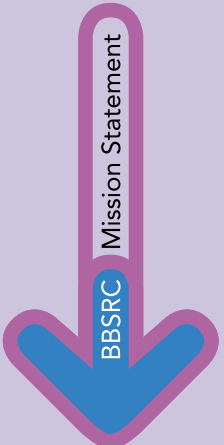





intellectual
property

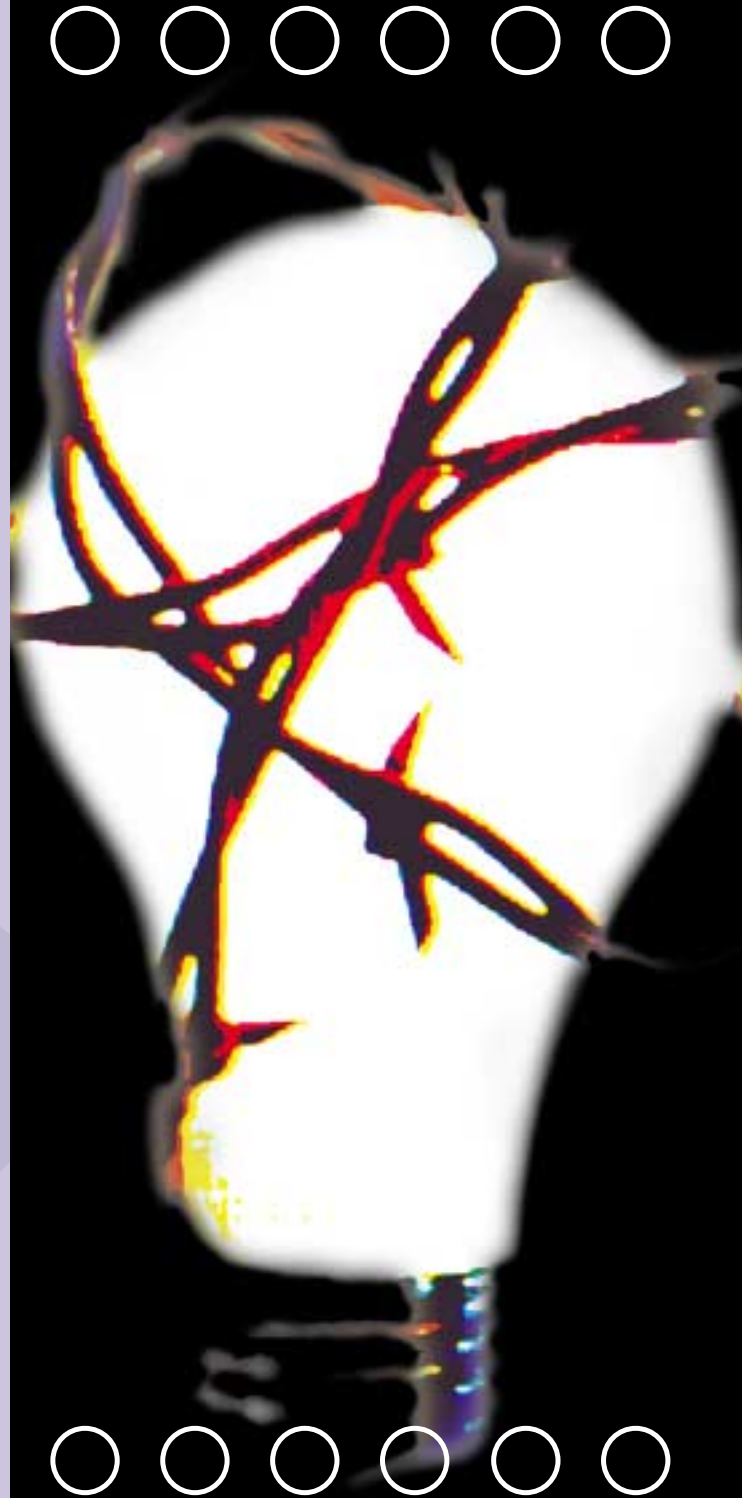


Mission Statement

BBSRC

The Biotechnology and Biological Sciences Research Council is established by Royal Charter for three purposes:

- to promote and support high-quality basic, strategic and applied research and related postgraduate training relating to the understanding and exploitation of biological systems;
- to advance knowledge and technology, and provide trained scientists and engineers, which meet the needs of users and beneficiaries (including the agriculture, bioprocessing, chemical, food, health care, pharmaceutical and other biotechnologically related industries), thereby contributing to the economic competitiveness of the United Kingdom and the quality of life;
- to provide advice, disseminate knowledge, and promote public understanding in the fields of biotechnology and the biological sciences.





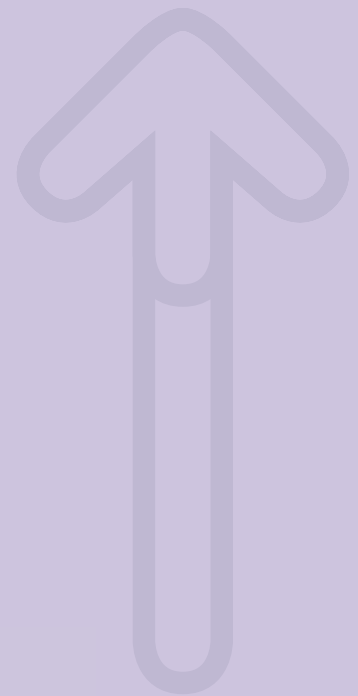

Your Questions Answered

This guide is intended for all recipients of BBSRC research funding. It is made up of two parts. Part 1 gives details of BBSRC's intellectual property policy. Part 2 answers some of the more frequently asked questions concerning intellectual property.

Before this, however, the starting point is:

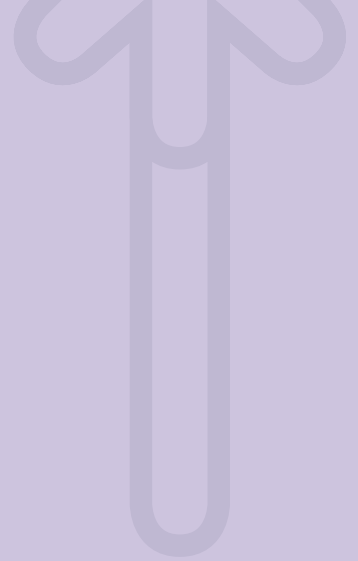
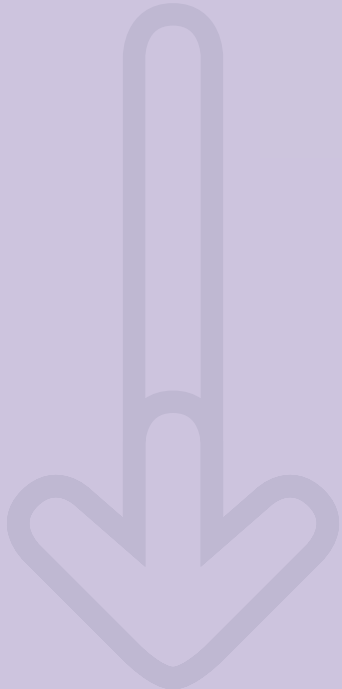
What is Intellectual Property?

The term "intellectual property" refers to the outputs of creative endeavour in literary, artistic, industrial, scientific and engineering fields, which can be identified and protected under legislation relating to patents, plant breeders rights, trade marks, copyright, and design rights. Of the different forms of intellectual property, patents for new technology are of prime interest to scientists and engineers, although copyright can also be important (for example, for the protection of computer software). Like any other form of property, intellectual property can be sold, leased or mortgaged - so long as ownership has been established unambiguously. By providing security of knowledge, and establishing rights and rewards, intellectual property stimulates the innovation process.





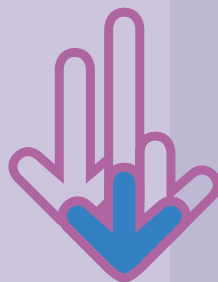
Part one



What is BBSRC's intellectual property policy?



BBSRC positively encourages the exploitation of the results of all research it sponsors at universities, colleges and other research institutions, in order to enhance the competitiveness of UK industry and create wealth for the UK economy. Particular emphasis is, therefore, placed on the process of identifying and protecting intellectual property. BBSRC policy is to delegate responsibility for managing intellectual property arising from the work it supports to the host institution.

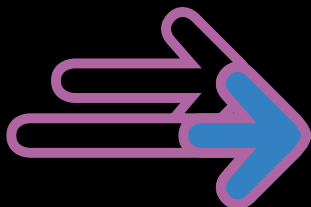


BBSRC does not place prescriptive rules on the ownership of intellectual property in sponsored or collaborative research. The Council advocates a flexible approach. The details of specific agreements between partners on ownership, user rights and royalty payments should reflect the individual circumstances of each case.

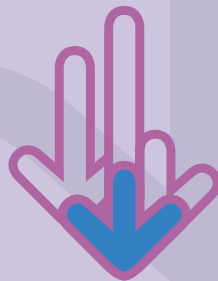
Efficient commercial exploitation of new technology produced in the research community, leading to new industrial processes and products and benefits to the national economy, requires the active participation of industry. Successful partnerships or agreements with industry will usually depend upon secure ownership of intellectual property.

Benefits to research workers and their institutions are an important element of the Council's policy. Such benefits are an incentive to effective exploitation.

Does BBSRC claim ownership of intellectual property?

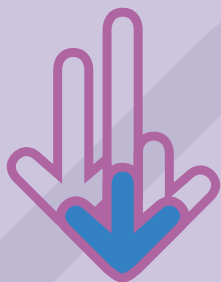


BBSRC itself usually makes no claim to the intellectual property rights arising from research which it supports. It is BBSRC's policy that any results obtained in the course of research it supports should be exploited wherever possible, and that arrangements should be made to secure a suitable return to the institution and the generators of the intellectual property.



Responsibility for identifying and protecting intellectual property rests with the research institution - not with BBSRC. But since substantial public funds are invested in research, BBSRC needs to be assured that suitable arrangements are in place.

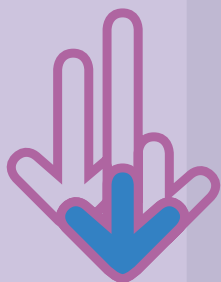
BBSRC is always prepared to offer advice on best practice regarding intellectual property, however the Council will not normally get involved directly in detailed negotiations between the research institution and a third party.



Ownership of intellectual property arising from a studentship lies initially with the student themselves. However, BBSRC expects the institution to enter into an agreement with the student which transfers ownership of any intellectual property arising during the studentship to the institution. The institution may then retain the intellectual

property rights or assign them to an industrial partner under exploitation arrangements in the same manner as for research grants. It is, however, expected to treat a student in a similar manner to other research staff in terms of sharing revenue under the institution's "rewards to inventors" arrangements.

Who owns intellectual property arising from a BBSRC Studentship?



The best arrangements should have the following aims:

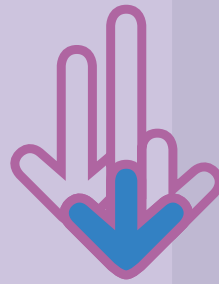
- To ensure all researchers are aware of the importance of identifying potential intellectual property before the opportunity to protect it has been lost by premature disclosure, and to get the cooperation of researchers in protection and exploitation.

- To provide all researchers with ready access to professional advice and training on intellectual property issues, usually through an industrial liaison office.
- To develop good links with a number of bodies which are potential licensees of intellectual property or who may be able to undertake its licensing. These include industrial firms, venture-capital organisations and technology transfer agencies.
- To have access to seedcorn funds where the most appropriate route to commercialisation is through the establishment of a spin-out company.

What arrangements should institutions have in place?



What arrangements
should individual
researchers make?



Researchers have an obligation to themselves and to their employers to safeguard intellectual property. A first step must be to become familiar with the arrangements within the host institution for dealing with intellectual property matters. Researchers are encouraged to attend short training courses on intellectual property either internally or externally.

It is strongly recommended that, as part of the discipline for identifying and exploiting intellectual property, researchers should regularly maintain dated laboratory notes. These should be written in ink, with numbered pages in a bound notebook - not on miscellaneous scraps of paper - and witnessed and signed by a colleague not involved in the discovery. Such safeguards are important in the event of patent disputes.

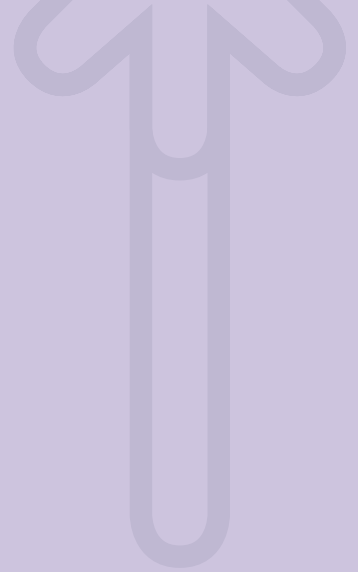
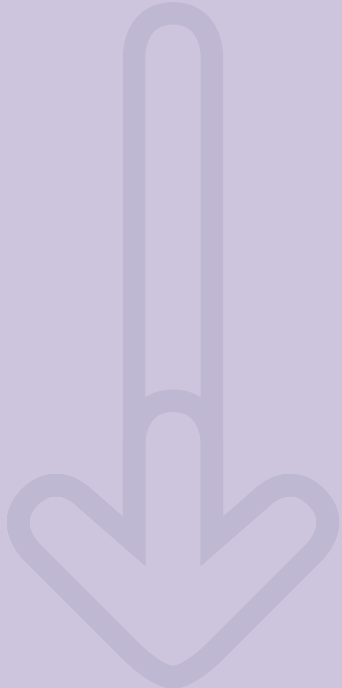
In the event of a valuable discovery, the appropriate institutional authority needs to be informed. Where intellectual property arrangements exist with collaborators, these must be honoured. Avoid any form of disclosure which could compromise the patentability of the invention. Legislation relating to intellectual property is extremely complex, and it is essential that you talk through with an expert the nature of the discovery, its potential applications, the extent that it has drawn on existing knowledge, and the involvement of collaborators. **ALWAYS SEEK EXPERT ADVICE.**

The exchange of ideas and communication of results is an inherent part of science and engineering research. Openness is an important part of the academic culture. There are established practices to uphold the integrity of science, allocate credit, and acknowledge the contributions of others. However in the area of adequately protecting intellectual property judgement must be exercised; delays in the announcement of results or the publication of papers may be necessary to ensure that ownership of intellectual property has been secured.

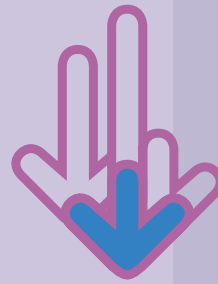




Part two



What is a patent?

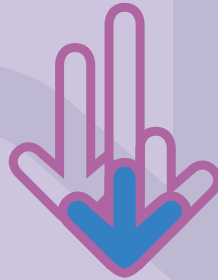


A patent gives an inventor a period of exclusive exploitation (up to 20 years in the UK) in return for a disclosure of the invention. This does not give the inventor any rights to manufacture their work but rather prevents other people doing so without permission. The disclosure through a patent must contain sufficient detail to allow an individual "skilled in the art" to reproduce the invention.

To qualify for a patent an invention must meet four main criteria. It must be:

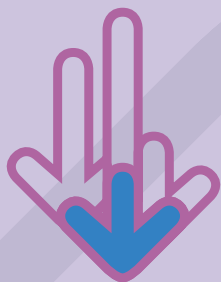
- industrially applicable,
- novel,
- include an inventive step, and
- not be among the list of excluded inventions.

What is industrial applicability?



The need to show industrial applicability is a good demonstration of the practical nature of patents and patent law. It requires that the invention must be able to be used in some way, i.e. be turned into a product or an industrial process. It has to be something that can be physically worked and this is the major

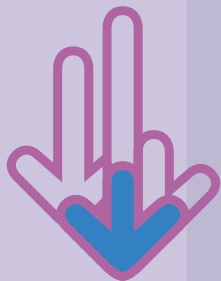
difference between patents and other forms of intellectual property protection such as copyright.



What constitutes a significant advance in prior art is a judgement to be made by the patenting authorities. A natural or obvious extension of previous knowledge is unlikely to be patentable - but if in doubt, seek advice.

One of the services offered by the Patent Office is access to the patent data base. This is a unique source of technical information, of benefit to businesses and researchers. The data base helps to avoid duplication of work, and to define what has gone before in order to draft a strong patent application. Further information on how to access the data base is available directly from the Patent Office.

This means that the patent must be new and cannot have been previously detailed anywhere in the world. It must exceed what is termed the 'prior art'. Prior art has no exact definition, but a patent must not lay claim to what, by written or oral description or by use in any other way, was available publicly before the priority date of the invention. There are no restrictions as to age, place or language of any document included in the prior art.



exhibitions is more restricted than was previously the case. Confidential disclosure to individuals is possible, but must be accompanied by a clear written statement that disclosure is on a privileged and confidential basis; confidentiality must be agreed in advance otherwise it cannot be enforced.

United States law permits a grace period of 12 months during which publication of an inventor's own paper does not prejudice US patent applications. Under the European system, which covers the UK, publication is an immediate bar to patentability.

The general advice is do not disclose to anyone, until you have discussed potential exploitation and patentability with the appropriate institutional authority and any collaborating partners.

In the UK potential patent rights will be prejudiced by publication, public announcement, or non-confidential disclosure of a discovery prior to filing a patent application. Publication is now interpreted very broadly and covers anything made available publicly in writing, orally, by use or demonstration, or in any other way before protection is sought.

Exceptions for learned society publications no longer exist, and provision for privileged display at

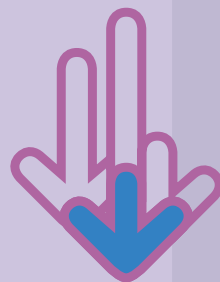
What is novelty?



What represents prior disclosure?

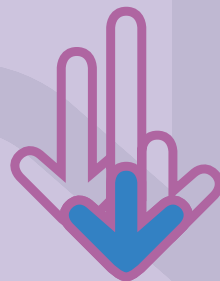


Could my BBSRC grant application be deemed prior disclosure?



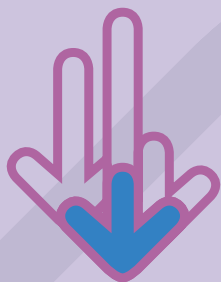
All BBSRC grant applications are confidential documents and at all stages in the peer review process, including refereeing, are treated on a confidential basis. Under this process your application could not be deemed to be in the public domain and would not therefore preclude a subsequent patent application.

Could my PhD Thesis be deemed prior disclosure?

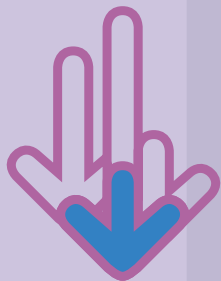


Yes, a PhD thesis is generally made available to a wider public without limits on confidentiality. For example, a copy may be placed in your University or department library. Most Universities do, however, have procedures in place whereby a thesis can be kept confidential

while appropriate patent protection is obtained. If you think that your thesis contains patentable material then seek advice from your Head of Department or University Industrial Liaison Officer before copies are circulated within the University.



This is really asking is the invention obvious? Would someone who was skilled in the field and in possession of all the related public information be able to predict the invention? This is clearly a highly subjective criterion and great care is needed when writing patent applications. Phrases such 'it was therefore logical to' or 'as expected' need to be avoided as they imply a degree of obviousness.



This covers certain categories such as discoveries, scientific theories or mathematical methods. In addition methods of surgery, therapy and diagnosis are also not patentable in the UK but the latter two can be in the United States. Microbiological processes are patentable but plant and animal varieties and essentially biological processes for producing plants and animals are not. There are, however,

different arrangements for obtaining intellectual property rights on plant varieties.

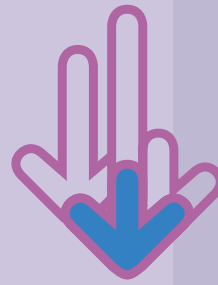
What is an inventive step?



What are the excluded inventions?



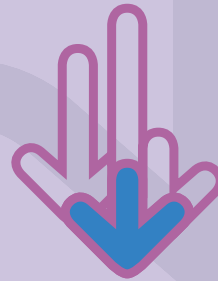
What is the difference between a discovery and an invention?



In this context a discovery is any substance that exists in nature, as is finding a physical property of such a substance. To be an invention a discovery needs some form of intervention to provide a technical effect and therefore an industrial application. Essentially there must be some change wrought by the inventor in order for the discovery to become patentable. Many inventions that are patented arise out of a

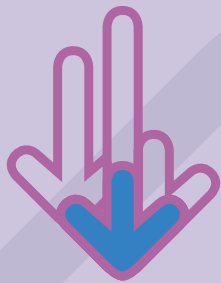
discovery, however something further is needed to make that discovery patentable.

How long does it take to get a patent and what are the various steps?



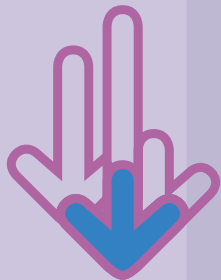
Exactly how long it takes to get a patent depends largely on the individual circumstances of each case. There are, however, a number of key stages and dates. The first key date is when the patent application is filed at the Patent Office. This is called the filing date and establishes what is termed the priority date. In the event of any disputes it is this date that is used to judge who was first to file. It is also the date from

which prior art is judged. During the next 12 months applications may be filed in other countries using the first filing date and during this time the invention can be further developed. At this stage the patent is still undisclosed and can be withdrawn without disadvantage. After 18 months, however, the application is published and all rights to protection will be lost if it is then withdrawn. After 30 months the application is examined by the various countries to which applications have been made and during this process competitors can challenge the patent. There is no fixed timescale for this element but it normally takes about 3/4 years to grant a patent in the UK and up to 5 years for countries like Japan.



The difficulty is that a commercial judgement is required to establish exactly when to publish. This is because during this 18 month period it is possible to amend or even withdraw the patent without it becoming public. If, however, you have published the day after filing then this route is closed to you and the patent must stand as it is without any changes or improvements.

There is to some extent a natural tension between academics need to publish and the requirements of the patent system. If details of an invention have been published then it is not possible to patent in the UK or Europe. It is possible, however, to balance the demands of the patent system with the scientists need to publish. Once a patent application has been filed then there are no formal barriers to publication, details will in any event be published by the Patent Office at the end of an 18 month period.



It needs to be stressed, however, that researchers are not being funded by BBSRC specifically or solely to generate intellectual property. Even strategic research is largely curiosity driven and is chosen by peer review under criteria of scientific excellence. Thus the outcome of research is rarely certain, and this inherent uncertainty means that unexpected exploitable results will sometimes arise, and the history of many major discoveries demonstrates that fact. The ability of a researcher to recognise potentially exploitable research as it arises, and take appropriate action, is enormously important.

For many businesses a secure portfolio of intellectual property is the foundation on which their success depends, and for research institutions the generation of intellectual property forms one of the bases for successful collaboration with industry and commerce.

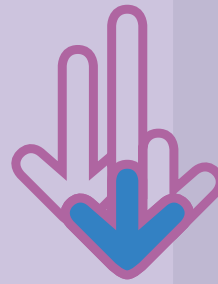
Will patenting delay the publication of my research results?



What are the advantages of owning intellectual property?



Should research institutions always insist on retaining ownership of intellectual property?



Publicly funded research

Intellectual property (like all forms of property) can be traded, sold, leased and mortgaged. The costs of developing inventions, and protecting patents, are significant - and for inventions with a long time to market, the financial risks and the uncertainty of the eventual level of return often require companies who wish to exploit to insist on the transfer of ownership of the intellectual property. In many situations, especially when time to market is relatively short, companies may be less concerned with ownership of intellectual property and will be content to have an exclusive exploitation agreement.

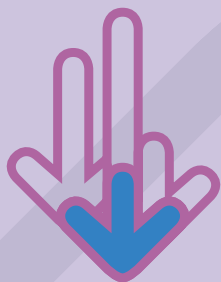
Dogmatic insistence by an institution that ownership of intellectual property must be retained could well mean that an exploitation opportunity is missed. Since institutions rarely have the resources or expertise to enforce protection, while major companies certainly do, a revenue-sharing arrangement which ensures a sensible return to the institution will often suffice. In such an arrangement, there should be an agreement which

allows intellectual property to return to the institution, after an agreed period, should the company decide not to exploit.

Company funded research

Companies may often wish to contract a research institution to provide a service. The company in such circumstances is the customer and the institution the supplier. In a straightforward case the company will have specified the service required, and must expect to pay at least the full economic costs of the service. A legally binding contract to provide the specified services is likely to form part of the arrangement. And there may be restrictions placed on the researcher regarding the publishing of results .

In such cases the company/customer will have paid the market rate for a particular service, device or system - and will as a consequence normally expect to own any associated intellectual property. Allowance for this fact will have had to be made by the institution in agreeing the price for the service provided under the contract. A revenue-sharing agreement may also be appropriate to reflect any associated underpinning work by the institution.



Collaborative research

Here the funding of the research will partly be from the public purse and partly from industry. Sometimes more than one company will be involved, and more than one research institution. Each collaborating partner will be bringing expertise to the collaboration.

A major aspect of the BBSRC's mission is to contribute to the economic competitiveness of the United Kingdom and, therefore, BBSRC requires that the partners make appropriate exploitation arrangements to promote that objective. In many cases, particularly those involving just one industrial and one academic partner, the industrial partner will be the obvious choice for taking a product to market, provided, of course, that it is willing and able to take that responsibility. It follows that the industrial collaborator should have the opportunity to acquire at least user rights and it is self evident that it should not be denied access to the results of the project in which it has participated. The arrangements would usually include a revenue-

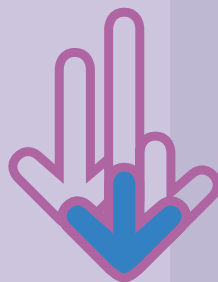
sharing agreement and penalties for non-exploitation by the industrial partner.

BBSRC will not normally get involved directly in negotiating an exploitation agreement for collaborative research, but will need to be assured that an arrangement acceptable to all parties exists before releasing its share of the funding.

It is often argued that transfer of ownership of intellectual property to a company, in return for an agreed royalty return from exploitation, could inhibit subsequent creative research in the same field by the academic researcher. This is very seldom the case; it would depend on the detailed conditions of the assignment which should include a license back to the institution for academic research purposes. The institution and researcher will in any case be free to use the subject of a patent application for non-commercial purposes.



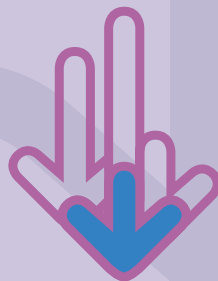
Summary



For all research, whether publicly or company-funded or collaborative, a sensible accommodation has to be reached between an institution and a company. Circumstances will differ, so that it is unlikely that a single approach can be adopted for all cases. BBSRC's principal concerns are that arrangements should be geared, where possible, towards enhancing the competitiveness of UK industry and to providing an appropriate

return to the institution and the investigator. Also that ownership should return to the institution after an agreed period if exploitation is not pursued, and that there should be no significant restrictions on the future research activities of individuals.

What aspects should collaborative research agreements cover?



At a minimum a collaborative research agreement should cover:

- arrangements for the management and coordination of the project
- responsibilities (including funding) and liabilities of the various parties
- arrangements for the treatment of intellectual property
- reporting arrangements, access to results, and confidentiality provisions
- consequences of termination/default, and ways of handling disputes.



Talk to your industrial liaison officer (or equivalent). Establish an awareness of the importance of intellectual property matters as part of the innovative culture of your research group. Make use of any available courses on intellectual property or of any training packages on patenting and licensing.

What other sources of information are there?

There are a number of useful sources for further information. These include:

The British Technology Group produce two very useful leaflets entitled 'Publish and be Damned' and 'Keeping a Laboratory Notebook'. Available from:
The British Technology Group
10 Fleet Place
London
EC4M 7SB
tel: 0171 575 0000
website: www.btgplc.com

The European Commission has an Intellectual Property Rights Helpdesk which can be accessed through their website at www.cordis.lu. It covers frequently asked questions and the latest news on patent issues.

Research Partnerships between Industry and Universities: a guide to better practice by the Association for University Research and Industry and the CBI, copies available from CBI Publications, telephone 0171 395 8033

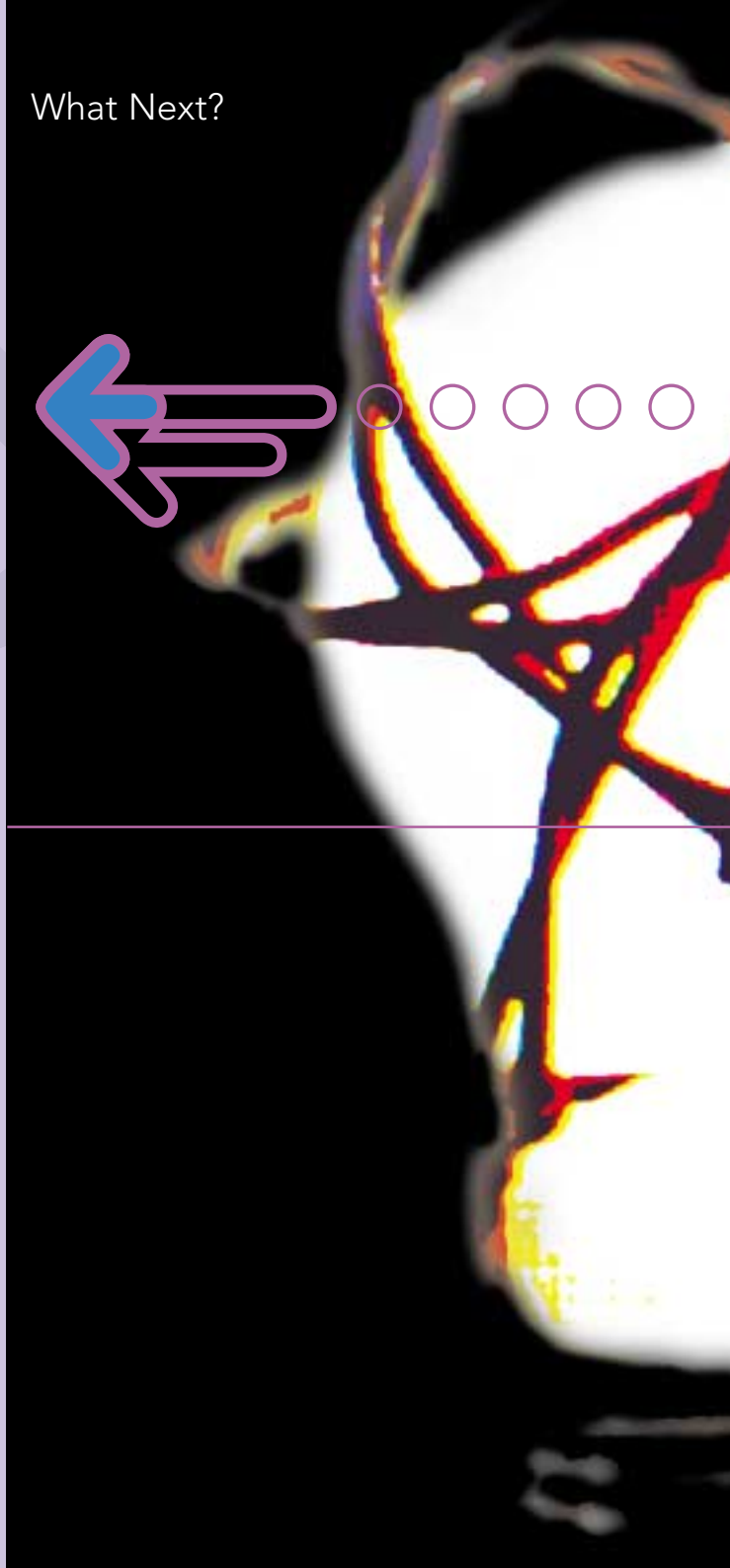
Technology Ventures have also produced a booklet on 'Intellectual Property Guidelines' available on their website at www.theros.co.uk.

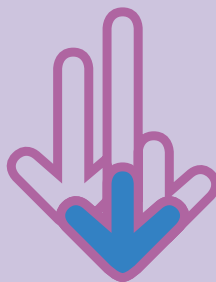
The Patent Office have an extensive list of publications and a web site giving details of the patent system and how to best utilise it.

Web address: www.patent.gov.uk

Patent Enquiry Desk telephone 0171 438 4700
(weekdays 10.00 - 16.00)

What Next?





Contact Points

The staff at BBSRC will be glad to advise on any queries, by letter, telephone, e-mail or fax.

The key contact point is:

Business and Innovation Unit
Biotechnology and Biological Sciences Research
Council
Polaris House
North Star Avenue
Swindon SN2 1UH

Tel: 01793 413275

Fax: 01793 414674

E-mail: busunit@bbsrc.ac.uk



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