TERMS AND CONDITIONS OF BCRT GRANTS

Definitions

Directly Incurred Costs: costs that are explicitly identifiable as arising from the conduct of a project are charged as the cash value actually spent and are supported by an audit record.

Dipstick Testing: a programme of visits and office-based tests to seek assurance that research grant funds are used for the purpose for which they are given and that grants are managed in accordance with the terms and conditions under which they are awarded.

Principal Investigator: the person to whom the research project is assigned. The Principal Investigator takes responsibility for the intellectual leadership of the research project and for the overall management of the research funding. The Principal Investigator is not only responsible for the management of the research project but also responsible for the accountability and administration of all funds provided.

Research Organisation: is the organisation, institute, hospital or university to which the research grant is awarded in conjunction with the Principal Investigator.

Co-Investigator: a person who assists the Principal Investigator in the management and leadership of a project.

BCRT: Breast Cancer Research Trust

Research Grant:
(i) only to be awarded to an investigator within a recognised research organisation in the United Kingdom.

(ii) a contribution to the costs of a stated research project which has been assessed as suitable for funding through the procedures established by BCRT. Research Grants provide a proportion of the full economic costs of a project.

(f FEC) grant applications calculated on the basis of full economic costs are not given.

Data Protection Regulations

BCRT will use information provided on the grant proposal form for processing the proposal, the award of any consequential grant to process and for the payment, maintenance and review of the grant. This may include:

* Registration of proposals;
* Operation of grants processing and management information systems;
* Preparation of material for use by referees and peer review panels;
* Administration, investigation and review of grant applications;
* Statistical analysis in relation to the evaluation of research and the study of trends;
* Policy and strategy studies.

To meet BCRT obligations for public accountability and the dissemination of information, details of grants may also be made available on BCRT's web site and other publicly available databases, and in reports, documents and mailing lists.

Freedom of Information Act and Environmental Information Regulations

Attention is drawn to the provisions of the Freedom of Information Act 2000 (FOIA) and the Environmental Information Regulations (EIRs). BCRT have an obligation to respond to specific requests and may be required to disclose information about or provided by Research Organisations. In some cases BCRT may consult the Research Organisation before disclosure but it is under no obligation to do so. If a Research Organisation considers that any information it provides to BCRT would be subject to an exemption under FOIA or the EIRs it should clearly mark the information as such and provide an explanation as to why it considers the exemption applies and for how long. BCRT will consider this explanation before disclosure, but is not obliged to accept it as binding.

Where BCRT determines that a Research Organisation is holding information on its behalf that it requires in order to comply with its obligations under FOIA or EIRs, the Research Organisation undertakes to provide access to such information as soon as reasonably practicable at the request of BCRT and in any event within 5 working days.

In some cases, Research Organisations may be directly responsible for complying with FOIA and the EIRs; in such cases BCRT accept no responsibility for any failure to comply by the Research Organisations.

1. Responsibilities of the Research Organisation

The Research Organisation must ensure that any part of the Full Economic Cost of the project not funded by the BCRT grant is committed to the project before it starts.

The Research Organisation must ensure that Principal and Co-Investigators are made aware of their responsibilities and that they observe the terms and conditions of research grants.

The Research Organisation must ensure that the research supported by the grant complies with all relevant legislation and Government regulation, including that introduced while work is in progress. This requirement includes approval or licence from any regulatory body that may be required before the research can commence.

The Research Organisation is expected to adopt the principles, standards and good practice for the management of research staff set out in the 1996 Concordat for the Career Management of Contract Research Staff and subsequent amendments. Research staff should be appointed on terms that are no less favourable than those of comparable posts in the Research Organisation.

The Research Organisation must notify BCRT of any change in its status, or that of any of the Investigators, that might affect the eligibility to hold a research grant.

The Research Organisation must ensure that the requirements of the Employing Organisation under the Department of Health's Research Governance Framework for Health and Social Care (or equivalent) are met for research involving NHS patients, their organs, tissues or data, and that the necessary arrangements are in place with partner organisations. Where it also accepts the responsibilities of a Sponsor (as defined in the Governance Framework), it must also ensure that the requirements for Sponsors are met.

The Research Organisation must ensure proper financial management of research grants and accountability for the use of public funds.

2.Research Governance

It is the responsibility of the Research Organisation to ensure that the research is organised and undertaken within a framework of best practice that recognises the various factors that

may influence or impact on a research project. Particular requirements are to ensure that all necessary permissions are obtained before the research begins, and that there is clarity of role and responsibility among the research team and with any collaborators. BCRT expect research to be conducted in accordance with the highest standards of scientific integrity and research methodology.

Research Ethics

The Research Organisation is responsible for ensuring that ethical issues relating to the research project are identified and brought to the attention of the relevant approval or regulatory body. Approval to undertake the research must be granted before any work requiring approval begins. Ethical issues should be interpreted broadly and may encompass, among other things, relevant codes of practice, the involvement of human participants, tissue or data in research, the use of animals, research that may result in damage to the environment and the use of sensitive economic, social or personal data.

Use of Animals in Research

Wherever possible, researchers must adopt procedures and techniques that avoid the use of animals. Where this is not possible, the research should be designed so that:

* The least sentient species with the appropriate physiology are used;

* The number of animals used is the minimum sufficient to provide adequate statistical power to answer the question posed;

* The severity of procedures performed on animals is kept to a minimum. Experiments should be kept as short as possible. Appropriate anaesthesia, analgesia and humane end points should be used to minimise any pain and suffering.

The provisions of the Animals (Scientific Procedures) Act 1986, and any amendments, must be observed and all necessary licences must have been received before any work requiring approval takes place.

Medical and Health Research

The Research Organisation is responsible for managing and monitoring the conduct of medical and health research in a manner consistent with the Department of Health's Research Governance Framework for Health and Social Care (or equivalent). There must be effective and verifiable systems in place for managing research quality, progress and the safety and well-being of patients and other research participants. These systems must promote and maintain the relevant codes of practice and all relevant statutory review, authorisation and reporting requirements.

Research involving human participants or data within the social sciences that falls outside the Department of Health's Research Governance Framework must meet the provisions and guidelines of the ESRC's Research Ethics Framework. While this research may involve patients, NHS staff or organisations, it is defined as research that poses no clinical risk or harm to those who are the subjects of research. Research Organisations must ensure that appropriate arrangements are in place for independent ethics review of social science research that meets local research ethics committee standards.

Significant developments must be assessed as the research proceeds, especially those that affect safety and well-being, which should be reported to the appropriate authorities and to BCRT. The Research Organisation must take appropriate and timely action when significant

problems are identified. This may include temporarily suspending or terminating the research.

The Research Organisation is responsible for managing and monitoring statutory requirements for which it accepts responsibility, for example, in relation to legislation on clinical trials, use of human organs, tissues and data.

Health and Safety

The Research Organisation is responsible for ensuring that a safe working environment is provided for all individuals associated with a research project. Its approach and policy on health and safety matters must meet all regulatory and legislative requirements and be consistent with best practice recommended by the Health & Safety Executive. Appropriate care must be taken where researchers are working off-site. The Research Organisation must satisfy itself that all reasonable health and safety factors are addressed. BCRT reserves the right to require the Research Organisation to undertake a safety risk assessment in individual cases where health and safety is an issue, and to monitor and audit the actual arrangements made.

Misconduct and Conflicts of Interest

The Research Organisation is required to have in place procedures for governing good research practice. The Research Organisation must ensure that there are reliable systems and processes in place for the prevention of research misconduct, e.g. plagiarism, falsification of data, together with well-defined and clearly–publicised arrangements for investigating and resolving allegations of misconduct. Where an allegation of misconduct arises in respect of a researcher supported by a research grant, BCRT must be informed immediately and notified of the outcome of any investigation.

The Research Organisation must ensure that potential conflicts of interest in research are declared and subsequently managed.

3. Use of Funds

Subject to the following conditions, grant funds may be used, without reference to BCRT, in such a manner as to best carry out the research. Research grant funds are cash limited and the grant made is made on the understanding that its value will not be increased, except as stated in these terms and conditions. Research grant funds are provided for a specific research project. Under no circumstances may funds be used to meet costs on any other project or activity.

4. Starting Procedures

The start date shown on the starting certificate will be regarded as the start date of the grant. Submission of the starting certificate will also constitute acceptance of the grant if no other acceptance procedure exists. The start of research may be delayed by up to 6 months from the start date shown in the award letter, the duration of the grant remaining unchanged. The grant may lapse if it is not started within this period. Submission of the starting certificate is required not more than 42 days after the start date.

Where there are staff funded by the grant who were intended to be appointed from the start date, payments will take effect from the date when the first such staff start work. Otherwise, payments will take effect from the start date given on the starting certificate.

Expenditure may be incurred prior to the start of research and subsequently charged to the grant, provided that it does not precede the date of the award letter.

5. Changes in Research Project

BCRT must be consulted in the event of any major change in the proposed research, including failure to gain access to research facilities and services, or to gain ethical committee approval for the research, particularly those which make it unlikely that the objectives of the research can be achieved. If appropriate, revised proposals may be required. BCRT reserves the right to make a new grant in place of the existing grant or to revise, retain or terminate the existing grant.

6. Transfer of Funds between Fund Headings

Transfers of funds between fund headings are not permitted.

7. Extensions

After a research grants has started, the duration may be extended by a total of up to 6 months, subject to prior written approval. Extensions may cover breaks or delays in the appointment of staff, periods of maternity leave or paid sick leave exceeding 3 months for staff funded by the grant, or other exceptional circumstances with the agreement of BCRT. Requests for extensions should be made as soon as the requirement is identified and confirmed when the period required is known. All requests for extensions must be made before the grant ends.

8. Staff

The Research Organisation must assume full responsibility for staff funded from the grant and, in consequence, accept all duties owed to and responsibilities for these staff, including, without limitation, their terms and conditions of employment and their training and supervision, arising from the employer/employee relationship.

The Research Organisation must provide research staff with a statement, at the outset of their employment, setting out the provisions for career management and development, including personal skills training, and ensure that they have access to appropriate training opportunities Research staff may undertake teaching and demonstrating work for up to 6 hours a week (pro rata for part-time staff) during normal working hours, provided that this work is related to the research project to which they were appointed.

9. Procurement of Equipment

The procurement of equipment, consumables and services, including maintenance, must comply with all the relevant national and EU legislation and the Research Organisaion's own financial policy and procedures. Accepted procurement best practice in the higher education sector must be observed. For all equipment and services where the contract value is more than £25,000 excluding VAT, professionally qualified procurement staff must be consulted before the procurement process begins, and, where appropriate, at the market research stage, and must approve the order/contract before it is placed with a supplier.

10. Ownership and Use of Equipment

Equipment purchased from grant funds is primarily for use on the research project for which the research grant was awarded, and belongs to the Research Organisation. In certain circumstances, BCRT may wish to retain ownership throughout the period of the grant and possibly beyond. In such cases, the grant will be subject to an additional condition.

BCRT must be informed if, during the life of the research grant, the need for the equipment diminishes substantially or it is not used for the purpose for which is was funded. BCRT reserves the right to determine the disposal of such equipment and to claim the proceeds of any sale.

Any proposal to transfer ownership of the equipment during the period of the grant is subject to prior approval by BCRT. After the research has ended the Research Organisation is free to use the equipment without reference to BCRT but it is nevertheless expected to maintain it for research purposes as long as is practicable.

Where there is spare capacity in the use of the equipment, BCRT expects this to be made available to other users. Priority should be given to research supported by BCRT and BCRT-funded students.

11. Transfer of a Grant

The Research Organisation must notify BCRT if the Principal Investigator intends to transfer to another organisation. If this organisation is eligible to hold research grants and is able to provide a suitable environment to enable the project to be successfully completed, the expectation is that the grant would be transferred with the investigator. Written agreement to this is required from both the relinquishing and receiving organisations.

BCRT will wish to be assured that satisfactory arrangements have been agreed that will enable the project to be undertaken, or to continue, in accordance with its research objectives. If suitable arrangements cannot be agreed, BCRT will consider withdrawing its support or terminating the grant.

Where there is a basis for continuing involvement by the relinquishing organisation, agreement should be reached between both organisations on the apportionment of work and the distribution of related funding.

Research Grants will not be re-costed following transfer. The unspent balance of Directly Incurred and Exceptions, together with a pro rata share of Directly Allocated and Indirect costs, will be transferred to the new Research Organisation. The receiving organisation will be required to confirm, by return of a starting certificate, that it will provide any balance of resources needed to complete the project.

12. Change of Principal Investigator

The Research Organisation must consult BCRT if it is proposed to change the Principal Investigator, for example, following retirement or resignation. Where the Principal Investigator is transferring to another organisation eligible to hold a research grant, the provisions of RG 11 will apply. In other circumstances, the Research Organisation may nominate a replacement Principal Investigator. BCRT will wish to be assured that the replacement meets the eligibility criteria for Principal Investigators and has the expertise and experience to lead the project to a successful conclusion, in accordance with its research objectives.

13. Annual Statement

The Research Organisation may be required to return a statement each year showing payments made by BCRT during the previous financial year for all the research grants it holds. Where a statement is required, the Research Organisation must certify, by signing and returning the statement that:

Expenditure has been incurred in accordance with the grant conditions, and those grants shown as current are continuing.

No further payments will be made until the signed annual statement has been received by BCRT.

14. Expenditure Statements

The Research Organisation must complete and return an expenditure statement within 3 months of the end date of a research grant. Once an expenditure statement has been received and the expenditure incurred has been reconciled against payments made, it will be considered as final.

BCRT reserves the right to require the Research Organisation to complete and submit a statement of expenditure at any time during the course of a research grant, or to provide supplementary information in support of an interim or final expenditure statement.

15. Inspection

BCRT reserves the right to have reasonable access to inspect the records and financial procedures associated with research grants, or to appoint any other body or individual for the purpose of such inspection.

The Research Organisation must, if required by BCRT, provide a statement of account for the grant, independently examined by an auditor who is a member of a recognised professional body, certifying that the expenditure has been incurred in accordance with the terms and conditions under which they are awarded.

BCRT will undertake periodic reviews of Research Organisations within the Dipstick Testing programme to seek assurance that research grants are managed in accordance with the terms and conditions under which they are awarded.

16. Final Report

A report on the conduct and outcome of the project must be submitted by the Research Organisation within three months of the end of the research grant. No further application from a Principal Investigator will be considered while a final report is overdue.

17. Sanctions

If the final report or the final expenditure statement is not received within the period allowed, BCRT may recover 20% of expenditure incurred on the grant. All payments may be recovered if the report or statement is not received within 6 months of the end of the grant.

18. Public Engagement

It is the responsibility of the Research Organisation and the Principal and Co-Investigators to actively communicate the research to the public at both local and national level, and to raise awareness of the role of science and research in any related issue of public interest.

19. Commercial Exploitation

Unless stated otherwise, the ownership of intellectual property and responsibility for its exploitation rests with the Research Organisation. BCRT may in individual cases, reserve the right to retain ownership of intellectual property and to arrange for it to be exploited for the national benefit and that of the Research Organisation involved. This right, if exercised, will be set out in an additional condition.

It is the responsibility of the Research Organisation, and all engaged in the research, to make every effort to ensure that any potentially valuable results obtained in the course of the research are exploited, and that there is a suitable return to the Research Organisation and the researchers from any such exploitation. The Research Organisation must ensure that all those associated with the research are aware of, and accept, the arrangements for exploitation.

Collaborative arrangements are expected to be put on a formal basis through an agreement covering the contributions and rights of the organisations and individuals concerning exploitation. Such agreements must be in place before the research begins. The terms of collaboration agreements must not conflict with BCRT terms and conditions of research grants.

20. Research Monitoring and Evaluation

While it is the responsibility of the Research Organisation to manage the research, BCRT reserves the right to call for periodic information on progress or to visit the project team. The Principal Investigator may also be asked to attend meetings to exchange information and ideas with others undertaking research in the same or similar fields.

The Principal Investigator must make all reasonable efforts, if so invited, to attend events or activities organised by BCRT concerning the research undertaken. Such events may be held after a grant has finished.

21. Publication and Acknowledgement of Support

The Principal Investigator should, subject to the procedures laid down by the Research Organisation, publish the results of the research in accordance with normal academic practice. Publications and other forms of media communication, including media appearances, press releases and conferences, must acknowledge the support received from BCRT quoting the grant reference number.

22. Disclaimer

BCRT accept no liability, financial or otherwise, for expenditure or liability arising from the research funded by the research grant, except as set out in these terms and conditions, or otherwise agreed in writing.

Where studies are carried out in an NHS Trust, the Trust has a duty of care to its patients. BCRT does not accept liability for any failure in the Trust's duty of care, or any negligence on the part of its employees.

BCRT reserves the right to terminate the grant at any time, subject to reasonable notice and to any payment that may be necessary to cover outstanding and unavoidable commitments.

If a grant is terminated, no liability for payment or redundancy or any other compensatory payment for the dismissal of staff funded by the grant will be accepted, but, subject to the provisions of RG 16, negotiations will be held with regard to other contractual commitments and concerning the disposal of assets acquired under the research grant.

23. Status

These terms and conditions will be governed by the laws of England and Wales; all matters relating to the terms and conditions will be subject to the exclusive jurisdiction of the courts of England and Wales.

If any provision of these terms and conditions is found by a court or other legitimate body to be illegal, invalid or unreasonable, it will not affect the remaining terms and conditions which will continue in force.

These terms and conditions, together with any additional conditions set out in the grants, contain the whole agreement between BCRT and the Research Organisation in relation to the stated research grant. BCRT and the Research Organisation do not intend that any of these terms and conditions should be enforceable by any third party.