UNIVERSITY OF DUNDEE

Guidelines on Research and Service Contracts, Institutional/Private Consultancies, Patents and Commercial Exploitation through Licensing and Spinout Company Activity

This document is designed to assist staff in the securing of external income to support research, service and consultancy.

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Should you have difficulty accessing the document, or have a query regarding any aspect of its content, please contact Head of Research Grants & Contracts, Research & Innovation Services (see Section 15 - Contacts).
SECTION 1 - INTRODUCTION

1.1 This document is issued with the authority of the University Court in replacement of the Guidelines issued in November 1999. Whilst these Guidelines provided an effective framework for the management of research and related activities of University staff, it is necessary, as a result of changes in the University's resource allocation and financial control procedures, and sector-wide developments in the management and funding of research within higher education, to provide this update.

1.2 The University encourages academic staff to undertake externally funded research contracts, consultancies, service style activities and to participate in the commercialisation and exploitation of the output of research, including accepting directorships of limited companies. Because of the complexity of legal liability associated with undertaking this type of work and the risk to which the University may be exposed, it is very important (i) that members of staff should be fully aware of the implications of becoming involved in external interactions and (ii) that they should act within the requirements of the University Court. The Research and Innovation Services office of the University ("RIS") is established as the principal source of advice and information to support academic staff when undertaking such activities and members of staff wishing advice in respect of a prospective project must consult the Director of RIS or one of his colleagues. RIS is charged with ensuring that there is adequate protection against major claims which might arise from work carried out for external funders and that sufficient legal safeguards are put in place. If a question relates primarily to the interpretation of the terms and conditions of appointment of a member of staff, the Director of Human Resources or the Secretary of the University may be consulted as an alternative. (Note: the standard contract of employment for full-time academic and related staff precludes the undertaking of outside employment except with the prior approval of the University Court).

1.3 Under the Patents Act 1977 the Intellectual Property Rights (IPR) of members of staff developed in the course of their normal duties belong to the University. It is important to protect this IPR for the potential benefit of the University, Faculties and individual members of staff. It is therefore important not to surrender to the demands of external funders for their ownership of IPR developed during or in relation to a research project, unless suitable compensation is agreed. The Director of RIS is under particular instruction to safeguard the University's interests in all transactions. He will also ensure that agreements do not unreasonably restrict the ability of a member of staff to work for another funder in the same field.

SECTION 2 – DEFINITION OF RESEARCH, SERVICE AND DONATIONS

2.1 The University is required by the Scottish Higher Education Funding Council (SHEFC) to distinguish between the categories of income derived from research, service and donations. It is therefore important that members of staff are clearly aware of the following definition of research, as laid down by SHEFC.
2.2 Definition of “Research”:

“Research is thus to be regarded as original investigation undertaken in order to gain new knowledge and understanding. It includes the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes including design and construction. It excludes routine testing and analysis of materials, components, processes, etc, e.g. for the maintenance of national standards. The later stages of some clinical drug trials may be more akin to routine testing, particularly in cases where the original research has been done by a drug company or other contractor.”

2.2.1 Within the general research classification, it is also a requirement that the University shows separately in its annual accounts, research income (to the extent that directly related expenditure has been incurred) from the following categories of sponsor:

a) OST Research Councils including the British Academy  
b) UK-based Charitable Foundations, Trusts, etc  
c) UK-Central Government Bodies, Local Authorities, Health and Hospital Authorities  
d) UK Industry and Commerce, Public Corporations  
e) Government bodies operating in other European Union Countries  
f) Other bodies operating in other European Union Countries  
g) Overseas bodies operating outside the European Union  
h) Other sources

2.2.2 Usually research funding obtained from industry and commerce will be subject to VAT. Advice on the VAT status of individual research contracts can be obtained from Research Finance Manager, Finance Office, see Section 15 - Contacts (see also, references to VAT under Definition of “Service”, below).

2.3 Definition of “Service”:

“Service” includes testing, analysis and the provision of goods or staff time to outside bodies in return for an income.

2.3.1 Service will generally be subject to Value Added Tax. Note: (The provision of short courses, seminars and conferences falls outwith the scope of these guidelines).

2.3.2 Advice on matters relating to VAT liability in relation to service can be obtained from Financial Manager, or the Deputy Director of Finance, Finance Office, (see Section 15 - Contacts)

2.4 Definition of “Donations”:

Income for general or specific purposes, which is not received in return for the provision of research, service or other consideration will generally be treated as a “donation”, and should be reported as soon as possible to the Director of Finance or University Secretary. Donations in kind (e.g. equipment) should be included in this notification procedure.
SECTION 3 - PROCEDURES SUPPORTING RESEARCH AND SERVICE AGREEMENT FUNDING

3.1 A member of staff wishing to engage in an externally funded research or service project must first obtain the approval of his/her Head of Department/Division based on notice of the nature of the work to be undertaken, the estimated time to be spent on it and of the University facilities to be used. A Head of Department wishing to undertake such work must seek the approval of the Dean of Faculty or, for Central Service Units, the University Secretary based on similar notice. In cases of applications involving staff from more than one department/division, it will be necessary to obtain the approval of all the Heads of Department/Division concerned, including the Dean(s) of Faculty if a Head(s) of Department/Division is applying for funding.

3.2 It is strongly advised that applicants make contact with Research and Innovation Services (RIS) at an early stage in preparing or considering application documents and draft contracts. The nature of the work, the wording of any terms and conditions or contract to govern its undertaking and the costing of the project (including the level of indirect cost) must be discussed with the Director of RIS or one of his colleagues. The Director of RIS is under instruction to ensure that research and service agreements do not assign or license IPR to a funder without adequate financial or other benefit accruing to the University. The Director will similarly ensure that agreements do not contain clauses introducing exclusivity or confidentiality elements which are detrimental to the University's interests. The Director of RIS has the discretion to refer any project proposal to the Dean of Faculty for his/her approval. In the event of dispute, the matter may be referred to the Principal whose decision will be final. The Director of RIS should normally be given ten working days within which to deal with an application.

3.3 The main authorised signatories for approval of research and service agreements with external funders are: Director or Deputy Director of RIS. In exceptional circumstances the Head of Research Grants & Contracts, Director of Finance, Secretary of the University and the Principal are alternative signatories.

3.4 In the case of an approved agreement subsequent billing, payment of fees and other expenses, and any other financial transactions will be carried out by the Finance Office in accordance with the terms of the agreement.

3.5 All applications for research or service funding (commercially and non-commercially funded) must be accompanied by a Project Registration Form – please refer to Section 6 below for guidance on completion of this document.

SECTION 4 – INSTITUTIONAL AND PRIVATE CONSULTANCY

4.1 Consultancy can be defined as the provision of expert advice to external clients by University staff and is one way in which productive interaction is developed between the University and business/industry. Consultancy yields benefits in
terms of generation of external income and in broadening the commercial knowledge and experience of staff. It can also provide an additional income stream to employees.

4.2 Despite the benefits of engaging in consultancy, there are potential risks to the University and the individual member of academic staff including: the potential for unforeseen legal liabilities; the linking of institutional reputation with the work of an individual acting as a consultant; consultancy taking too high a proportion of the time and effort of the member of staff; and potential conflict of interest. It is therefore crucial that consultancy is properly managed and coordinated, in order to capitalise on the benefits available and minimise the risks outlined.

4.3 When a member of staff applies to undertake consultancy he/she must decide whether or not the work will be carried out as “institutional consultancy” or “private consultancy”. The difference between these two forms of consultancy are explained in sections 4.5 and 4.6 below.

4.4 External examining appointments, review activities for other institutions and service on QA or RAE panels are part of normal academic duties and are not judged to be consultancy activity. Should members of staff receive payment for such activities which exceeds in aggregate £10,000 in any one period of 12 months, this should be reported to the University Secretary in advance of the work being undertaken.

4.5 Institutional Consultancy

4.5.1 The co-ordination of institutional consultancy activities will be carried out on behalf of the University by Research and Innovation Services (RIS). RIS will be responsible for supporting the provision of institutional consultancy services in areas where the Director of RIS judges that either an enhanced income stream or other attendant benefits are likely to accrue to the University.

4.5.2 Where it is considered to be in the University’s interest, staff may be released from teaching or administration duties or accorded sabbatical leave to undertake institutional consultancy. Decisions on these matters will be taken by the Principal acting on the advice of the head of the relevant academic unit and RIS.

4.5.3 Institutional consultancy will be based on full economic cost recovery. In addition to the cost of direct staff time and direct non-staff costs (travel, consumables etc), supervision/management and indirect costs that permit the activity to take place will be charged. It is important that prices are set consistently and fairly, and to achieve some profit beyond the full economic cost of carrying out the work. Pricing will be coordinated by RIS and new work will be signed off by the Director of RIS or one of his authorised deputies. In instances where the Director of RIS and the member of staff cannot agree on a proposed pricing model, the matter will be referred to the University Secretary for a decision.

4.5.4 A member of staff wishing to engage in institutional consultancy must first obtain the approval of his/her Head of Department/Division based on notice of the nature of the work to be undertaken, of the estimated time to be spent on it and of the University facilities to be used. A Head of
Department/Division wishing to undertake such work must seek the approval of the Dean of Faculty based on similar notice.

4.5.5 A member of staff proposing to undertake institutional consultancy must discuss the matter with the Director of RIS or one of his colleagues. The Director of RIS has the discretion to refer any project proposal to the Dean of Faculty for his/her approval. In the event of dispute, the matter may be referred to the Principal whose decision will be final.

4.5.6 As institutional consultancy binds the University into legal relationships with third parties, it is critical that formal contractual agreements, Professional Indemnity Insurance (see Section 10 below) and financial/project monitoring procedures are established. RIS will assist members of staff with the drafting/review and pricing of institutional consultancy contracts. The Finance Office will ensure that appropriate financial controls are in place and in the case of approved agreements, subsequent billing, payment of fees and other expenses, and all other financial transactions are carried out in accordance with the terms of the agreement. Responsibility for operating the budgetary controls that are put in place by the Finance Office/contract lies with the member of staff responsible for the undertaking of the project.

4.5.7 After full costs have been allowed for, any balance of income is available for distribution. The member(s) of academic staff, academic unit and University will normally receive equal shares of any profits accruing from institutional consultancy. This may be varied in particular instances with (on behalf of the University) the approval of the Director of RIS and the University Secretary. Departments/Divisions will be responsible for determining any subsequent internal allocation of their share of the income. A member of staff may elect not to take a personal payment under an institutional consultancy agreement but to waive it in advance, in whole or in part, in favour of the Department/Division or University Central Funds to finance travel, research or other costs related to his or her academic activities.

4.5.8 While it is not normally an aim of institutional consultancy to generate new intellectual property, where required, RIS will negotiate on behalf of the University to protect the University’s interests with regard to Intellectual Property generated in the course of institutional consultancy work.

4.5.9 A member of staff undertaking institutional consultancy except where projects involve the treatment of patients or healthy volunteers, will normally be afforded protection under the University’s Professional Indemnity Insurance policy (see Section 10 below). The University does not hold "blanket" Medical Malpractice Insurance cover. Clinically qualified staff are expected to have personal "medical protection" insurance. Staff involved in the treatment of patients etc., who are without such cover should seek advice on this matter from Finance Manager - Insurance, (see Section 15 - Contacts)

4.5.10 A member of staff's undertaking of institutional consultancy does not count against his/her entitlement to carry out 30 days private consultancy per annum (see section 4.6.2 below).

4.5.11 A form requesting approval on behalf of the University is not required before undertaking institutional consultancy. Subsequent to receiving internal departmental/divisional approval for the work to go ahead
4.5.4 Above refers) a member of staff should contact the Director of RIS or one of his colleagues to discuss the necessary contractual documents required to govern the work. The Director of RIS should normally be given ten working days within which to deal with an application.

4.5.12 All applications to undertake institutional consultancy (commercially and non-commercially funded) must be accompanied by a Project Registration Form – please refer to Section 6 for guidance on completion of this document.

4.6 Private Consultancy

4.6.1 Private consultancy may be defined as external paid work done by a member of staff, which makes no demands on the institution, and for which the institution claims, and has, no liability or responsibility. In cases of private consultancy (as opposed to institutional consultancy – Section 4.5 above refers) an approval system is necessary to ensure that the University is aware of work being undertaken by its staff, and that safeguards are in place to avoid institutional liability being assumed in any contractual arrangements.

4.6.2 The University permits staff to undertake up to 30 days private consultancy or other external work per annum, so long as approval is obtained from the University Court. Applications must:

- be supported by the member of staff's Head of Department/Division who must confirm that the work involved will not interfere with the applicant's University research, teaching or administration duties; a Head of Department/Division wishing to undertake such work must seek the approval of the Dean of Faculty;

- include certification by the applicant that no use, direct or indirect, will be made of University facilities whatsoever and that the work will involve no other reference to the University (e.g. use of University stationery, the University address);

- be approved by the University Secretary if the expected remuneration in aggregate for all private consultancies undertaken by a member of staff does not exceed £10,000 in any period of 12 months or by the Principal and the Convenor of the Finance & Policy Committee, if the sum exceeds £10,000.

4.6.3 Staff who wish to undertake private consultancy work will be responsible for (i) arranging their own professional indemnity insurance cover (see Section 10) and VAT registration if appropriate and (ii) establishing and meeting the cost of any additional tax liabilities.

4.6.4 The services of RIS or any other office of the University are not available to assist staff with the undertaking of private consultancy. Staff are recommended to take independent legal advice before entering into a contract to govern private consultancy.

4.6.5 Staff are prohibited from using University Intellectual Property when undertaking private consultancy. The ownership of IP arising from private consultancy is not a matter for the University and must be dealt with solely
4.6.6 The form contained in Appendix 1 requires to be completed by staff wishing to undertake private consultancy. It should be submitted to the University Secretary when completed.

SECTION 5 – COSTING OF PROJECTS

5.1 Project Costings

It is University policy that the costing of all applications for research or service agreement funding or institutional consultancy (commercially and non-commercially funded) must be undertaken in conjunction with Research & Innovation Services (RIS). Staff within RIS are skilled in calculating the cost elements of projects, including rates of pay, national insurance contributions and superannuation, etc. They can also provide advice on the pricing of commercial contracts.

5.1.1 Non-Commercial Funding Bodies

Where an application is being made to a non-commercial funding body (Research Council, Charity, Government Department etc.) staff should contact the Grants Section of RIS (Grants Officer, see Section 15 - Contacts) for assistance with the calculation of staff costs, application of indirect cost rates and advice on eligible costs. The Section is experienced in dealing with the different terms and conditions of funding bodies which directly affect project costing calculations. Many non-commercial funding bodies now operate electronic application systems which require joint input from the academic applicant and staff within the Grants Section of RIS – applicants who are unfamiliar with such systems should contact the Section for advice.

Note: - Eligible costs vary from funder to funder; if in doubt contact RIS for advice.

5.1.2 Commercial Funding Bodies

Where an application is being made to a commercial funding body, staff should contact the relevant Faculty Business Development Manager to assist with the costing/pricing of the proposal - see RIS web page for details at: https://secure.dundee.ac.uk/research/CONTACTS1.htm Staff should note that in some cases the price of the project may be set at a level in excess of the full project cost, either because of the nature or demands of the projects, or because current market rates so direct. Faculty Business Development Managers can advise on this matter.

5.2 Full Economic Costing (fEC) and Indirect Cost Rate Recovery

5.2.1 TRAC (the Transparent Approach to Costing) is the standard method now underpinning research cost calculations within the UK HEI sector and is currently being extended by RIS to cover the Full Economic Costing of research, service and institutional consultancy projects. Advice from the National Audit Office to universities stresses that in all cases the full economic cost of providing a service to an outside body should be
assessed, even if it may be intended or subsequently decided to limit the actual charge to something less.

5.2.2 The total indirect cost recovery on a project will be credited to the Faculty concerned through the University’s Budget Model. It may be open to the relevant Faculty, however, to propose the abatement of some or all of this income if it is anxious to obtain the contract for the benefit of teaching or research. In the event of dispute, the matter may be referred to the Principal whose decision will be final.

5.2.3 Advice on Full Economic Costing including indirect cost rate recovery is available from Head of Research Grants & Contracts, (see Section 15 - Contacts)

5.3 Personal Payments – Research and Service Contracts

5.3.1 In certain cases, it may be appropriate for RIS to build into the costings of a research or service project a personal payment, inclusive of employer’s on-costs, payable to a member of staff; such a personal payment will require the prior approval of the Head of Department/Division or Dean of Faculty. Personal payments will be subject to the University’s revenue sharing rules (see Section 13) and will be paid only after the full costs of a project have been deducted from the project award value. The University Secretary shall be the arbiter in any decision on a proposed personal payment. In the event of dispute, the matter may be referred to the Principal whose decision will be final.

5.3.2 The form contained in Appendix 2 requires to be completed by staff wishing to apply for a personal payment.

SECTION 6 – PROJECT REGISTRATION FORM

6.1 All applications for research, service or institutional consultancy funding (commercial and non-commercial) must be accompanied by a Project Registration Form prior to submission to RIS. The Project Registration Form captures the costs of a project, governance issues (e.g. ethics approval) and authorizing signatures. The document is available from the RIS web page at:

https://secure.dundee.ac.uk/research/main/dundeeonly/projectcost.htm

6.2 The Project Registration Form contains a section to identify whether or not a project falls under the Research Governance Framework for Health and Community Care “RGF”


(see also Section 9 below). It also identifies if any NHS resources such as staff time (e.g. Consultants, Nurses, Administrative Staff, University employed staff partially funded by the NHS) or support services (e.g. Radiology, Biochemistry, Pharmacy) are required. If a project requires NHS resources or support services, or involves patients, the R&D Office, Level 9, Ninewells Hospital & Medical School (contact Non-Commercial Research & Development Manager, see Section 15 - Contacts) should be contacted to approve the project. Further guidance on this matter is contained within the Project Registration Form.
6.3 Any enquiries regarding completion of the Project Registration Form should be directed to the relevant Faculty Business Development Manager in RIS (for commercially funded projects) or the RIS Grants Team (for non-commercially funded projects, see Section 15 - Contacts) –; further contact details are available at http://www.dundee.ac.uk/research/

Note: RIS cannot sign any application for research, service or institutional consultancy funding unless the Project Registration Form has been fully completed, including all necessary signatures.

SECTION 7 – “POST AWARD” ADMINISTRATION OF AWARDS: FINANCE OFFICE

7.1 Administration of Grants and Contracts

Once an application for research or service agreement funding or institutional consultancy has been awarded, its financial administration will be controlled by the Finance Office. In the case of research grants and contracts, this control is exercised through the Research Finance Section. Awards within the Research Finance Section are distributed and managed on a departmental basis. To find out who your departmental contact is, follow this link: http://www.somis.dundee.ac.uk/finance/emaillist.html

7.2 Services provided by Research Finance Section include:

- setting up correct classification of cost centre;
- notifying Principal Investigator and their departmental administrator(s) of cost centre details;
- setting up a control sheet to facilitate the invoicing process and review of expenditure against budget;
- calculation of staff renewals and new staff appointments against research awards and confirmation of funding availability of posts to Personnel Services - in cases where there is insufficient funding, correspondence with Principal Investigator to determine solution for funding shortfall;
- producing invoices or cost statements for awards on a regular basis in accordance with terms and conditions of award;
- clarification of unusual items of expenditure with Principal Investigators; please note that it is the responsibility of the Principal Investigator to utilize the funds in accordance with the terms and conditions of award;
- answering queries relating to awards from Principal Investigators, other members of Finance Office, Personnel Services, awarding bodies and other external parties e.g. Auditors, Customs & Excise etc.;
- calculation and processing of department overhead journal in agreement with terms and conditions of award.

7.3 CODA Accounting System

Access to the CODA Accounting system can be arranged through your department Link Manager. To find out who your department Link Manager is, follow this link: http://www.somis.dundee.ac.uk/finance/mainfunctions/account_services/management/link.html
7.4 Service and Institutional Consultancy Contracts

All contracts should be costed/priced appropriately – RIS provides assistance with this task (see Section 5 above).

At the outset of a service or institutional consultancy contract, any discrepancy between the final provisions and the original proposal will be addressed by RIS and the Link Manager(s) servicing the Faculty or Directorate of the member(s) of staff undertaking the contract; a list of Link Managers available at: http://www.somis.dundee.ac.uk/finance/mainfunctions/account_services/management/link.html

Where appropriate Link Managers will authorise the opening of a new code, and will have that code communicated to the member(s) of staff concerned.

At monthly intervals printouts will be distributed to the Heads of Departments/Divisions/Schools who are responsible for further distribution within their own department, division or school. Direct on-line access to Coda can be arranged through this link: http://www.somis.dundee.ac.uk/finance/mainfunctions/account_services/managementcoda/access.html

The issuing of invoices relating to service or institutional consultancy contracts is the responsibility of the Link Managers of the Management Accounting Services (MAS) section within the Finance Office. In certain instances it may be arranged that the member(s) of staff undertaking the service or consultancy (or the support staff representing them), can take the initiative in producing a sales invoice through either filling in a sales invoice request, and sending this to MAS, or through direct input in the Coda Sales Invoicing System, or through direct contact with the Link Manager(s) concerned. Alternatively the Link Manager(s) may arrange invoicing as per the contract stipulations.

SECTION 8 – “POST AWARD” ADMINISTRATION OF AWARDS: PERSONNEL SERVICES

8.1 Appointment of Staff to Research and other Externally-funded Posts

Procedures for the advertising of posts, appointment of staff, and issue of staff contracts are controlled by Personnel Services. Investigators should always work in liaison with Personnel Services in communications (either in writing or orally) with candidates. The normal* recruitment procedure is as follows:

(*certain different arrangements apply for Wellcome Trust Building appointments):

8.1.1 Personnel Services places advertisements for staff since there is a central advertising budget.

8.1.2 Personnel Services receives applications, in order to monitor responses, and sends these to Grantholders immediately after the closing date. Normally the Department/Division arranges interviews and obtains references for posts up to RA3 level (for appointments at RA3 level or above, Personnel Services will arrange the interviews and obtain references) using the recruitment procedure guidelines which can be accessed at:
8.1.3 If required, a member of Personnel Services staff assists with interviewing.

8.1.4 Personnel Services issues the employment contract, with copies to the Grantholder, the Head of Department/Division and the Finance Office once the availability of funding has been confirmed by the Finance Office.

Note: In order that Personnel Services has all the necessary information and approvals to issue an employment contract associated with a research grant, a "Recruitment Authority Form" from should be completed by the Grantholder and sent to the Personnel Services along with the appointee’s curriculum vitae via the Research Finance Section – the form is available at: https://secure.somis.dundee.ac.uk/personnel/do/p3procedures/staffrecruitment.html

8.1.5 The Department/Division (or Personnel Services if RA3 or above) issues letters to unsuccessful candidates.

8.1.6 Personnel Services advises the Grantholder and/or Head of Department/Division when the written acceptance is received.

8.1.7 Copies of standard terms and conditions of appointment are available (for each category of staff) from Personnel Services. (Investigators who wish to employ non-UK non-EC citizens on projects should note that work permits must be obtained from the Department of Employment and Personnel Services will obtain these). A “Leave to Remain” application will also have to be made by the appointee. The appointee will not be permitted to commence work until both “Leave to Remain” and a “Work Permit” have been obtained. Personnel Services should be contacted as soon as practicable and applicants should allow for three months for formalities to be completed.

8.2 Further Guidance for Appointment of Staff to Research and other Externally Funded Posts

Further guidance on matters relating to staff is available from Personnel Services. However, prospective Grantholders should note the following:

8.2.1 Many funding bodies, e.g. Research Councils, implement automatically annual 'cost of living' salary awards. Prospective Grantholders should establish whether this is to happen with their particular funding body by contacting RIS (contact Grants Officer, see Section 15 - Contacts) during the application stage.

8.2.2 Increments for research staff are normally on the anniversary of the appointment date, but for technicians, secretarial and administrative staff the increment date is fixed, i.e. 1 August or 1 October each year (provided the member of staff has had 6 months service prior to this date).

8.2.3 Externally funded staff are eligible for promotion or advancement, but Grantholders should seek the prior approval of the funding body if such a member of staff is to be recommended for promotion by the Head of Department/Division.
8.2.4 Superannuation and National Insurance contributions should be included as a percentage of salary when making applications. – this is undertaken by RIS during the application stage (contact Grants Officer, see Section 15 – Contacts).

SECTION 9 – PROJECTS INVOLVING HUMAN PARTICIPANTS

9.1 Various UK and European guidelines and legislation govern research and testing involving human participants (patients or healthy volunteers), their organs, tissues, samples or data. These include but are not limited to the Research Governance Framework for Health and Community Care (RGF), the EU Clinical Trials Directive (EUCTD), The Medicines for Human Use (Clinical Trials) Regulations 2004, the Human Tissues Bill and the Data Protection Act.

9.2 The University’s Ethics and Research Governance Policy uses the terms of the RGF as a recognised standard for research involving human participants or the collection of identifiable human data. The Policy is not limited to research involving the use of a medicinal product or device, or to research involving the collection of human biological samples. For example, psychological or behavioural studies on healthy volunteers or questionnaire-based studies are also governed by this Policy. The policy is available at: http://www.somis.dundee.ac.uk/court/policy/Ethics & Res_Gov.pdf

9.3 Details of the specific responsibilities for those carrying out research involving humans are provided in the University’s Ethics and Research Governance Policy, however, the main aims are to ensure that:

- A Chief/Principal Investigator is identified for each project
- A Sponsor (that accepts primary legal liability) is identified for each project
- All projects (whether in receipt of external financial support or not) involving human participants are registered with the University (via RIS)
- Research projects are well managed and monitored to demonstrate compliance to the relevant guidelines and legislation
- All research projects have relevant ethical approval
- Where appropriate, NHS approval is in place

9.4 RIS must be consulted concerning any proposed project (whether externally or internally funded) involving human participants.

9.5 RIS staff can provide advice on the terms of the Research Governance Framework and EU Clinical Trials Directive in general terms or on a project by project basis. Chief Investigators/Principal Investigators seeking such advice should contact their Faculty Business Development Manager – a list is available at: https://secure.dundee.ac.uk/research/CONTACTS1.htm

9.6 The University expects staff to work to the Codes of Practice of any professional body or subject association of which they are members. Such professional bodies provide detailed advice specific to the particular area of research.

9.7 Other key sites providing useful information and guidance include:

- Chief Scientist Office: http://www.show.scot.nhs.uk/cso/
- Department of Health: http://www.dh.gov.uk/Home/fs/en
- Medicines and Healthcare Regulatory Authority: http://www.mhra.gov.uk/
• NCCHTA: http://www.hta.nhsweb.nhs.uk/
• NHS Tayside: http://www.nhstayside.scot.nhs.uk/

SECTION 10 - PROFESSIONAL INDEMNITY COVER

10.1 The exercise of professional expertise in carrying out research, providing services or undertaking institutional consultancy, places the University in a contractual relationship with a range of “clients” (funders, sponsors, partners etc.).

10.2 Professional indemnity (PI) insurance provides financial protection in the event that a client suffers financial loss arising out of an alleged negligent act, error or omission by the University.

10.3 The University’s cover will help it meet the cost of defending claims and its liability at law to pay compensation (damages). The limit of indemnity is £10M per annum inclusive of legal costs. In the event of a successful claim against it in the USA or Canada, the University would have to meet the cost of the first £50,000.

10.4 Members of staff undertaking research, service or institutional consultancy are required to agree to specific inclusion under the University’s policy. The policy excludes cover in the event of alleged “medical malpractice”. Medical and Dental Practitioners are required to have appropriate “medical defence” insurance cover with respect to the delivery of medical care.

10.5 It is a strict condition of the University’s insurance policies that its insurers are informed without delay, of any material fact, occurrence, dispute or investigation that might give rise to an insurance claim. The aforementioned should be fully reported via the Finance Office and RIS without delay; examples of such instances include:

   i) failure to deliver/meet deadlines or targets
   ii) dispute about methods/techniques, reports, conclusions or advice
   iii) design fault

10.6 The following is a brief, and far from exhaustive list of the sorts of occurrences for which PI insurance provides cover to the University.

   • negligent act, error or omission
   • breach of warranty or authority
   • breach of trust or breach of confidence
   • infringement of copyright or patent right or trademark or design rights
   • breach of confidential information protection under the Data Protection Act 1998
   • libel and slander (defamation of character) committed in good faith by reason of words written or spoken by any person covered by the policy.

The University has protection against any liability arising from dishonest or fraudulent acts or omissions but the policy does not indemnify any individual person committing or condoning such fraudulent acts or omissions.
SECTION 11 - PATENTS AND THE COMMERCIAL EXPLOITATION OF RESEARCH RESULTS

11.1 The principal Statute covering patentable inventions is the Patents Act 1977, Section 39 of which states:

“(1) notwithstanding anything in any rule of law, an invention by an employee shall, as between him and his employer, be taken to belong to his employer for the purpose of this Act and all other purposes if –

(a) it was made in the course of the normal duties of the employee or in the course of duties failing outside his normal duties, but specifically assigned to him, and the circumstances in either case were such that an invention might reasonably be expected to result from the carrying out of his duties; or

(b) the invention was made in the course of the duties of the employee and, at the time of making the invention, because of the nature of his duties and the particular responsibilities arising from the nature of his duties, he had a special obligation to further the interests of the employer's undertaking.

(2) any other invention made by an employee shall, as between him and his employer, be taken for those purposes to belong to the employee.”

Most patentable inventions by a member of University staff, unless in an area quite distinct from that of his/her University appointment, will belong to the University as employer. (The position of student members of research groups is often less clear and may need special provision if commercial potential is expected from a research programme). The inventor retains, however, certain important statutory rights, in particular to compensation out of benefits subsequently received by his/her employer. The University's general policy is that such inventions should, wherever practicable, be exploited by the member of staff and the University working in co-operation.

11.2 Members of staff are encouraged to prepare descriptions of inventions before publication with a view to their submission through patent agents for provisional patent protection for a period of one year during which the prospects of successful commercial exploitation can be explored in detail. Protection in the UK is sufficient, provided certain additional steps are taken, to ensure backdating of patents in most countries to the date of the original UK application.

11.3 The University officer to advise on patents and to co-ordinate the preparation of submissions is the Director of RIS who, when necessary, can arrange for the involvement of a patent agent. It is important for staff to realise that premature disclosure of research results, for example through a scientific paper or even a presentation at a scientific conference, may well prevent the award of patent protection. In this connection it should be stressed that the Director of RIS is normally in a position to respond quickly on securing initial patent protection. Members of staff are urged, therefore, whenever there may be commercial potential in research work, to let the Director of RIS have prior sight of any proposed publication of research results so that any appropriate emergency action can be taken to protect the financial interests of the member of staff and the University.

11.4 If the University agrees that an invention is sufficiently promising to warrant patent protection, the costs of preparing patent submissions and of obtaining patent protection in the UK and more widely will be met in the first instance by
the University, with reimbursement of costs as a first charge against royalties received. Where the University decides not to proceed to seek a patent or other commercial protection, and provided no other body has a contractual interest in the invention, the inventor will be free to take whatever action he/she wishes to seek commercial exploitation. In such event the University shall inform the inventor in writing of its intention not to proceed.

11.5 Where research work has been supported by grants from outside bodies, rights in patents or other commercial exploitation may, under the terms of the award of the grants, accrue to the funding body. Normally both the research grant holder and the University have accepted contractual obligations in this regard which cannot be evaded except by mutual agreement.

11.6 Commercial exploitation of inventions, whether patented or not, may be undertaken in a number of forms, on which the Director of RIS is best placed to advise. In addition to the assignation of a patent to an existing company or the signing of a licence agreement, the University is prepared also to consider the establishment of, or at least involvement in, a new company formed for the specific purpose of exploiting an invention. In this regard the Court in March 1999 approved certain Principles which have now been incorporated into this set of Guidelines (see Section 14).

SECTION 12 – COPYRIGHT

12.1 Ownership of copyright rests with the University Court where a member of staff has, within the normal scope of his duties, developed computer software or produced other copyright works (e.g. audio-visual materials or distance teaching material). The Court would wish to promote the commercialisation of computer software or other copyright work on a similar basis to that for patentable inventions.

12.2 Except where specifically provided by agreement between the Court and the member of staff concerned, the Court does not claim copyright in books, articles for learned journals or works of fine art (i.e. paintings and sculptures).

SECTION 13 - REVENUE SHARING FROM COMMERCIAL EXPLOITATION

13.1 Royalties and Other Licensing Income

13.1.1 Royalties and other licensing income payable to the University as a result of a patented invention, licensing arrangement or other commercial exploitation of research results will, after deduction of costs incurred by the University in obtaining patent protection and in otherwise securing commercial exploitation, normally be divided between the University and the inventor(s) in accordance with the University's then current policy as approved by the University Court from time to time.

13.1.2 The University reserves the right to determine (subject to any minimum entitlement the member of staff may have under the Patents Act 1977) the arrangements for revenue sharing in the light of the individual circumstances of each case. As general guidance, however, the following principles will normally be applied:

- Direct costs incurred by the University in prosecuting the commercial exploitation (e.g. patent costs) will be a first deduction.
Subject to the proviso in section 13.2 below “Total Personal Remuneration” the revenue will be allocated in the proportions:

<table>
<thead>
<tr>
<th>Range of Income</th>
<th>Division of Net Royalties and Other Licensing Income</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inventor</td>
</tr>
<tr>
<td>First £500k</td>
<td>50%</td>
</tr>
<tr>
<td>Sums between £500k and £2M</td>
<td>33.3%</td>
</tr>
<tr>
<td>Sums between £2M and £10M</td>
<td>25%</td>
</tr>
<tr>
<td>Sums in excess of £10M</td>
<td>20%</td>
</tr>
</tbody>
</table>

13.1.3 An inventor who is a retired or former member of staff will be accorded similar treatment.

13.1.4 The University will enter into a formal revenue sharing agreement with each inventor in advance of the commercialisation of an invention.

13.1.5 In the event of the death of an Inventor during the period where royalty or other income is being received by the University such sum or sums due to the Inventor in accordance with the formula above shall continue to be payable to the Inventor's successor(s) if known to the University.

13.2 Total Personal Remuneration

13.2.1 Total personal remuneration will be negotiable where, by a combination of projects under section 13.1 above “Royalties and Other Licensing Income”, a member of staff stands to receive exceptional additional remuneration.

13.2.2 A member of staff may elect not to take royalty or other payments as personal income but to waive them in advance, in whole or in part, in favour of the department/division or the University Central Funds to finance travel, research or other costs related to his or her academic activities.
SECTION 14 - SPIN-OUT COMPANY ACTIVITY

14.1 It is now widely recognised that the commercialisation of the Science Base is an essential element to the future well-being of the economy. Through the services of Research & Innovation Services (RIS), the University of Dundee has made a commitment to the process.

14.2 The protection and commercialisation of the University’s emerging intellectual property creates a very valuable source of unfettered income to the University. In addition, through the revenue sharing formula (section 13 above refers) which has been agreed by Court, it is recognised that academic inventors should receive financial reward for their activities in this field.

14.3 The two main routes through which the University may become involved in the commercialisation of its research base may be identified as:

14.3.1 Licensing intellectual property rights to an established company; and

14.3.2 Setting up a spin-out company which would develop and commercialise a specific package of intellectual property, also under licence from the University. A spin-out company may be defined as a company which is set up specifically to commercialise a particular University-owned technology. The Company may be set up between the inventors and the University alone or in partnership with third party investors.

14.4 The University may consider spin-out companies an appropriate route in the following situations:

14.4.1 An academic inventor who also has the commercial drive and aspirations to head up a new spin-out company directed at commercialising his/her invention.

14.4.2 An academic inventor with an exciting technology but who has no aspirations to play a lead role in setting up a new company to commercialise an invention. In this instance, a commercial “driver” would be sought for the MD position in the new company while the inventor may occupy the position of research director.

14.4.3 The University may identify an activity within the University which it considers to be highly commercial but to carry with it an unacceptably high level of liability.

14.5 The University would not normally wish to be in a controlling equity position with respect to spin-out company activity mainly because of the associated liability. The University may, with respect to the scenarios defined in 14.4.2 and 14.4.3 above, put in place a management team to direct the new company.

14.6 In all cases, the University will seek an equity stake in the new company. This stake will normally be not less than 20% of the pre-funding stock of the proposed company and will be negotiated on behalf of the University by the Director of RIS. The justification for this position is that the equity stake gives the University some comfort that its intellectual property has a value to the new company. The position also allows funders to dilute the University pro-rata with other equity holders.
14.7 In advance of approaching funders, the University and the inventors should agree upon equity share between them. If this is done, then all income derived by the University from its subsequent sale of the equity will be retained by the University and will not be shared with the original inventors.

14.8 In cases where the academic inventors do not become involved in the spin-out company which is directed at the commercial exploitation of their invention and who therefore do not receive any equity share at the outset, should share with the University any income derived from downstream sale of the equity. The revenue sharing will normally be based upon the formula used for royalty sharing – section 13 above refers. To that end, a register of inventors will be set up and maintained by RIS and in each case the University and the inventors will enter into a formal revenue sharing agreement.

14.9 Members of academic staff who wish to be involved in commercialisation activity through spin-out companies must first obtain the permission of the University through the Head of Department/Division, the Dean of Faculty, the Director of Finance and the Principal following discussion with the Director of RIS. Once this has been obtained, the University's position will be represented by RIS. RIS will negotiate the equity share on behalf of the University and negotiate and prepare the licence agreement between the University and the new company. RIS may also assist the company to raise grant funding for the new venture and aid the evolution of business plans with a view to attracting venture capital funding. In certain circumstances it will be appropriate for the individual member of staff's contract of employment to be amended for the individual's involvement in the spin-out company (or alternatively a charge levied on the company). This will be co-ordinated by RIS and Personnel Services.

14.10 The University will not be obliged to provide any administrative or financial services to any spin-out company once set up and except under exceptional circumstances will not do so. In addition, the University will have no involvement in the routine running of the company but will in all circumstances reserve the right to be represented on the Board of the Company.

14.11 All of the parties involved in this activity must recognise the potential for "conflict of interest" and must undertake to take advice on this important issue as appropriate.
# SECTION 15 - CONTACTS

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