified.

- 1.4 The MRC reserves the right to disallow the final Financial claim if the Scientific Report is not submitted within the three month period, unless prior approval has been given. Failure to provide a satisfactory report may preclude any subsequent research grants being awarded.
- 1.5 The principal grant holder is held responsible for completing the Scientific Report on behalf of all named applicants (this is also true for multi-centre awards).
- 1.6 You should complete the Scientific Report form attached (also available on the WWW @ <http://www.mrc.ac.uk>) and send it to your Institution's Finance Officer and not direct to the MRC. Your Finance Officer will return the Report, along with the Financial Statement and an explanation of any significant variances between award and expenditure to the MRC. The final payment on the grant will only be made if satisfactory returns are received, and provided this occurs within 3 months of the end of the award. Your Finance Officer may need to seek information from you regarding any differences between amounts awarded and actually spent, before s/he completes and authorises the Financial Statement.
- 1.7 The Final Report form may be used as part of a Progress report or when requesting a Renewal or Extension.

Research Outputs and Dissemination of results

Holders of MRC research grants are expected to promote the dissemination of the results of their research by their publication in appropriate scientific journals.

MRC support for an individual or a research project must be acknowledged on all publications where support has played a significant part (that is accounts for at least 20% of funding). MRC also expects acknowledgements in exhibitions, press announcements and other similar events.

From time to time the MRC may request additional information on research progress from MRC grant holders who are or have been holders of MRC research grants. Unless the grant holder can give good reasons for maintaining confidentiality, the information may be made public.

Aims of reports

- 2.1 The submission of the Scientific Report enables the Council:-
 - (i) to assess whether the work carried out under the research grant was of an acceptable standard and whether value for money has been achieved;
 - (ii) to quantify the overall value of the research investment made;
 - (iii) to assist in the development of Board and Council strategies and expertise in particular areas;
 - (iv) to maintain a track record of teams and individual investigators suggested by the MRC;
 - (v) to enable the measurements of outputs such as publications, dissemination of results and potential for catalysing future work; and
 - (vi) to account to Government Departments (especially the Office of Science and Technology, and the Health Departments) and to the public at large.

Assessment of Reports

- 2.2 Reports may be used in the consideration of any new applications.
- 2.3 The information contained the grant holder's report will be for the MRC's use only. If the research has been particularly interesting or successful the Council may seek further information for possible use in MRC publications or newsletters and by Government Departments.
- 2.4 The following points will be taken into

- account in the assessment as measured against objectives.
- The success of the research, including any agreed changes in meeting its original objectives at the time of the award.
- The quality of the work carried out under the research grant.
- The general scientific and practical significance of any specific outputs, such as publications, patents, collaborations with other scientists in industry or academia.
- The extent to which it will (or has the potential to) advance knowledge and/or enhance UK industrial competitiveness and increase wealth and improve health and/or health care or quality of life.
- The extent to which the project has contributed to meeting the MRC's overall strategic objectives or special initiatives (where appropriate).
- Were the outputs of high quality and genuine originality?
- Did the work provide good value for money?
- Any operational circumstances which may have aided or impeded progress.
- Was the research of high risk.

Terms and Conditions for MRC Grants and Fellowships

General Conditions

Responsibilities of the Host Institution: General

MRC grants are awarded to the Institution at which the research is to be carried out (the Host Institution) and not to individual researchers. MRC fellowships are awarded to an individual researcher at a designated Host Institution.

Institutions (and individual grant and fellowship award holders) in receipt of MRC awards must comply with these Terms and Conditions.

Host Institutions are responsible for:

- ensuring that MRC award holders are made aware of their responsibilities and that they observe these Terms and Conditions.
- providing the basic facilities needed to carry out the research as detailed in the application to the MRC.
- ensuring that researchers supported through MRC awards adopt the highest achievable standards in the conduct of their research - exhibiting impeccable scientific integrity and following the principles of good research practice detailed in the MRC Good Research Practice Guidelines.
- ensuring that local research ethics committee/multi-centre research ethics committee approval is granted for the research supported through the MRC award and that no research requiring such approval is initiated before it has been granted.
- ensuring that all necessary regulatory body licence or approval for the research supported through the MRC award has been granted prior to the commencement of any research.
- ensuring that MRC-funded clinical trials are conducted in accordance with the MRC/Department of Health guidelines on Good Clinical Practice in MRC-funded trials.
- ensuring that the requirements of the Employing Organisation under the Department of Health's Research Governance Framework for Health and Social Care (RGF) are met.
- ensuring that the research supported through the MRC award complies with all relevant current Government regulations including those introduced whilst work is in progress.
- ensuring that all staff involved in animal research, and in the breeding, housing and care of animals, are properly trained and supervised.
- ensuring that all partners in multi-centre/collaborative grants comply with these Terms and Conditions.
- notifying MRC of any change in the employment status of MRC award holders eg secondment, resignation, transfer to another institution, extension of a probationary period, charges of professional misconduct, in order that the terms of the award can be reconsidered.
- ensuring that award holders notify the MRC of any development that will adversely affect the progress of the MRC supported research.
- accepting individuals paid from funds awarded on an MRC award as its employees for the duration of the award, offering terms and conditions of service equivalent to established staff.
- in the case of universities and colleges, managing the development and careers of contract research staff funded through the MRC award and implementing conditions of employment for such staff in accordance with the standards set by the 1996 Concordat on Contract Research Staff Careers between the Committee of Vice-Chancellors & Principals (CVCP), the Research Councils and other bodies.
- in the case of other institutions, adhering to the good practice set out in the Concordat.
- maintaining accountability for proper use of public funds.
- maintaining proper expenditure records for each award and making these records available to the MRC (in collaboration with other Research Councils) when requested.

Responsibilities of the Host Institution: Clinicians

The Host Institution is responsible for ensuring that all clinicians working under an MRC award are aware that they are individually responsible for maintaining appropriate cover with a professional defence organisation for any activities not covered by NHS indemnity arrangements or by any additional provision made by the host institution. MRC will not meet the costs of such cover.

The Host Institution is responsible for ensuring that any honorary clinical contracts required by clinical staff working under an MRC award have been obtained prior to the start of the award.

Responsibilities of the Host Institution: Scientific Misconduct

The Host Institution must have in place adequate systems for ensuring the quality of research that is carried out by their staff so that scientific misconduct (e.g. plagiarism, falsification of data, improper selectivity of data) can be prevented. Host Institutions should have effective mechanisms for identifying scientific misconduct and clearly publicised and agreed procedures for investigating allegations of such misconduct.

MRC has established procedures for dealing with allegations of scientific misconduct for its own staff. This may prove a useful reference document for award holders and institutions - **MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct(1997)**.

Extent of MRC's Liability

MRC accepts no responsibility, financial or otherwise, for expenditure (or liabilities arising out of such expenditure) or liabilities arising out of the work funded by an MRC grant other than those specifically identified in the formal award letter or in these Grant Terms and Conditions. Nor does MRC indemnify the Host Institution against claims for compensation or against other claims for which the Host Institution may be liable as an employer.

Indemnity

MRC will give sympathetic consideration to claims for non-negligent harm suffered by a person as a result of trial or other work supported by MRC. This does not extend to liability for non-negligent harm arising from conventional treatment where this is one arm of a trial. MRC acts as its own insurer and does not provide cover for non-negligent harm in advance for participants in MRC-funded studies.

Where studies are carried out in a hospital, the hospital continues to have a duty of care to a patient being treated within the hospital, whether or not the patient is participating in an MRC-supported study. MRC does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of employees of hospitals. This applies whether the hospital is a NHS Trust or not.

Conditions of Employment

These Grant Terms and Conditions relate to the conditions of employment of MRC grant-supported, Host Institution-employed staff only. They do not apply to staff the MRC directly employs itself (e.g. MRC Institute and Unit staff, MRC External Scientific Staff) whose research may be supported by an MRC grant or fellowship award.

Conditions of Service: General

Under the 1996 Concordat on Contract Research Staff Careers between CVCP, the Research Councils and other bodies, Universities and Colleges must have in place, and apply, effective policies ensuring standards for the following aspects of the career management of researchers whose salaries are provided through a Research Council grant:

Recruitment - so that the opportunities provided by research posts supported through an MRC grant or fellowship award are, as far as possible known and used:

- to provide research training and continuing development for researchers at an early stage of a research career, which may subsequently be pursued in academia, industry, commerce, or the wider public sector, or
- planned career development of more experienced research staff employed on fixed term contracts, again with the possibility of that development subsequently taking place in academia, industry, commerce, or the wider public sector; or

have been awarded an MRC Fellowship or are actually employed by the MRC.

Tenure

The tenure of appointment of staff employed through an MRC award must be confined to the period of the award, unless the Institution wishes to retain the staff beyond the period of the MRC award for its own purposes and at its own cost.

Part-Time Working Arrangements

MRC Fellowships can be awarded on a part-time basis to individuals wishing to combine their research/research training with domestic responsibilities. Fellowships can be requested for a minimum of 50%, and on the understanding that the approved programme of research can be carried out effectively.

Exceptionally MRC may also consider applications for clinical fellowships to be held on a part-time basis to allow the award holder to combine their research with professional clinical responsibilities (but not for professional training). Applications of this kind would normally only be considered for GPs, nurses, and members of the professions allied to medicine and should only be submitted following discussions with the Research Career Awards Group.

Other Work Responsibilities

Research staff supported by a grant or fellowship may work up to 6 hours a week during normal work hours on teaching, demonstrating or NHS clinical sessions (with the exception of surgeons who may undertake up to 3 clinical sessions and fellows undertaking a patient-oriented award who may undertake up to 4 clinical sessions). The payment for such work may be retained in full by the researcher, if this is in accordance with the Institution's normal conditions.

Clinical Researchers

All clinicians employed through an MRC award whose qualifications and experience are appropriate to the Specialist Registrar grade must contact their Regional Postgraduate Medical Dean, or equivalent, to discuss their higher clinical training and to ensure that where appropriate one year of the MRC-funded research counts towards the Certificate of Completion of Specialist Training. MRC does not provide support for researchers to undertake excess duty hours.

Registration for Higher Degrees

MRC fellows may be expected to register for a higher degree (normally a PhD/DPhil) as part of an award, research or technical staff supported on MRC awards may also register for a higher degree provided this does not conflict with responsibilities to the research supported by the award, and it is consistent with the employing institutions policy. MRC will not normally meet any costs associated with such registration, but may consider support for a 'Fellow' on a discretionary basis.

Promotion

Where promotion of staff employed on an MRC award was not predicted at the time of the application, funds can be vired within the grant to provide the additional funds required to support the promotion. However, where this relates to an MRC fellow, Council may consider a proposal for additional funds to support the promotion.

Maternity/Paternity Pay and Leave

Members of staff supported on an MRC award are entitled to paid maternity/paternity leave where they fulfil the qualifying conditions of the employing institution. Support may be sought by institutions to cover either:

For grant awards

- as 're-entry' routes for researchers who have taken time out from their careers.

Performance Management Arrangements - to ensure that research supervisors, mentors and sponsors provide effective research environments for the training and development of researchers. In addition, there should be in place systems of:

- supervision, in order that researchers employed through grants gain the maximum benefit from the training and development opportunities provided in the research environment in which they work;
- regular review, enabling the contract researcher and his/her supervisor - and ultimately the university or college as the employer - to form the best possible assessment of, and feedback on, the individual's potential, whether for a research career in academia, industry, commerce, the wider public sector or in some other direction;

Rewards and Other Terms and Conditions of Service for research staff employed through MRC awards (for example, rates of pay, provisions for leave and sick leave, pensions, access to facilities) which are in line with those for established staff. A key element is an assurance of equal opportunities and the elimination of practices linked to the short-term nature of contracts which indirectly discriminate against women. Maternity leave and pay provisions for researchers employed through grants should be in line with the provisions for established staff, subject to the fixed-term period of the employment contract.

In-Service Training in the form of appropriate specialist or general training. Demonstrating and teaching duties should be encouraged within the limits detailed within these Terms and Conditions.

Career Guidance and Development, for example to inform decisions by research staff employed through an MRC award on a change of career direction if the opportunities are limited or if they do not wish to remain in research or are not suited to such a career, and encouragement of talented researchers with advice on opportunities inside and outside the employing institution.

Institutions must provide research staff employed through an MRC award with a statement, at the beginning of the contract period, of the provision they make for career development and management, and of the conditions of employment used.

Conditions of Service and Salary

Staff funded through MRC grant and fellowship awards are employees of the Host Institution holding the award (with the exception of MRC-employed External Scientific Staff) and as such are subject to the salary scales and terms and conditions of service of that Institution, in line with established/tenured staff. Host Institutions must, therefore, accept all duties owed to, and responsibilities for these staff arising from the employer/employee relationship.

MRC will provide funds to support normal salary increments, and nationally agreed pay awards throughout the period of a grant, plus National Insurance and Superannuation contributions. MRC funding for any staff supported on an award will not continue beyond the termination date of the award. Other increases in salary (e.g. promotion) would normally be met from within the funds originally agreed for the award (see Promotion, Virement and Cash limiting.)

Appointing Staff

Host Institutions may appoint staff into grant funded posts and research support posts, without reference to MRC, as long as this is in accordance with normal practices and the undertakings detailed in the Concordat on Research Staff Careers. MRC does not need to grant permission for recruitment to occur to a different grade or payscale to that detailed in the award letter as long as this is within the total cash-limit of the award.

Titles

Grant-supported staff and grant-holders should not be described as 'MRC staff' or 'MRC Fellows', unless they

- making a substitute appointment to compensate for the whole, or part, of a period of paid maternity/paternity leave by a member of staff provided that the direct salary costs of the substitute do not exceed those of the member of staff on paid leave, or
- extending the duration of a grant for a period equivalent to the paid maternity/paternity leave taken by the member of staff, for which no substitute appointment has been made, so that the research may be completed.

For fellowship awards

- making a substitute appointment to compensate for the whole, or part, of a period of paid maternity/paternity leave by a member of research support staff provided that the direct salary costs of the substitute do not exceed those of the member of staff on paid leave, or
- extending the duration of a fellowship for a period equivalent to the paid maternity/paternity leave taken by the fellow, so that the research may be completed.

MRC will consider making funds available to cover costs associated with the above, only for a period of maternity/paternity leave falling within the tenure of the grant, and only where commitments take expenditure on the award over and above the original cash-limited sum. The additional costs associated with paid maternity/paternity leave should be claimed at the end of the award as an 'exceptional item'. If costs can be met from the original cash-limited sum, no additional award will be granted. Requests for extensions to the length of the award should be made as soon as the need is known rather than at the end of the award.

MRC will consider placing an award into abeyance (where there are no other staff involved) should a researcher wish to take a period of unpaid maternity/paternity leave. It is not usual for an award to be placed into abeyance for longer than one year. Requests must be made in writing prior to the event as backdated arrangements cannot be made. Institutions are required to notify MRC at the time they agree to maternity/paternity leave, to help monitor the Concordat arrangements and to inform end of award financial reconciliation.

Sick Pay and Sick Leave

Provision of sick pay to members of staff supported on an MRC award, which fulfil the qualifying conditions of the employing institution, is an allowable use of the salaries element of an MRC award. Where a period of paid sick leave in excess of three months is likely to affect the completion of a research, MRC is willing to consider funding a temporary appointment to safeguard the work of the project, or an extension to the duration of the award where the period of leave can be predicted.

MRC will consider making funds available to extend a grant or recruit a replacement for the period of sick leave that falls within the normal tenure of the grant. As with maternity/paternity arrangements, any additional costs associated with sick leave, which take expenditure on the award over and above the agreed cash-limit, should be sought as an 'exceptional item' at the end of the award. Request for extensions to the length of the award should be made as soon as the need is known rather than at the end of the award.

Gaps in Employment

MRC will consider requests to extend a grant or fellowship for up to a maximum of six months where there have been gaps in the employment of staff. It must be demonstrated that work on research has been held up by the gap in employment, and applicants are advised to consider, should the delay occur early in the life of the award, whether time could be 'made up' by the original end date. Award holders are also reminded that they can put a grant into abeyance if there are gaps in employment where the whole grant is compromised (i.e. all staff are involved, or where a researcher, with no support staff, is affected).

Annual Leave

Annual leave entitlement is determined by the employing institution and would normally be in line with those of established/tenured staff.

Removal Expenses

MRC does not provide assistance with removal expenses.

Redundancy Costs

MRC will not meet any redundancy costs of research staff whose employment ends on or before the termination of a grant.

Financial Arrangements

MRC grants and fellowships are intended to cover the full direct costs of the approved research and include a contribution to the indirect costs of the Institution. Institutions must ensure that funds awarded on MRC awards are used to support the research approved by the MRC.

Award Letters

All awards (and associated individual periods of support e.g. supplements, extensions) are made on the basis of individual identification numbers (ID). MRC will issue to the Finance Officer (or equivalent) of the Host Institution:

- an award letter detailing the funds awarded under specific financial headings and providing the ID number.
- a profile of expected payments over the duration of the grant (for grants only)
- capital equipment (over £25k) claim form
- start certificate
- acceptance of award form

Copies of the award letter are also sent to the award holders via the Finance Officer.

Cash Limiting and Indexation

All MRC grants are cash limited. The total cash-limited award includes an element (indexation) for future pay awards, promotion and merit pay, and inflation in respect of indirect costs, travel and subsistence, consumables and exceptional items. No provision is made for inflation on equipment as it is expected that such purchases will be made in the early months of an award (unless stated otherwise in the award letter). Indexation is non-negotiable; it is calculated by the MRC according to the HM Treasury indices.

MRC will not meet costs over and above the agreed cash-limit except for additional support (over and above the cash-limited total) to cover any additional costs on a grant or fellowship associated with sick leave in excess of three months or maternity/paternity leave.

MRC fellowships are not currently cash limited, Fellows and Finance Officers must ensure that annual award values as shown on the award letter are not exceeded. Fellowships are currently paid through reimbursement on receipt of an invoice. As a publicly accountable body MRC cannot honour invoices for costs that have not been granted formal approval.

Indirect Costs

Indirect costs are defined as those central and departmental costs that underpin the research activities but which cannot be readily assigned to a particular research project. Where the Institution is eligible to receive indirect costs, they are calculated as 46% of direct eligible staff costs. The indirect costs awarded through an MRC grant or fellowship are intended to cover:

- central institutional libraries (charges associated with open access publishing).
- departmental services (administrative and secretarial services not included under direct support, local finance, minor consumables, photography/printing/photocopying below £2,500 overall, publishing costs

& article processing charges, minor stores items, laboratory and workshop support).

- financial services (finance, accounting, tendering, marketing).
- personnel services.
- public relations.
- recruitment costs.
- staff development and training.
- staff facilities (transport, health & safety, welfare services, laundry)
- part-time staff effort that cannot be easily identified or allocated to the research proposal but contributes to the general background level of departmental administrative, secretarial or technical support.

Equipment & Major Purchases Procurement

The purchase of equipment, services, or other commodities through an MRC award is subject to the achievement of value for money and propriety. MRC expects the Host Institution to have in place approved procedures, separation of duties and authorities to ensure these general principles are met. MRC reserves the right to examine these systems.

MRC expects the Host Institution to follow best procurement practice (the guidance offered by the CVP/HEFCs Joint Procurement and Purchasing Strategy Group in its Procurement Guide should be followed as a minimum requirement). Institution procurement staff must be involved in the procurement of equipment at or above a threshold of £25k per purchase.

For a grant award reimbursement of individual items of equipment costing up to £25k will be included in quarterly payments to the Institutions, for fellowship awards invoices should be included as part of the quarterly invoice. If appropriate during the tenure of the award, these funds can be vired to other expenditure heads. Reimbursement for items over £25k will be paid on receipt of proof of purchase and an official claim form from the Host Institution, at the next quarterly payment date. Unless otherwise specified in the award letter, it is expected that equipment will be purchased during the first year of an award when claims should also be made. Savings made on the purchase of equipment costing £25k or more can be vired to other financial headings subject to the prior approval of the MRC.

Ownership of Equipment

Equipment purchased through an MRC award will normally become the property of the Host Institution subject to the following conditions:

- the investigator/fellow has free use during the tenure of the award (or for at least three years if the award is for equipment only) provided the investigator/fellow continues to work at the same institution
- the MRC has the right to require the equipment to be transferred with a principal investigator/fellow in the event of their moving to another institution during the tenure of the award (or for at least three years if the award is for equipment only)
- the MRC has the right to require the equipment to continue to be made available to an investigator/fellow receiving subsequent MRC support
- the institution maintains the equipment in good condition, and is responsible for its safe operation.

In exceptional circumstances, MRC may retain ownership of the equipment purchased through an MRC award, as a condition of award specified in the award letter.

Profiled Payments

Payment for MRC grants is made to the host institution through a grant profiled payments system. The cash-limited value of the award is profiled over the tenure of the grant and paid automatically by the MRC, with the exception of large single pieces of equipment (over £25k) which are outside of the profiled payment system and must be claimed individually, as expenditure arises. Profiled payments are made in arrears on a quarterly basis according to the fiscal year. Payments for small items of equipment (less than £25k) are made in the first quarter (unless stated otherwise in the award letter). Grants starting in the first half of a quarter will receive a full first quarter's payment. Those that start in the second half of a quarter will receive the first payment in the following quarter. Payments may be made at any time between 45 days before and 15 days after the end of a

quarter. Each quarter the Host Institution will receive a single payment for all current MRC grants held at that time, accompanied by a Customer Account statement listing the payment made against each grant.

In April each year, Institutions will receive an annual statement detailing the payments made in the previous financial year for each MRC grant. This must be signed by the recognised official and returned to the Grants Payments Office at MRC Head Office, by the stated deadline, indicating that the funds have been received and used to support the work approved in the MRC grant and that the work on the MRC grant is expected to continue for a further year or until completion, if sooner. Revised payment schedules will only be issued if there is a substantial change to the value of the award.

Fellowship awards are not currently paid through profiled payments but are reimbursed in arrears, quarterly on receipt of invoices submitted by the host institution

Starting the Award

MRC grants must commence within 6 months of the date of the proposed start specified on the award letter (and not before), otherwise the offer of the grant be withdrawn. In the case of some specific schemes the period allowed may be shorter, and this will be set out in the official award letter. Only in exceptional circumstances will MRC waive this rule and a case must be made in writing to MRC well in advance of the 6-month grace period.

MRC fellowships must commence on the date shown on the award letter unless changes are subsequently approved by the MRC.

Activating Payments

As soon as work commences on a grant (either the date on which the first member of staff starts work, or the date on which the first expenditure is incurred) the Start Certificate should be completed, signed by the Finance Officer and returned to the Grants Payments Office at MRC Head Office confirming that the work on the grant has commenced.

For fellowship awards, the completed Start Certificate should be returned to the Accounts Reimbursement Section, MRC would not normally expect any work to commence on the award until the Fellow has taken up their position. Claim forms, for the reimbursement of salaries, research expenses and conference allowance, will then be sent to the host institution. These should be certified by the Finance Officer (or other appropriate official), and submitted quarterly (quarters ending March, June, September and December) in arrears. It is essential that claims are received on a regular basis – the MRC may not be able to accept claims that cover a period longer than 3 months.

The purchase of large single items of equipment (£25k and over) does not activate the award.

Supplements and Extensions

MRC will supplement or extend a grant or fellowship only for the following reasons:

up to a maximum of six months where there have been gaps in the employment of staff, to cover maternity, paternity and sick leave.

MRC expects that any other costs not predicted at the time of the application will be met by transfer of funds between expenditure headings, within the cash-limited sum or awarded values (see **Virement of Funds**).

MRC will not meet any costs associated with changes to institutes' internal financial charging systems, which are not predicted at the time of application.

Virement of Funds

Award-holders may vire funds between expenditure headings without reference to MRC, except:

A final statement of expenditure is required from the original Institution before any funds can be transferred to the new Institution.

Early Termination

MRC reserves the right to terminate an award at any time without prior notice. For example, in circumstances affecting patient safety or with regards to scientific misconduct, MRC will, however, endeavour to provide a notice period before early termination. Circumstances which might lead to termination include:

- a breach in the terms and conditions under which an award was made.
- scientific misconduct.
- ethical issues such as patient safety.
- non-receipt of the Start Certificate within 6 months of the start date agreed at the announcement of the award.
- the work is diverging markedly from the originally approved project (including lower than predicted recruitment rates in trials) - award holders must inform the Council immediately they are aware of this, although there may be circumstances in which the change is acceptable on scientific grounds.
- progress targets specified at the time of the award have not been reached.
- work has stopped on the award, or the investigator/fellow has ceased to be actively involved in the project - again the Council must be informed immediately this situation arises.
- in the case of **MRC Co-operative Groups**, if the group falls below the minimum configuration, MRC may withdraw some or all of the funding awarded through the Co-operative Group Core Grant depending on an assessment of the needs of the remaining MRC Component Grants.

If the MRC terminates an award early, the Council will meet any costs properly and necessarily incurred under the award up to the termination date.

Renewal of an Award

MRC will consider applications to renew grants funded through specific schemes. Details on which grants are potentially renewable can be found in scheme specific guidance.

MRC Senior Fellows, who at the end of the award do not hold established positions, are eligible to compete for renewal of their fellowship. Applications for renewal are considered in open competition alongside new and other renewal applications. With the exception of these Senior awards no other MRC fellowships are renewable. Senior Fellows considering renewal are advised to contact the Research Career Awards Group.

Interim Statements of Expenditure

In the case of MRC grants lasting 5 years or more, an interim statement of expenditure must be completed and signed by the Finance Officer of the Institutions, by the deadline notified by the MRC Grants Payment Office. Interim statements of expenditure are not currently required for MRC fellowships.

Annual Statements

In April each year, the Finance Officer of each Institution holding MRC grants will receive an annual statement detailing for each grant the payments made during the previous financial year. Further payments cannot be made by the MRC Grants Payment Office until the statement has been signed and returned to MRC. Annual statements are not currently provided for MRC fellowships.

Final Payments

See **Final Financial Reports** section of the website.

Eligible Staff Costs

All salaries (full or part-time) supported through an MRC grant attract indirect costs. For an MRC fellowship

- sums awarded for major capital items (£2.5k and over) – where MRC approval must be sought before virement can take place
- sums awarded for indirect costs (46% of direct staff costs). Any indirect costs associated with a vired post must be returned to MRC at the end of the grant.

If sums are vired into salary costs, an additional 46% must be vired into indirect costs.

Should a grant holder whose salary is provided through the grant subsequently obtain salary support from elsewhere, the salary provision in the grant cannot be transferred to another individual and must be returned to the MRC at the end of the grant. Where a fellow obtains salary support elsewhere the award will be terminated and all unspent funds returned to the MRC.

Grant Holders and Fellows must seek authority from MRC if they wish to vire extra funds into animal costs in excess of 30% of the original award for such costs.

Where the use of funds is significantly different from that awarded, in particular where expenditure under a financial heading differs from the sum awarded by more than 20%, and for any use of staff funds for non-staff expenditure, specific explanation must be given in the final financial report.

Placing an Award on Hold

Grant holders may seek approval for placing a grant on hold (in abeyance) e.g. while a replacement is found for a member of staff who has left, or if there is a reason for delaying the start of the grant beyond the 6 months start period. Grants cannot be placed on hold where another member of staff continues to be funded through the grant.

Fellows may also seek approval to place an award on hold e.g. to undertake a period of clinical training, or to deal with domestic purposes. MRC may consider continuation of support for research staff employed on the award where arrangements have been made for the supervision of staff and the research project.

Early notification of such a request is essential, as awards cannot be put into abeyance retrospectively. No quarterly payments will be made, or invoices met, during any period when an award is placed on hold.

Transfer of an Award

MRC will consider requests to transfer awards from one host institution to another. For a grant award this would normally result from the principal investigator being offered an appointment at another institution. For a fellowship this may follow the fellow being offered a tenure-track appointment at a new institution, better career prospects or changing domestic circumstances.

Awards can normally be transferred (including the balance of funds) to a new institution provided:

- notice is given well in advance
- the head of departments and administrative authorities of both institutions concerned agree to the transfer in writing
- the new institution offers a suitable scientific environment to enable the project to be completed and for the career development of staff employed through the award. (For junior and intermediate fellowships the institution should also provide a suitable research training environment and supervisory arrangements).
- in the case of a grant held by more than one investigator or as a component within a Co-operative Group that the aims of the project can still be achieved through a split site arrangement
- the new institution is eligible to hold the MRC award to be transferred.

The potential transfer of any award must be discussed with MRC Head office prior to any transfer arrangements being made. MRC will not supplement an award to meet any additional costs associated with a transfer from one Institution to another e.g. location allowance. Award holders can vire funds from elsewhere in the award to meet any additional costs. Funds cannot be provided from within an MRC award to meet relocation costs.

indirect costs are payable on the salaries of research support staff only but not for the fellow themselves. Salaries eligible to attract indirect costs include:

- Principal Investigators and Co-applicants salaries (not MRC Fellows)
- Research staff (e.g. post-graduate and post-doctoral scientists, statisticians, research nurses) salaries
- Technical staff salaries
- Other staff salaries
- Collaborative Researchers' salaries

Salaries not eligible to attract indirect costs include:

- MRC Fellows
- MRC Professors
- Replacement of staff for applicants
- Retired Workers
- Students
- Sandwich students
- Field workers
- Casual workers

Reporting, Publishing and Exploitation

Monitoring and Evaluation

MRC places great importance on monitoring and evaluating its research grants. Although it is the responsibility of the grant holder to manage the grant, MRC reserves the right to call for periodic information on progress on the research or to visit grant holders. In some circumstances, there may be special conditions attached to an award in relation to monitoring and evaluating. These will be detailed in the official award letter.

Final Scientific & Financial Reports

MRC understands that in order to follow scientific developments which arise during the tenure of an award, grant holders may need to modify the aims and direction of their research. Any such modification must be justified in the final scientific report. Where work is diverging markedly from the originally approved project, grant holders must inform MRC immediately they are aware of this; there may be circumstances in which a significant change is acceptable.

Institutions are responsible for ensuring that a final scientific report (completed by the principal investigator) and a financial statement (completed by the Host Institutions finance officer) are completed and returned at the end of a grant or period of funding. These will be sent to the finance officer one month before the end of the grant. Both of these documents must be received by MRC within three months of the termination date of the grant. It is the responsibility of the Finance Officer to ensure that both these reports are returned on time. The final quarterly payment of the grant will be withheld until satisfactory returns have been received, and will not be paid at all if the scientific reports are overdue. Once final statements are received the final payment (or clawback of funds, if there has been an underspend) will automatically be released with the next quarterly payment to the Host Institution.

For the purposes of the scientific report, the grant holder will be expected to list scientific achievements such as publications, and address questions on the original objectives of the research, the methodology used, scientific advances made (and any consequent changes in objectives of the work), actual and potential impact on wealth, health and quality of life, efforts taken to disseminate results to user communities (application and exploitation) and to inform the general public, staff development and training, and collaborations.

For the purposes of the final financial report, Institutions should record the actual sums spent on the grant, even if this is above the cash-limited total, and provides explanations for any significant variances (greater than 20%) between awarded values and actual expenditure, and any use of funds awarded for staff costs for non-staff expenditure. The final quarterly payment of the grant will be withheld until satisfactory returns have been received, and will not be paid at all if the scientific reports are overdue.

Submission of final statements of expenditure should not be delayed until the outcome of pay award negotiations are known. If extra salary costs are chargeable to the grant at a later stage, an invoice can be submitted to the

Grants Payments Office, if the final payment has been made already. Such claims are processed once a month and payments are made outside of the grant profiled payments.

Training and career development questionnaires will be made available at the same time, for completion by contract research staff employed through the grant. The questionnaire will include questions on the training and career development opportunities provided by the grant and the next employment destination of the contract research staff. The researchers themselves and not the Finance Officer are responsible for returning the questionnaire to the MRC and processing of the final statement of expenditure is not dependent upon receipt of the questionnaire.

More detailed progress reports are requested on longer-term MRC funded research supported through programme grants and Co-operative Groups, at the time of a request for renewed support is submitted (see scheme specific notes for more detail). MRC reserves the right to seek additional scientific reports on work which it funds at any time.

Publication and Acknowledgement of Support

MRC attaches great importance to the dissemination of the results of research undertaken with its grant support. Grant holders must acknowledge the MRC's support in publications and communications (including media appearances and releases, as well as journals and conferences). MRC financial support should always be acknowledged, even when the contribution to individual papers may be small. This is essential in helping to publicise MRC's work, and also provides MRC and the Government with an indicator of the success of its investment. Acknowledgements should mention the form of MRC support (e.g. Programme Grant) and grant reference numbers, wherever journal rules permit.

Grant holders are responsible for ensuring that articles, programmes or papers give an accurate account of the research.

MRC may decide to publicise the award of a specific grant and will work with the successful applicant and the host institution to prepare publicity material accordingly. Research results and achievements should, where possible, be communicated to the MRC Press Office before publication.

Public Engagement in Science

Grant holders are expected to participate in activities which seek to raise the awareness of science amongst lay audiences (see Government 2000 White Paper 'Excellence and Opportunity for the 21st Century'). To this end, MRC's own research establishments are expected to develop and deliver their own individual communication strategies and in some cases, if relevant, local grantholders might be able to involve themselves with these communication initiatives. Universities also have a role in developing opportunities for science dialogue with lay audiences. Key audiences for MRC grantholders to consider in their communications activities are:

- Opinion Formers, Influencers and Policy Makers
- Scientific Community
- Health Professionals
- Consumers/Patients
- Next Generation of Citizens
- The Public

Exploitation of Research Results

Host Institutions and grant holders should ensure that research results are protected and exploited wherever possible for the benefit of UK industrial competitiveness, whilst ensuring incentives and returns to the university/research institute and inventor(s).

Ownership of any intellectual property arising from MRC grants is vested initially in the Institution administering the award. The institution may retain these intellectual property rights or assign or license them to industrial partners under exploitation arrangements. The institution is entitled to retain any income arising from its exploitation agreements. There are a few exceptions e.g. where the grant has been awarded to an employee of MRC, or is made under a programme of research where it is important to avoid or reduce fragmentation of intellectual property. The arrangements to apply in such cases will be specified in the grant award letter. Institutions are required to ensure that all those associated with MRC supported research are aware of, and accept, their procedures for the notification of any device, material, product or process, computer software or

other result which it is considered might have commercial significance, whether patentable or not, in good time before publication or other disclosure.

Specific Conditions and Considerations

Use of Animals

Award-holders are expected to abide by the core principles set out in the Council's Booklet: **Responsibility in the Use of Animals in Medical Research (1993)**. A new edition of this book is expected to be produced later this year.

The objectives of MRC funded experiment(s) should be clearly defined and, where possible, award-holders must adopt procedures and techniques which avoid the use of animals. Where this is not possible, the research should be designed so that:

- Species with the most appropriate physiology for the work are used; where possible simple organisms should be used.
- The number of animals used in an experiment must be the minimum sufficient to create adequate statistical power to answer the question posed.
- The severity of the procedures performed upon animals is kept to a minimum. The experiment should be kept as short as possible, and anaesthesia/analgesia used to minimise pain where possible.

Peer review bodies will have looked carefully at applications involving animals and any recommendations arising from the MRC peer review process with regards to animal use must be followed by grant-holders.

The provisions of the Animals (Scientific Procedures) Act 1986 must be observed. Institutions and award-holders are responsible for ensuring that all appropriate personal and project licences required under the Act have been granted by the Home Office. All MRC awards are made on the absolute condition that no work which is controlled by the Act will begin until the necessary licences have been obtained.

Award holders should ensure that any new procedure likely to reduce the number of animals for research or testing, lead to replace or refine their use, is reported to MRC and is disseminated through the usual scientific channels to all those who might make use of it.

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

When a project involves the use of simians or their tissues, the investigators should act in accordance with the practices set out in MRC statement on the "Management of Simians in Relation to Infectious Hazards to Staff" (revised 1990), copies of which are available from the Publications Group at MRC Head Office.

MRC is a public body legally obliged to provide information on its work to Parliament and to the public, and is committed to improving public communications on animals. MRC will make public information about animal experiments it funds when needed (e.g. as anonymous examples, or in response to direct queries). MRC will resist all requests for information that might lead to the identification of places or individuals, except with the express permission of the individuals concerned.

Mouse Strains

MRC supports a central repository of mouse strains - the MRC Mouse Frozen Embryo and Sperm Archive (FESA) at the Mammalian Genetics Unit, Harwell. Award holders are expected to contact FESA to highlight mouse strains engineered, or characterised using MRC funds, and are encouraged to deposit these strains with the archive. Depositors retain ownership of strains and there is currently no charge for depositing strains to make freely available to the academic community. FESA aims to ensure that valuable mouse strains are safeguarded, that the need to maintain colonies of live mice for long periods of time is reduced, and that the significant investment in engineering strains is capitalised upon fully. MRC award holders planning mouse research should

contact FESA at the earliest opportunity, at the MRC Mammalian Genetics Unit, Harwell.

Health Department's Research Governance Framework for Health & Social Care

The Council expects to be the Research Governance Framework for Health & Social Care (RGF) Sponsor for research programmes and projects involving NHS patients, their organs, tissues or data and which falls within the scope of the UK Health Department's Research Governance Framework, for which the Council has (a) assessed the quality of research and the risks to the Council, and (b) which it has agreed to fund either in the form of a grant or fellowship awards to universities, NHS Trusts or directly as an allocation within an MRC Institute, Unit or Team. Sponsorship does not include MRC Studentships awarded in the form of a block grant.

RGF Sponsorship is project-specific and does not extend to new work or to the continuation of work beyond the agreed funding period without specific MRC approval. On the other hand, it does accommodate reasonable changes within the scope and duration of the approved project or required by research ethics committees.

Ensuring that management and monitoring systems are in place is the responsibility of the institution to which the grant has been awarded. Key to good governance is the allocation, acceptance and execution of responsibilities within a sound research and project management framework and consistent with standards. Systematic documentation of key decisions and approvals, particularly in relation to work with patients, their organs, tissues and data is crucial.

MRC requires Host Institutions to ensure that the research undertaken under an award by the institution itself complies with MRC Terms and Conditions including MRC's ethics and best practice guidance and the requirements of the Employing Organisation set out in the Research Governance Framework.

MRC requires Host Institutions to ensure that agreements and systems are in place with NHS Trusts and other partner organisations including Commercial Organisations so as to comply with MRC Terms and Conditions and the Research Governance Framework.

MRC requires Host Institutions to ensure that it or a partner organisation systematically documents NHS Trust, ethical and regulatory submissions, approvals and amendments. No work involving patients, their organs, tissues or data should be permitted by Host Institution or its partners without these approvals being in place.

There are more detailed responsibilities for the Host Institutions conducting research involving a commercial organisation manufacturing, formulating, packaging or supplying an investigational product. Click here for full details.

MRC has produced guidance to help institutions to help Host Institutions identify MRC requirements of them in relation to research which falls within the scope of the Research Governance Framework.

Human Participants in Research

MRC expects all work involving human participants to be undertaken in accordance with its statements: **Responsibility in Investigation on Human Participants, Human Material and Personal Medical Information (1992)**, **Ethical Conduct of Research on Mentally Incapacitated (1993)**, **Personal Information in Medical Research (2000)** and **Human Tissue and Biological Samples for Use in Research (2001)**.

Institutions and award holders have absolute responsibility for ensuring that investigations being undertaken within an organisation such as a factory, school or service establishment or NHS premises, do not take place without the explicit approval of the appropriate authority in advance.

Payments to healthy volunteers participating in clinical trials are allowable, provided that the payment is for expense, time and inconvenience and is not at a level which would induce people to take part in studies against their better judgement. In the case of non-clinical investigations which do not involve invasion of the body's integrity, payment of a fee (not normally exceeding £4.00 per hour) plus travelling and other out-of-pocket expenses is permissible.

Independent research ethics committee approval is required for research that involves human participants (whether patients or normal volunteers) or records. It is also required for certain studies of human tissues. In the case of research involving NHS patients, premises or records, this will be a Local Research Ethics Committee (LREC) set up by the local Health Authority or Board, or a Multi-Centre Research Ethics Committee (MREC), as appropriate. In the case of psychological research on volunteers, the relevant institution's ethics committee will usually be appropriate (see the MRC statements Responsibility in Investigation on Human Participants - 1992, Personal Information in Medical Research - 2000). Institutions and award holders have absolute responsibility for ensuring that such approval is granted before any research is undertaken. In the case of clinical trials a copy of the approval, and the original submission to which the approval refers, must be forwarded to MRC Head Office before an award letter can be issued. In the case of multi-centre trials or studies involving 5 or more different centres, approval from Multi-Centre Research Ethics Committees must be granted in addition to the LREC approval for each of the participating centres, before any research can commence/an award letter can be issued.

Any variation in a project that affects the nature or degree of the hazards to which the human participants are exposed should be treated as a new investigation and fresh ethical approval must be obtained from the LREC/MREC. Institutions and award holders have absolute responsibility for ensuring that such approval is granted before any research is undertaken.

Any serious incident arising in the course of an investigation that has been approved by a LREC/MREC should be reported immediately to the MRC, as well as to the ethics committee. The investigation must be suspended until the ethics committee has decided whether it may be continued or should be abandoned.

Research involving human participants in developing societies presents specific ethical challenges and the MRC guidelines, *MRC Sponsored Studies in Developing Societies Involving Human Participants (interim)*, must be followed.

Clinical Trials

There are a number of requirements specific to MRC-funded clinical trials:

- Host institutions and the award holders are responsible for ensuring that an MRC-funded trial is conducted in accordance with the general MRC terms and conditions of an award, and those set out in set out in Council's guidelines on *Good Clinical Practice in MRC-Funded Trials*(1998).
- On making an award the MRC requires that an independent Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC) should be set up to oversee the conduct of the trial. Membership of these committees will have been detailed in the application approved by the appropriate Research Board.
- MRC requires an annual report from the TSC. Details can be obtained from the **MRC Trials Manager**.
- Before the results of an MRC-funded trial are published they must be discussed in draft form by the TSC.
- In very exceptional circumstances requests for extension to MRC-funded trials will be considered. All such proposals should be discussed in advance with the **MRC Trials Manager**.
- Any contribution to an MRC-funded trial by another body, such as a pharmaceutical company, (including the donation of drugs etc.), must be the subject of a contract between the MRC and the company. Further information should be sought from the **MRC Trials Manager** at the earliest opportunity.

The following sections of these Terms & Conditions are particularly relevant to clinical trials: **indemnity, human participants in research, medical records and data protection.**

Human Fertilisation

Award holders whose project involves the use of human gametes or embryos must act in accordance with the Human Fertilisation and Embryology Act 1990. This will include obtaining a licence to undertake activities covered by the Act. Further information can be obtained from the Human Fertilisation and Embryology Authority, 30 Artillery Lane, London, E1.

Medical Records

When a project involves the use of medical records, the award holder must act in accordance with both the principles set out in the Data Protection Act 1998 and the Council's statement *Personal Information in Medical Research (2000)*. All research staff handling personal data must have clearly established (through written guidance and direct instructions) obligations to maintain confidentiality.

All NHS bodies should routinely inform patients that medical information may be used in research statistics, etc., and should give patients who wish to discuss any concerns an opportunity to do this (*Protection and Use of Patient Information, 1996*). Identifiable data should not be used in research if a patient has made clear that they do not wish it to be.

Use Of Human Fetal Material

Award holders whose research involves the use of the pre-viable fetus, the whole head fetus, fetal tissues, or fetal material (i.e. placenta, fluids or membranes) must have been granted approval for such work from an independent local research ethics committee. Institutions and grant holders have absolute responsibility for ensuring that no research is undertaken prior to permission being granted. Research workers must comply with Health Department guidance issued in the light of the Polkinghorne Report.

Removal of Human Tissue

Award holders whose research involves procedures for the removal of human tissue at post-mortem examination (Human Tissue Act 1961) must follow the guidance detailed in the *MRC Statement Human Tissue and Biological Samples for Use in medical Research (2001)* and issued by the Health Departments and Local Health Authorities.

Use of Radioactive Substances and Neutron Irradiation in Humans

Award holders whose research requires the use of radioactive substances or in vivo neutron activation analysis in humans, must have sought advice and approval from the Administration of Radioactive Substances Advisory Committee before any research is undertaken. Approval and advice from the Unit does not remove the obligation to have in place separate approval from an independent research ethics committee. Institutions and award holders have responsibility to ensure that no research is undertaken before approval from both bodies has been granted.

Genetic Modification

The Genetically Modified Organisms (Contained Use) Regulations 1992 and The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 1996 require laboratories that carry out genetic modification to be registered with the Health and Safety Executive. All such work is subject to risk assessment and according to the assessment some work may additionally require specific consent. Institutions and award holders undertaking genetic modification must be registered with the HSE, have under taken risk assessment and have been granted consent (where appropriate). All notifications and annual returns must be sent to the Directorate of Science and Technology, Unit E4, Magdalen House, Stanley Precinct, Bootle, L20 3QZ (Tel: 0151 951 4772).

Detailed guidance notes are provided by the Advisory Committee on Genetic Modification (ACGM) to every registered Centre. It is important that grant holders who carry out genetic modification are familiar with the legislative requirements and with ACGM guidance. Advice can be obtained from the Bootle address of the HSE or from HSE Health Directorate B2, Floor 7SW, Rose Court, 2 Southwark Bridge, London, SE1 9HB, (Tel: 020 7717 6348).

Dangerous Pathogens

Institutions/Departments accommodating projects involving the use of dangerous pathogens must comply with the safeguards recommended by the Advisory Committee on Dangerous Pathogens in their report: *Categorisation of Biological Agents According to Hazard and Categories of Containment*, HMSO, 4th Edition, 1995.

Controlled Drugs

Award holders whose research requires the use of one or more of the drugs controlled under the Misuse of Drugs Act, 1971 and its subsequent amendments, must hold an appropriate Home Office licence. Institutions and award holders have absolute responsibility to ensure that no research is carried out before a licence has been granted.

Data Protection Act 1998

The 1998 Data Protection Act requires data controllers to notify the processing of personal data with the Office of the Information Commissioner. MRC award holders and their teams should register with the Office through their Host Institution, and are expected to comply with the principles of good practice outlined in the Act.

Use of Information

Sharing information and knowledge about MRC funded research is central to the MRC's mission. The following details will be made available through the Research Portfolio Search on this website:

- Research title
- Abstract
- Grant holders and Fellows
- Host Institution
- Value & duration of award

All applications for MRC grants and fellowships, and subsequent awards, are uploaded to INFORM (the MRC research management information database). The MRC may also provide details of grants and grantholders to other organisations and allow the information to be incorporated into their publicly available databases and websites.

Recent Change to MRC's Terms and Conditions:

MRC may agree to a time only extension of a grant or fellowship, only for the following reasons:

- up to a maximum of six months where there have been gaps in the employment of staff,
- to cover paid maternity, paternity or sick leave.

MRC will not supplement a grant or fellowship financially once awarded apart from for maternity/paternity or sick leave where a member of staff has been replaced by a temporary staff member in their absence and an extra salary has therefore been paid.

Should a researcher wish to take a period of unpaid maternity/paternity leave, MRC will consider placing an award into abeyance (where there are no other staff involved). It is not usual for an award to be placed into abeyance for longer than one year. Requests must be made in writing prior to the event as backdated arrangements cannot be made. Award holders retain the option to vire funds between headings to cover unexpected shortfalls.

This change brings the MRC grant terms and conditions into line with the other Research Councils. This change applies from 31 January 2003 and covers all MRC grants and fellowships currently in existence and those yet to be awarded. All award letters from now on will contain the above information. Existing award holders will be informed via their institutions. All extensions and supplements are made at the discretion of the MRC.

Research involving NHS patients, their organs, tissues and data needs to be consistent with the Department of Health / NHS Research Governance Framework for Health and Social Care.

The MRC has recently merged its Terms and Conditions for grant and fellowship awards. Details of the revised Terms and Conditions can be accessed by clicking on the left-hand navigation menu.

This section of the MRC website details the Terms and Conditions under which all MRC Grants and Fellowships are awarded. Any additional/exceptional conditions applying to specific schemes or individual awards will be incorporated in the official award letter, or are detailed in the guidance relating to each specific research funding scheme.

The MRC reserves the right to amend these terms and conditions. Institutions will be notified of significant changes, others will be posted here. All of the pages in this Terms & Conditions section can be printed with one simple click.

**RESEARCH GOVERNANCE
FRAMEWORK
For
HEALTH AND SOCIAL CARE**

Research Governance Framework

Research is essential to the successful promotion of health and well-being. Many of the key advances in the last century have depended on research, and health and social care professionals and the public they serve are increasingly looking to research for further improvements.

This country is fortunate to be able to draw upon a wide range of research within the health and social care systems. Most of this is conducted to high scientific and ethical standards. However, recent events have made us all painfully aware that research can cause real distress when things go wrong. The proper governance of research is essential to ensure that the public can have confidence in, and benefit from, health and social care research.

This Research Governance Framework reflects a wide range of discussions with the NHS and all the Department of Health's partners in health and social care research. We have considered carefully the responses to our earlier consultation and the issues raised in meetings with stakeholders.

I am grateful to all who have helped us with this important task. We now need to continue to work together to ensure that this Research Governance Framework for Health and Social Care is implemented successfully. In this way, we can provide the public with the reassurance it has the right to expect, and ensure that we can continue to reap the benefits of research.

Lord Hunt of Kings Heath

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This document builds on a range of earlier published work and draws extensively on the following documents:

The NHS Plan	2000
Research and Development for a First Class Service – R&D Funding in the New NHS	2000
An Organisation with a Memory – Report of an expert group on learning from adverse events in the NHS	2000
A First Class Service: Quality in the New NHS	1998
Clinical Governance – Quality in the New NHS	1998
The New NHS: Modern and Dependable	1997
A Quality Strategy for Social Care	2000
Modernising Social Services	1998
<i>All the above are available on www.doh.gov.uk</i>	
Valuing Diversity - Equality and Diversity in Policy Making	2000
Diversity in the Civil Service/Public Service	2000
www.cabinet-office.gov.uk	
OST Guidelines on Use of Scientific Advice in Policy Making	2000
http://www.dti.gov.uk/ost/ostbusiness/index_policy_making_old.htm	
MRC Guidelines for Good Clinical Practice in Clinical Trials	1998
http://www.mrc.ac.uk	

1. PURPOSE AND SCOPE

- 1.1 The Government is committed to enhancing the contribution of research to health and social care, and to the partnership between services and science. Research is essential to the successful promotion and protection of health and well-being and to modern and effective health and social care services. At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and well-being of the research participants. Proper governance of research is therefore essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.
- 1.2 This document sets out a framework for the governance of research in health and social care. The standards in this framework apply to all research which relates to the responsibilities of the Secretary of State for Health - that is research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken by or within social care services that might have an impact on the quality of those services. This includes clinical and non-clinical research, research undertaken by NHS staff using NHS resources, and research undertaken by industry, the charities, the research councils and universities within the health and social care systems.
- 1.3 The framework is offered as a model for the governance of research in other areas where poor practice could have a direct impact on the health or well-being of the public.
- 1.4 The framework is of direct relevance to all those who host, conduct, participate in, fund and manage health and social care research. It is not restricted to principal investigators, managers or to any one professional group. All service and academic staff, no matter how senior or junior, have a role to play in the proper conduct of research. Participants in research and the public in general can also help to ensure that standards are understood and met.
- 1.5 This framework seeks to promote improvements in research quality across the board. As with clinical governance and best value in social care, research governance involves

Research Governance

- Sets Standards
- Defines mechanisms to deliver standards
- Describes monitoring and assessment arrangements
- Improves research quality and safeguards the public by:
 - Enhancing ethical and scientific quality
 - Promoting good practice
 - Reducing adverse incidents and ensuring lessons are learned
 - Preventing poor performance and misconduct
- Is for all those who:
 - Participate in research
 - Host research in their organisation
 - Fund research proposals or infrastructure
 - Manage research
 - Undertake research
- Is for managers and staff, in all professional groups, no matter how senior or junior.

bringing general performance up to that of those at the leading edge. The framework provides a context for the encouragement of creative and innovative research and for the effective transfer of learning, technology and best practice to improve care.

1.6 The framework also aims to prevent poor performance, adverse incidents, research misconduct and fraud, and to ensure that lessons are learned and shared when poor practice is identified. Achievement of these aims, drawing on the work of the Chief Medical Officer's expert group on learning from adverse events¹, will promote good practice, enhance the ethical and scientific quality of research and safeguard the public.

1.7 Health and social care generate and draw upon a wide range of innovative work and ideas from professionals, organisations and the public. Services must promote innovation and its benefits whilst protecting participants from risk and waste. Innovation embraces a much wider range of activities than those managed formally as research. Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.

1.8 This document sets out the responsibilities and standards that must be applied to work managed within the formal research context. Other documents on clinical governance and on quality in the NHS and social care set out standards and systems for assuring the quality of innovative work in non-research contexts.

1.9 In common with other quality assurance and governance systems, this research governance framework describes:

- arrangements to define and communicate clear quality standards;
- delivery mechanisms to ensure that these standards are met, and
- arrangements to monitor quality and assess adherence to standards nationally.

1.10 Recent enquiries into adverse incidents relating to research have criticised the lack of clarity in relation to responsibilities and accountabilities for research in health and social care. This is of particular importance, given the very wide range of individuals and organisations that can be involved. The framework pays particular attention to clarifying responsibilities and accountabilities.

¹ An Organisation with a Memory – Report of an expert group on learning from adverse events in the NHS, 2000

1.11 Listed are some of the individuals and organisations involved in health and social care research:

- Patients/users, their relatives and organisations representing them.
- The public.
- Research workers.
- Universities.
- Research charities.
- Research councils.
- Health and social care professionals and professional organisations.
- Health and social care organisations.
- Local authorities.
- The pharmaceutical and other industries.
- Department of Health.

1.12 Achieving high quality in research depends on co-operation between all those involved. Figure 1 illustrates how the Department of Health will continue to work with patients, users and care professionals, the public and its research partners to develop and implement this research governance framework to assure quality in health and social care research.

1.13 Following the model in Figure 1 the remainder of this document is structured as follows:

- Section 2 (with the Annex) sets out standards.
- Section 3 details responsibilities.
- Section 4 outlines delivery systems, and
- Section 5 describes local and national monitoring systems.