Additional Dimbleby Marie Curie Cancer Care Research Fund grant terms and conditions

The following additional Dimbleby Marie Curie Cancer Care Research Fund grant terms and conditions form part of theconditions referred to in paragraph RG24.

- AC1 Responsibilities of the Administering Institution: Clinicians
- AC2 Other Work Responsibilities
- AC3 Profiled Payments
- AC4 Training and Career Development Questionnaire
- AC5 Dimbleby Marie Curie Publicity for Grants
- AC6 Health Department's Research Governance Framework for Health & Social Care
- AC7 Human Participants in Research
- AC8 Clinical Trials
- AC9 Medical Records
- AC10 Removal of Human Tissue
- AC11 Use of Radioactive Substances and Neutron Irradiation in Humans
- AC12 Controlled Drugs
- AC13 Data Protection Act 1998

AC1 Responsibilities of the Administering Institution: Clinicians

The Administering Institution is responsible for ensuring that all clinicians working under a Dimbleby Marie Curie Cancer Care Research Fund 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 Administering Institution. The Dimbleby Marie Curie Secretariat will not meet the costs of such cover.

The Administering Institution is responsible for ensuring that any honorary clinical contracts required by clinical staff working under a Dimbleby Marie Curie Cancer Care Research Fund award have been obtained prior to the start of the award.

AC2 Other Work Responsibilities

Research staff supported full time by the grant may work up to 6 hours a week during normal work hours on teaching, demonstrating or NHS clinical sessions.

AC3 Profiled Payments

Payment for Dimbleby Marie Curie Cancer Care Research Fund grants is made to the Administering 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 Dimbleby Marie Curie Secretariat as expenditure arises. Profiled payments are made in arrears on a quarterly basis according to the fiscal year.

Payments for equipment 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 Administering Institution will receive a single payment for all current Dimbleby Marie Curie Cancer Care Research Fund grants held at that time, accompanied by a Customer Account statement listing the payment made against each grant.

AC4 Training and Career Development Questionnaire

Researchers might also be required to return a training and career development questionnaire at the same time, to be completed 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.

AC5 Dimbleby Marie Curie **Publicity for Grants**

The Dimbleby Marie Curie Secretariat may decide to publicise the award of a specific grant and will work with the successful applicant and the Administering Institution to prepare publicity material accordingly.

Research results and achievements should, where possible, be communicated to the Dimbleby Marie Curie Secretariat Press Office before publication.

AC6 Health Department's Research Governance Framework for Health & Social Care

Research involving NHS patients, their organs, tissues or data and which falls within the scope of the UK Health Department's Research Governance Framework, must comply with the NHS Research Governance Framework for Health & Social Care (RGF) **(http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962)**

The Dimbleby Marie Curie Secretariat will not be the RGF sponsor of grant funded work. New research proposals must identify the sponsor: Dimbleby Marie Curie Secretariat's expectation is that the Administering Institution will accept all the sponsor's responsibilities.

The Administering Institution to which the grant has been awarded is responsible for ensuring that quality and risk management and monitoring systems are in place.

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.

The Dimbleby Marie Curie Secretariat requires Administering Institutions to ensure that the research undertaken under an award by the Administering Institution itself complies with the Secretariat's Terms and Conditions.

The Dimbleby Marie Curie Secretariat requires Administering 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 the Dimbleby Marie Curie Secretariat's Terms and Conditions and the Research Governance Framework.

For any research involving human participants the Dimbleby Marie Curie Secretariat requires:

- The Administering Institution to demonstrate promptly to the Dimbleby Marie Curie Secretariat, on request, that the required permissions (ie regulatory authorisations and

Research Ethics Committee approvals) are in place, or were in place when the activity occurred.
- The Corresponding Applicant to notify the Dimbleby Marie Curie Secretariat if amendments required by a regulator or a research ethics committee will substantially affect the research question, methodology or costs such that the project or programme is no longer the same as the Secretariat approved.

Exceptionally, in cases where the research may be especially sensitive, the Dimbleby Marie Curie Secretariat will ask for and require evidence of permissions from investigators before releasing funding.

AC7 Human Participants in Research

The Dimbleby Marie Curie Secretariat expects all work involving human participants to be undertaken in accordance with appropriate ethical standards.

The Administering Institution 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.

The guide of INVOLVE (**http://www.invo.org.uk/Other_frequently_asked_questions.asp**) should be followed for payments to members of public actively involved in research.

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, the relevant system to apply for approval will be the Integrated Research Application System (IRAS).

Research involving individual patient data, where the patient's consent will not be obtained, is covered by "Section 60" of the Health and Social Care Act, 2001, and requires additional procedures. In medical research involving adults who cannot consent, applicants might want to refer to the MRC Ethics Guide 2007: Medical Research involving adults who cannot consent.

In the case of psychological research on volunteers, the relevant research organisation's ethics committee will usually be appropriate (see the MRC statements Responsibility in Investigation on Human Participants - 1992, Personal Information in Medical Research - 2000).

Administering Institutions and award-holders have absolute responsibility for ensuring that such approval is granted before any research is undertaken.

In the case of multi-centre trials or studies, approval via the Integrated Research Application System (IRAS) must be granted 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.

Administering 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 via IRAS should be reported immediately to the Dimbleby Marie Curie Secretariat, 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.

AC8 Clinical Trials

There are a number of requirements specific to clinical trials

- Trials of medicines that fall within the scope of the EU Clinical Trials Directive must comply with the UK regulations (The Medicines and Healthcare Products Regulatory Agency (MHRA) is the statutory body). Dimbleby Marie Curie Secretariat's expectation is that the Administering Institution will identify itself as the sponsor (or one of a group of individuals/organisations that accepts the sponsor's responsibilities).
- Administering Institutions and the award-holders are responsible for ensuring that an Dimbleby Marie Curie Cancer Care Research Fund-funded trial is conducted in accordance with the general Dimbleby Marie Curie Cancer Care Research Fund terms and conditions of an award, and that all legal & regulatory requirements are followed. The Dimbleby Marie Curie Secretariat recommends the use of MRC's guidelines on Good Clinical Practice in Clinical Trials (1998) **(http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416)** and MRC/DH joint project to **Good Clinical Practice (http://www.ct-toolkit.ac.uk/)**
- On making an award the Dimbleby Marie Curie Secretariat requires that an independent Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC) be set up to oversee the conduct of the trial.
- Before the results of a Dimbleby Marie Curie Cancer Care Research Fund-funded trial are published they must be discussed in draft form by the TSC.
- Any contribution to a Dimbleby Marie Curie Cancer Care Research Fund-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 Administering Institution and the company.

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

AC9 Medical Records

When a project involves the use of medical records, the award holder must act in accordance with the principles set out in the Data Protection Act 1998 **(http://www.informationcommissioner.gov.uk/)**.

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.

AC10 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 legal and regulatory requirements and issued by the Health Departments and Local Health Authorities. An example of the guidance can be found in the **MRC Statement Human Tissue and Biological Samples for Use in medical Research (2001**)
(http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420)

AC11 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.

Research Organisations and award-holders have responsibility to ensure that no research is undertaken before approval from both bodies has been granted.

AC12 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.

Research Organisations and award-holders have absolute responsibility to ensure that no research is carried out before a licence has been granted.

AC13 Data Protection Act 1998

The 1998 Data Protection Act **(http://www.informationcommissioner.gov.uk**/) requires data controllers to notify the processing of personal data with the Office of the Information Commissioner.

Dimbleby Marie Curie Cancer Care Research Fund award-holders and their teams must register with the Office through their Research Organisations, and are expected to comply with the principles of good practice outlined in the Act.