



Intellectual Property Guide



**A handbook for scientists and researchers
involved in life science research**

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Introduction & Index



Introduction

The Institutes funded by RERAD are involved in both fundamental and applied research in the broad area known as life sciences. Much of the research has commercial applications and wide implications for public policy. It is important for the scientists actively involved in research to have a basic understanding of this asset to help commercial development and to maximise future research opportunities for their work.

Knowledge transfer and end user relevance now play an important role in the overall assessment of each organisation supported by RERAD. Now more than ever it is important that every scientist involved in research has an understanding of intellectual property issues and how they relate to these measures of activity.






This Intellectual Property Guide is intended to provide a single, simple point of reference for everybody involved in scientific research. The guide is not intended to baffle you but to provide a practical introduction to intellectual property and how it affects your work as research scientists. It also aims to dispel some common misconceptions concerning intellectual property, indicate where intellectual property issues are important or relevant to your work and importantly when and where you should go when professional advice or assistance is needed.



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What are Intellectual Property Rights (IPR)

The term 'intellectual property' is most commonly associated with Patents. In fact the term is far more wide reaching and is better used to describe all the products of a person's creative output.






IPR are generated on a daily basis and their careful management is essential particularly, as in the case of research institutes, where there is likely to be interactions outside the organisation. These interactions include contact with other researchers, companies and government departments.

Like any form of property IPR can be sold (assigned), licensed, leased or mortgaged. Clearly since institutes are primarily involved in research and innovation IPR is a valuable asset both to the individual research scientist and the institute. IPR issues are likely to arise in most of the activities undertaken in research institutes including core research, externally funded and/or collaborative research, consultancy and other specialist services. With the growing diversity of the research environment it is essential that scientists have a basic understanding of how intellectual property is created, owned or transferred to others to help protect their interests.



Types of IPR

There are five main types of IPR:

-  Patents
-  Confidential information and/or know how
-  Copyright
-  Trade Marks
-  Design Rights

A general outline of the types of IPR and what they relate to is shown in Section 8:

A single project or activity may generate more than one type of IPR. Whilst some IPR can arise automatically (Unregistered) other types only arise through a formal registration process (Registered). In the United Kingdom, the UK Patent Office is the official body responsible for all registered rights. Examples of the typical situations where IPR can arise in research work are shown in Section 8.





Types of Intellectual Property Rights (IPR)



Patents

General

Patents are the best known form of IPR and potentially have the highest value. They concern the technical and functional aspects of a product and have to be formally registered to be enforceable.

From mediaeval times inventors have had the right to have 'Letters Patent' granted to protect a monopoly and this remains the underlying basis of the modern patent system which is now governed by the United Kingdom under the 1977 Patents Act.

In return for a complete disclosure to the state (Patent authority) of a technical invention the inventor is given exclusive rights to exploitation for a period of up to 20 years. This right may be licensed or sold on to others. During the existence of the patent the owner can take legal action against others to prevent unlicensed manufacture, importation, use or sale of the invention protected by the patent. After the patent has lapsed or expired, the technical information falls into the public domain and can be freely used by anybody.

Patents are territorial; a patent granted in the United Kingdom will only give rights in the UK and the right to stop others importing the patented product into the UK. There are, however, a number of international arrangements which simplify the process for patenting the same invention in more than one country. Applications for patents in other countries can only be made during the first year of life of a patent although, through international arrangements, this process can be initiated simultaneously in a number of countries, with the final decision being able to be deferred to later.

Do not forget that patents are also an important, and often forgotten, source of scientific literature. Some 36 million patents have been filed, of which approximately 5 million are still active. They represent some 80% of the world's published technical information and much of their content, particularly from commercial organisations will not be found elsewhere. Using the now well established international patent databases they can be searched easily.

What is patentable?

For an invention to be patentable an invention must fulfil a number of qualifying conditions:

- It must have an industrial application. A patent cannot be granted if there is no identifiable commercial use for it.
- It must be new. This means that it must be different (or novel) from what has gone before and importantly must not have been disclosed previously in any form in the public domain. If an idea has been disclosed whether in published papers, speeches, lectures, exhibitions of scientific posters or any discussion or communication the novelty will be destroyed unless disclosure was under strict obligations of confidentiality. This is particularly important for research institutes where there is traditionally a commitment to open disclosure and exchange of scientific information.



- 👉 There must be an inventive step. The invention must not be 'obvious' to someone with a reasonable knowledge of the subject. The inventive step does not however need to be a 'quantum leap'. Many of the best patents have been based on incremental improvements to existing technology which were not obvious or routine.
- 👉 The invention must not be of a type excluded by law. The law excludes a number of specific types of discovery from patent protection particularly where they might have a negative moral or social impact. It also excludes areas where the scientific base of invention is blurred. A more detailed list follows in Section 8.

The process of patenting is a long, complex and potentially expensive process. The stages and a typical timescale for a patent application are shown in Section 8. Drafting a patent to ensure the maximum security for the invention is a specialist skill and it is best guided by experts in knowledge transfer within individual institutions with the assistance of specialist Patent Agents or Attorneys. In each case, the exact scope of the novelty, industrial applications and inventive step must be defined. Given the cost of patenting, which, whilst initially modest, rises quickly as the geographic scope of the patent is extended and individual patent offices undertake their examinations, it is important to evaluate the commercial potential at an early stage and, where possible, plan routes for commercial development through, for example, licenses. In addition, the need to undertake further development and/or the ability to maintain confidentiality will also be a driving force in deciding when an application is submitted.

What is excluded?

The following types of innovation are specifically excluded from Patent protection:

- 👉 *A discovery, scientific theory or mathematical method*
- 👉 *A dramatic, literary, musical or other artistic work*
- 👉 *A scheme, rule or method for performing a mental act, playing a game or doing business*
- 👉 *An invention that encourages offensive, antisocial or immoral behaviour*
- 👉 *Some animal, plant or biological processes, though microbiology can be protected*
- 👉 *Methods of treatment or therapy of the human or animal body*
- 👉 *Computer programmes*

Exclusions are not however as simple as they might appear above. For example, it may be possible to patent a manufacturing process where the novelty relies on a computer program controlling it. There are also variations in interpretation between national offices. In the USA for example programs performing a specific function such as business analysis or banking documentation have been patented. In the UK, the interpretation of the exclusion criteria has been rigorous even in comparison with European colleagues. Again, it is important to seek professional advice whenever considering a patent application.

When should a patent be filed?

The timing of any patent application is critical. If a patent is filed too early there is a risk that the invention will be disclosed to competitors too early and that the scope of the patent itself will not be as broad as possible. File too late and there is the risk someone



else will have beaten you to it especially in fields that are highly competitive. The date of filing or 'Priority Date' and the dates on which the novel inventive steps were made are vitally important for the success of any application. The Priority Date, once established, allows an invention to be disclosed to third parties (if desired) and importantly provides an initial period of 12 months during which the technical and commercial viability of the invention can be explored. During this period any modifications or developments to the invention discovered since the application was made may be added to the patent. Once the anniversary has passed this cannot be done.

On the first anniversary of filing the applicant must decide whether to proceed to a full application and if international applications are to be made. These applications will be backdated to the Priority Date. After this details of the invention will be generally available from the Patent Office. It is important to have documented records of the work done leading to the patent application and for these to be verified independently. In some countries such as the USA the invention date as well as the Priority Date are important in establishing the right of the inventors. Later in this guide we will show ways to develop good practice in recording laboratory work as a route to supporting this. Your commercialisation team can also help by preparing a confidential technical disclosure document to help establish the timetable of any novel invention.

As indicated above it is essential that there has been no disclosure prior to filing a patent and you should always think carefully about disclosing any of your research results outwith your research group unless a confidentiality agreement has been set in place. Your commercialisation team will be able to help with preparation of these. Remember, disclosure includes any published (or submitted) papers, conference papers and speeches and discussions with anyone not bound by a confidentiality agreement. It may also include grant applications, especially where these are peer group reviewed, and it is especially important to think carefully when considering collaborative applications with other researchers and organisations. A patent application does not take long to make and will not necessarily stop you from publishing or presenting results. Your commercial team is there to help you, so if you think that something might be patentable, please consult them before going any further.



Confidential Information and Know How

What is Confidential Information?

Confidential Information (and Know How) is essentially any ideas or information which its owner wishes to be regarded as secret. This may take a number of forms including research data and commercially sensitive information. Often this information may not be able to be protected as registered IP and exchange will depend on the agreement struck between the parties concerned and the law on confidential disclosure. In general, disclosure does not transfer any rights. Even where information may be capable of formal IP registration such as patenting, it may be appropriate or timely to treat it as confidential to protect interests. Certainly, as we have seen in the previous section, maintaining confidentiality prior to making a patent application is essential for success.

In order to be protected, whenever confidential information is likely to be disclosed, it is important that an agreement is struck that recognises that the information disclosed may either have been disclosed by you or have been disclosed to you. The obligations for each are different and, for security, there should be a written confidentiality or non-disclosure agreement (CDA/NDA), signed by all parties, in place before any disclosures take place. The scope of these may vary greatly and it is essential that everyone involved is fully aware of their personal obligation. For example, the existence of a research contract with a third party may in itself be confidential information.



How do you manage confidential information?

Working in scientific research, links with external organisations (funding and otherwise) are inevitable and with these will come exchange of information. It is essential that good practice be adopted both to prevent the release of potentially sensitive or proprietary information and to ensure that in receiving third party information this is kept confidential. There are some common sense precautions that scientists can set in place to protect themselves and colleagues:

- 🔒 Be aware of the risk of casual or outside visitors to laboratories or offices. Even whiteboards, open files and shelves may contain confidential information that can be easily accessed.
- 🔒 Before discussing work or planned work with visitors to the laboratory, or with third parties, make sure that there is a confidentiality agreement in place.
- 🔒 When releasing confidential information try to put it in writing (marking it as confidential), and keep a copy of the material together with record of the disclosure.
- 🔒 Make sure there are adequate security arrangements in the laboratory or office including secure filing for laboratory books, results etc.
- 🔒 Introduce a 'confidentiality 'review for draft papers before publication to help identify proprietary information.
- 🔒 Make sure you know what your obligations are under all the contracts in which you are involved. For example, what are the rules about publication or presentation of conference papers?
- 🔒 Make sure that any confidentiality agreements are mutual. That is, make sure it is not only you who is bound to secrecy.

Your commercialisation team will have confidentiality agreements which can be used if there is doubt. They can also advise you on what obligations may already exist and can help you to ensure that your interests are looked after.

Copyright

What is Copyright?

Copyright arises automatically whenever a literary, dramatic, musical or other artistic work is expressed in a tangible form. It relates to the form in which the creation exists and is a right to control the way in which the work that results from this expression can be exploited by others. In the UK, computer programs are treated as literary works as far as Copyright goes.

Copyright relates to the way in which an idea is expressed, not the idea itself. Owners have the right to control the ways in which their work is exploited and this may include copying, renting and lending, as well as sale. Copyright in the UK is created automatically by the creation of the work but, where possible, and to assert full international control, the familiar legend '©' with name and date, should be added. Unlike patents, there is no registration process, although it does last for 70 years after the death of the author.

Ownership

As with all forms of intellectual property, ownership is important if rights are to be protected. Whilst the creator will clearly make the initial inventive step they may not necessarily remain the owner. As with patents, works created in the course of employment



are invariably the property of the employer. Similarly, work commissioned (e.g. reports) by third parties may be owned by them unless specific arrangements have been set in place. In this context it is wise to remember that not all the material used by scientists will have Copyright owned by them or their institute. Items, such as photographs and publications, may be owned by third parties, and copyright regulations should be observed.







Trade Marks

What are Trade Marks?

Trade Marks identify a product or service through branding. A Trade Mark can be any 'sign' that is capable of being represented graphically and which distinguishes the goods or services of one trader from another. The sign can be a word, device, logo, legend label or even container. Trade Marks are very much associated with image and reputation and, as such, may be expensive to develop and to defend, particularly from counterfeits.

How are Trade Marks obtained?

Trade Marks can be registered in the United Kingdom at the Trade Mark Registry of the Patent Office. Registration (initially for 10 years) is renewable indefinitely. Cover can be extended to other countries through international agreements similar to those for Patents. The owner may use the '®' device as a sign that it has been registered. Once issued, the owner has the right to prevent someone else from using the same or similar Trade Mark. To be registered a Trade Mark must:

-  *Be distinctive, it cannot describe the product or incorporate a word that other traders might wish to use in connection with similar products, nor must it imply quality, quantity purpose or value of the product.*
-  *Not be deceptive, that is it must not lead to an expectation that does not exist.*
-  *Not break the law or break accepted rules of morality.*
-  *Conflict with any other Trade Mark*

A Trade Mark cannot be registered if its shape is a function of the nature of the product being protected, is necessary to obtain the technical properties of the product, or gives substantial added value to the product. Not all Trade Marks contain the inherent distinctiveness to be registered. This does not exclude their use, but does severely weaken their legal position. In such cases, many owners use the symbol 'TM' to declare their proprietary rights but this carries no legal status.



Registered Designs and Design Rights

What are Registered Designs and Design Rights?

Both forms of intellectual property relate to the visual (three dimensional) appearance of a product and take two forms. Registered Design is granted by application to the Patent Office in the UK and, as expected, gives stronger protection. A Registered Design gives a monopoly to use an outward shape or decorative appearance on an article for a maximum of 25 years. It gives the owner the exclusive right to make, import, sell or hire the article for which the design has been applied for. It also gives the right to take legal action against those who infringe this right. A Registered Design relates only to the outward design of an article and does not cover its function. This might be subject to other rights such as patents or know how.



To be registered a design must:

- 👉 *Have a significant and distinctive eye appeal which is not determined directly by its function.*
- 👉 *Be new. The design must be novel and have been kept confidential before the application is filed.*
- 👉 *Not be a work of art, for example sculptures, plaques, medals etc would all be excluded on artistic grounds.*

Unlike other forms of registered intellectual property rights, there is no international agreement between issuing authorities, and separate applications have to be made in each country for which protection is sought.

Design Rights offer a less formal way of establishing intellectual property rights. They usually relate to original but not commonplace designs and, like copyright, arise directly from the creative process, so no registration is needed. Unlike a Registered Design, there is no monopoly created, rather there is a right to prevent copying features of the shape. It also lasts for a shorter time; a maximum of 15 years from creation of the design. Unregistered Designs or Design Rights are unique to the UK.



Who owns Intellectual Property Rights?

In the United Kingdom, all aspects of Intellectual Property are governed by the Patent Act of 1977. The Act is very specific concerning ownership of rights. In general, an invention made by an employee as a result of their duties is owned by their employer and there is a duty of care on employees to notify their employer if they believe they have made an invention. This interpretation is generally restricted to cover only those staff or duties where an invention might reasonably be expected to arise or which are linked to the aims and objectives of the employer organisation. More simply, this means that research scientists are expected to come up with novel ideas linked to the aims of the research institute but gardeners would not necessarily be expected to do so! There are variations in the scope of this interpretation and to avoid confusion the RERAD supported organisations have generally signed up to follow the Code of Practice set up by the Biotechnology and Biological Sciences Research Council in their Employment Code.

In general, your employment contract and staff handbook will refer to the provisions and obligations concerning inventions and it is worthwhile checking these from time to time.

The Patent Act does not define what an 'invention' is. Generally, it is taken to mean any of the forms of Intellectual Property outlined in Section One of this guide. The Act is also clear that although the inventor may not be the owner of the invention their employer should, as far as they are able to do so, reward the inventor for any commercial development of the invention. This might include sharing of the revenues received, or a single payment in recognition of the contribution. Again, the RERAD supported organisations follow the BBSRC Employment Code and later in this guide we will cover briefly how this works.

The Patent Act assumes that all inventors will be employees of the organisation where any invention is discovered. Research institutes and related organisations frequently host students or visiting scientists who are not employees. Unless a special agreement is set in place with these people any inventions made by them will be their own property. This could lead to ownership disputes which are difficult to resolve. Without such an agreement it is also difficult to ensure that any laboratory or internal scientific discussions are confidential and that your intellectual property is not being weakened.



Sharing the Rewards

It is important that scientists are involved in and share in the successful commercial development of inventions made whilst working in RERAD funded organisations. Working under the umbrella of the BBSRC Employment Code there are general arrangements in place for staff to benefit from commercial developments. For the most part these relate to the situation where a company has been granted the right to commercialise the Intellectual Property and, in exchange, the owner receives income. New guidelines are emerging to cover the creation of new companies and other forms of commercialisation and your specialist commercialisation team can provide more information on this.

At a local level, an independent panel considers every invention and identifies who has contributed to the discovery and their relative contributions. This assessment is based on available information from, for example, laboratory note books and meeting notes and will also draw upon input from staff. It is important to remember that whilst a patent application will only name those staff directly responsible for the inventive step the 'rewards to inventors' scheme may include other staff, such as technicians, who contributed to the development process in other ways.



Based on the decision of the panel there is an agreed formula for sharing any income that comes directly from commercial exploitation, such as royalties, milestone payments or sale of the Intellectual Property. Income received from commercial partners as funded research is not included in the guidelines.

The income is distributed as follows;

Gross receipts	Relevant staff get
Up to £1000	£1000
From £1000 to £50000	20%
Net Receipts	Relevant staff get
From £50000 to £500000	10%
From £500000 to £1000000	5%
Over £1000000	2.5%

The rewards system is intended to benefit staff from the earliest stages of successful commercialisation. After £50000 of income has been received by the institute then it may start to recover some of its costs in developing and supporting the Intellectual Property. These costs may include filing, maintaining and enforcing patents and other rights, professional advice on patents, intellectual property and related matters and costs, such as market assessments etc., related to commercialisation of the intellectual property.

Some institutes in the RERAD system have additional rewards schemes to encourage people to come forward with ideas that may have commercial potential and your local commercialisation team can give you more details.

Much of the work undertaken by scientists nowadays is supported from external funds. These include research councils, government departments, European Commission and companies. External funders will have their own rules concerning ownership and management of intellectual property arising from their sponsored programmes. These rules will typically cover the less formal areas such as copyright, confidential information and know how, as well as registered intellectual property such as patents. The rules will generally form an integral part of any grant offer or contract, and it is important that all staff associated with sponsored projects are aware of the specific rules, as these may differ considerably from the general site rules of the Institute, and from project to project.



Foreground and Background Intellectual Property

Earlier in this guide we have seen that Intellectual Property Rights may take a number of different forms, some of which may have a formal registered status, such as patents, whilst others, such as copyright, might be established by their very existence. What ever their form, they have a common feature in that they are all created throughout the entire process of undertaking research activity.

In addition to specific forms of Intellectual Property, there are two important general definitions of Intellectual Property that research staff need to be aware of. These are Foreground and Background.



Foreground Intellectual Property

The term Foreground refers to all intellectual property that is generated in the course of a specific research programme. This is perhaps best demonstrated by example. A commissioned ROAME from RERAD is based on a specific, agreed research programme. All the results, data and material produced from this project, by all those involved in the project, is called Foreground when we start to consider Intellectual Property Rights.



Background Intellectual Property

Any information, results or other forms of Intellectual Property created outside of a specific project are regarded as Background Intellectual Property. Normally, this is confined to that intellectual property which is relevant to a new or Foreground generating project.

This Background may have been produced previously by the research workers involved, ie from an earlier project. It may be generated concurrently but outside of the scope of the project concerned. For example, an FSA sponsored project supervised by the same scientist but employing other staff. It may be generated by third parties, that is, someone who is not involved with the project. Typically, this might be another research group that is looking at a similar scientific problem. With the traditional free interchange of information amongst the scientific communities it is easy to overlook the implications for intellectual Foreground and Background.

Foreground generated in today's project becomes the Background for tomorrow's project. We have seen earlier that every sponsor will have its own rules concerning access and use of Intellectual Property. Care must be taken to ensure that scientists are free to undertake current and/or future research and are not restricted by lack of access to IP or the terms under which it is made available to a specific project. It is particularly important to try to ensure that if you have 'Core' intellectual property, that is IP that provides a platform for a number of research areas, you are not restricted from working with this in the future.



Protecting Your Core Intellectual Property

It is important to be able to protect and control the direction of your long term research. If Intellectual Property generated from one project or programme is important for the viability of other programmes, or forms the basis of future research, then it is important to ensure that

you have unrestricted access to it. Before starting a programme, particularly if it is externally funded, you should make yourself aware of the terms and conditions that will be applied to intellectual property. You should also try to consider how important this intellectual property will be to any future or associated research projects, and if restricted access to this could affect your future plans. If there is any doubt, then you should speak with your specialist commercial team before any agreements are signed, or grants accepted, to try to secure better terms with the sponsor. It is important for the commercial team to be aware of these concerns, as any restrictions on use may also hamper their ability to find long term partners for research alliances or commercial development.

In general, try to consider what is your core research area, and wherever possible, aim to secure support for this from central (for example, RERAD) funds or from external funders who either do not claim ownership or do not restrict use of intellectual property. Research which falls outside this area will in general be more applied and is more likely to be supported by organisations who may wish to restrict long term access to intellectual property, although special terms can often be negotiated on your behalf. Care must also be taken to ensure that support is not secured from more than one sponsor who will have the similar expectations of outcomes. (An example follows)

Example:

A scientist is working to understand how electric motors work, and how to improve their performance, and reduce power consumption. His core intellectual property concerns the construction of motors and the electronic circuits used to control them. Whatever the application, or use of the motor, it is important for him not to lose ownership or control of this. To maintain this he only undertakes basic underpinning research with funds from his institute or research councils neither of whom restricts use or ownership. As a result of his expertise, several companies approach him to collaborate and develop systems for their products and he is pleased to see real applications. He will not though use this as a way of developing an absolutely new control system for a motor. He is careful to choose whom he works with and the applied research is managed carefully with help and advice from the commercial team. Electric drill motors need to be small, high powered and light. They run at high speeds and need to reach this quickly. Washing machines are bigger, heavier and work for longer periods but at lower speeds. The application of the core technology to each application is distinctly different but does not create new Core IP. The scientist can conclude relations with a company from each sector, and licence IP in their application field. Working with more than one company from each sector, or with companies from other sectors with similar requirements, e.g. dishwashers, could cause problems. Although the Core IP is not affected, the companies may require the same application of the Core IP for their use, and separation would be almost impossible.

"Sometimes disputes may arise where individual sponsors, aware of the potential value of IP to them will try to claim ownership. To help fight this it is important to be able to demonstrate the origin of all intellectual property and in the next section we will outline some simple precautions that can be taken to help prevent this from happening."





Keeping a laboratory notebook



Why keep notebooks?

We have seen earlier in this guide that where ever Intellectual Property issues are concerned it is important to support any claims being made with evidence. This is particularly important in the case of patents where it is important to be able to prove the date of an invention. In many countries this has simply been taken as the date upon which the first patent application was filed. As the number of patents being filed increases this has become more difficult to monitor. Different procedures for filing patents in countries could lead to delays. As a result, the US Patent Office (a very important market for all patented products) has revised its definition from 'First to File' to 'First to Invent'. An applicant, who can demonstrate their invention predated a rival's or a publication cited against their patent, will have a stronger case for grant of a patent in the USA. The US Patent Office has also re-defined what they regard as an 'Invention' and it now comprises two parts; the 'Conception' or the creation of the idea, and 'The Reduction to Practice' or demonstration, by filing a patent and/or experimentation of the idea. Properly kept laboratory notebooks will help provide the evidence needed.

In recent years there have been a number of high public profile errors in experimentation, highlighted most recently, for example by, the Institute of Animal Health and allegedly misplaced or mis-labelled samples connected with BSE research. As a result, there has been a reduction of confidence in the research base, both from the public and, from sponsors. Increasingly, sponsors of research, including RERAD, will require confirmation that there are quality assurance systems in place before they will award monies. Properly kept laboratory notebooks will form an important part of this assurance process as well as reinforcing intellectual property ownership.



Evidence and Diligence

To support patent application inventors need to provide evidence of the date of invention and proof of the diligence of the reduction to practice. Evidence can take several forms but the most accepted one is a well kept laboratory notebook. This must show clearly the date of the inventive step and must be signed and dated by the inventor and a witness (someone who is not the inventor). Diligence of reduction to practice is also shown through a well kept laboratory notebook that illustrates a steady level of activity following the conception of the invention to exemplify the idea.



Good Practice in keeping a Laboratory Notebook

It is important to use a good quality record book that has a permanent binding. Any loose bound or temporarily bound book which allows pages to be removed, added or substituted is not suitable. To ensure that the books can be archived for future reference they should be made of good quality paper and each page should be numbered to reduce the possibility of being accused of tampering with data. To ensure that the record is permanent all entries should be made in pen, not pencil. Most Institutes now have stocks of suitable books which can be obtained from the stores. In general, these are produced exclusively for the Institute and also contain guidance notes on record keeping as a day to day aid. Many are sequentially numbered, again to help verify the origin of data.

The entries in the book should, of course, be legible and should contain detailed descriptions of the experimental procedures, supported if appropriate by drawings or diagrams. Avoid slang and over use of technical jargon. Data and results should be recorded carefully and, if appropriate, include details of the calculations used, for example, on analytical data. If there is data, for example, print outs from machines that needs to be included, then this should be fixed to the book permanently. Data that cannot be attached to the book, such as gels, should be properly referenced, and it is essential that this material is stored in an orderly and readily retrievable form. Any subsequent data or additions should be entered on separate pages with reference to the original entry. Any errors should not be erased or obliterated beyond recognition nor should liquid paper be used. Any errors should be marked through so that it is clear they exist. An explanation of the error together with a signature will add validity.

Many laboratories are moving towards electronic data capture and Laboratory Information Management Systems (LIMS). At present there remains concern that LIMS systems do not provide sufficient secure environments to prevent the date of entries to be altered. For such data to be admissible to the US Patent Office, each Laboratory must be able to demonstrate that electronic records cannot be altered subsequently. As a result, it is advisable for the foreseeable future, not to rely entirely on electronic record keeping but to keep paper records in conventional notebooks as well.

In general, it is better not to express opinions in notebooks but to restrict them to factual information, observations and results. Pages should in general, not be left part completed or blank. They should be clearly marked through to indicate they have not been used.

Each page should be signed and dated by the author and witnessed. The notebook is an important record (sometimes regarded as a legal document) and should be stored in a safe place.

A single laboratory notebook does not need to contain all the work undertaken by a scientist. Where research is supported by a number of sponsors, or there are a number of different projects underway, it is wise to have a notebook for each activity. In this way, it is easier to identify where individual inventive steps took place and to avoid conflicts of interest between sponsors. Your quality assurance and commercialisation teams can provide assistance and advice in keeping laboratory notebooks.





Information for scientists

In the previous sections of this guide we have introduced the basic concepts of intellectual property and how they relate to scientific research undertaken at the Rowett. In this section we aim to give you some pointers to the practical aspects of intellectual property management that you will come across in your everyday research and provide some guidance on how to address them.



Visiting Scientists

Most active research groups play host to visiting scientists. These scientists are typically on study leave and are supported either by their home institution or a third party (for example their government or a foundation). Visiting scientists will work along side staff employed by the host institute and will be integrated into activities such as internal seminars and workshops. They may, in the course of their stay, come into contact with information and results which have yet to be published or which might form the basis of commercially important intellectual property. They will also be conducting their own research programme which may, in its own right, generate intellectual property.

Visiting scientists will generally not be employees of the host institute and as such will not be automatically bound by the institute rules for intellectual property and confidentiality. The results of their research will remain their property and they need not acknowledge any contribution from the host's scientists. The normal induction process (issue of IDs etc) will ensure that visitors obey local site rules for experimentation but will not necessarily cover exchange of information or results. It is important that all visiting scientists are asked to sign an agreement which, as part of their conditions of stay, links them to the general terms and conditions for employees. If this is not done you must regard all information given to them (either directly or indirectly) as a non-confidential disclosure which may affect your ability to publish data in the future.



Students

Many institutes run research programmes involving students. Often these are supported by external funds (e.g. BBSRC) and the students are registered for degrees with a nearby university. Like visiting scientists, students are not employees of the institute and are not bound automatically by local intellectual property regulations. Unless a separate agreement is struck with the student, they are not held to keep information confidential and the results of their studies will be their property. The supervising scientist and the host institute may lose valuable publication and ownership rights. As with visiting scientists, it is important to set in place an agreement with students that allows free exchange of information and protects the interests of the host.



Grant and Contract Applications

The area of external funding is one in which scientists must increasingly be aware of intellectual property issues. More sponsors now need commercial exploitation and intellectual property issues to be covered at the application stage and are incorporating it as part of their performance monitoring systems.

There are issues that you need to consider at an earlier stage. Grant applications frequently incorporate novel ideas and concepts which may have a significant scientific and commercial impact. It is important to know before submitting any application if it will be treated in confidence by the potential sponsor and evaluators. If appropriate, try to have a confidentiality or non-disclosure agreement put in place before making the application. This is particularly important in the case of public sector sponsors where the evaluators may in fact be competitors.

Visitors






Institutes frequently play host to visitors. These will range from, fellow scientists who are giving lectures, presentations or exploring collaborations, to companies seeking to develop commercially intellectual property invented by you and your colleagues. At its widest, it will include any visitor to the site. In hosting visitors, think carefully about what they will see and hear. Confidential or proprietary information may unwittingly be released to visitors. Laboratory benches, for example, may have open laboratory books or information relating to experiments and projects. Office whiteboards and shelves can provide a wealth of information to the visitor about latest data, sponsors and projects. Think carefully about where visitors will go and what they will see. If in doubt, structure a visit to avoid sensitive areas. Think also of who they will meet and what they will hear. Make sure that staff are briefed on what they can, and cannot, tell visitors. Before the meetings think carefully about the information you intend to disclose and be clear what you are prepared to disclose.

It is always worthwhile trying to implement a two way non-disclosure or confidentiality agreement before visitors arrive. This protects everybody and allows free exchange of information.

Collaborations

Much external funding for research now requires the collaboration of one or more partners. This raises a number of intellectual property issues that the scientist needs to be aware of. As applications are developed, it is important to consider the confidentiality of the application process. Potential collaborators should be regarded as visitors whilst proposals are being developed. If necessary, set in place confidentiality agreements to allow you both to speak freely and develop ideas together. Remember, they will be just as worried about you having access to their information!

In developing your ideas you will need to consider how intellectual property issues are going to be handled when the project starts.

-  How are publications going to be handled?
-  Who will own the intellectual property rights?
-  Does the sponsor want to be involved in IPR development?
-  How will issues around Background and Foreground be handled?
-  How will decisions be made?
-  What is the status of each organisation?

It is important to remember that, in any project where you are using consultants or sub-contractors, you will need to control ownership of the results of your work.

The commercialisation teams can help to advise and support partners in addressing intellectual property issues and to draw up collaboration agreements with partners and sponsors. As with all IPR matters it is never too early to start thinking about the issues.





Exchange of Materials

Novel materials, including bacteria strains and chemicals, are often exchanged (sometimes free of charge) between research groups across the world as part of informal research collaborations. Requests often come as a result of publication of a scientific paper or a conference presentation. In the spirit of collaboration it often seems a simple matter to just send material. Doing this may compromise intellectual property that you have developed. Before agreeing to release any materials you should conclude a 'Materials Transfer Agreement' (MTA). This will detail the terms under which they can use it. For example, they do not own the material but simply have use of it for their research. It will also make it clear who owns any developments or inventions that use the material and cover publication of new results incorporating use of the materials.

Similarly, if you request materials from another laboratory, you should make sure an agreement is in place. Without it, you may not be able to publish your results or take credit for any inventions you make using it. MTAs are important documents and your commercialisation team can negotiate on your behalf to make sure your interests are looked after.



Publications and Conferences

Submission of papers to journals, or for inclusion in a conference, raise similar intellectual property issues for the scientist as making a grant or contract application. Before making any submission to a scientific journal or conference organiser, it is important to know if it will be treated as confidential until publication. In each case, peer group review is common and, in general, submission of any paper, poster or presentation should be regarded as a non-confidential disclosure. Confidentiality is, as we have seen earlier, essential if a Patent is to be filed, and you should think carefully before any paper or presentation is submitted. It is often said that filing a patent prevents publication. This is entirely untrue. Provided a patent is filed before the publication is submitted, there is no reason why publication should not go ahead. Filing a patent only takes a few days so it should not delay unduly the submission of papers to journals or conferences. Once again, consulting your local commercialisation team, as soon as possible, will help to speed things.



The Internet

The Internet has rapidly been accepted as one of the most effective ways to keep the scientific community across the globe in contact. The Internet is, however, very insecure and is easily open to malicious actions (e.g. implanting viruses) which are difficult to trace. The dependence on interpenetrating networks means that no transmission can be guaranteed to arrive at its intended destination or not to have been intercepted. For this reason, the Internet is generally regarded as a non-confidential network by lawyers and Patent Agents, and you should never transfer results or confidential material, even as attached files using email. Until systems improve, all confidential material should be sent only by conventional mail, and should be clearly marked as confidential. Your commercialisation team can advise you on how best to do this, as the style of wording is important.



Where do you go for help – the role of the Commercialism Team

Whilst research scientists need to have a basic knowledge of intellectual property issues, the area is, as we have seen complex. Expert advice and assistance is available locally through the commercialisation teams and knowledge transfer subsidiaries of RERAD funded organisations.

The knowledge transfer and commercialisation teams undertake a variety of activities and their structure varies from member to member. More detailed information about local arrangements at your site may be found in Section 8. There will be some common elements though. All the teams are staffed by people who have a wealth of expertise in the fields of intellectual property, commercialisation and, in many cases external funding. Most of these people will have direct experience of research in a life science environment and many will hold higher degrees in the subject. They will all, therefore, be familiar with the day-to-day concerns of research scientists.



Help Available

Research Proposals

The External Funding Unit (Kate Mason) and RRS are able to provide advice and support to staff seeking external research funding from public sector sources, such as government (e.g. DEFRA, FSA), research charities, European Commission and other agencies. They can help to identify the most appropriate organisation or scheme to apply to, assist in costing and pricing of proposals and, in some cases, provide background information on sponsor's priorities and help with non scientific areas of drafting applications. Where applications involve collaborations with other organisations, the teams can advise on the best ways to protect your intellectual property interests and manage the projects.

Advice on Contracts

Research contract documents are often long and complex and may be worded in jargon that is unfamiliar and confusing. They are legal documents and it is important for scientists to understand their rights and obligations under them. The knowledge transfer teams can provide help to scientists to understand these documents, and will provide assistance in negotiating, to ensure that your interests are best served. This is important, not only where commercial partners are involved, but also where the work involves public sector sponsors. This is particularly so where you are collaborating with other organisations.

Commercial Development of Intellectual Property

We have seen earlier in this guide that intellectual property will typically have a value and it is important to try to realise this on behalf of the owner and the inventor. The knowledge transfer teams have a central role to play in making this happen. The team will work with the inventors to develop the most appropriate exploitation strategy. This may also involve specialist input from Patent Agents, market analysts, and other consultants. It should always be remembered though that difficult decisions may have to be made. The exploitation strategy will be driven by the commercial demands. The quality of the underpinning science is, of course, essential. However, if routes to commercial development do not emerge then activity from the team may need to be reduced.



The team will take responsibility for submitting and supporting Patent applications and will in many cases meet the costs and risk associated with this. They will also implement the agreed exploitation plan. This may involve licensing, where ownership of IPR is retained but you allow someone the right to use it in return for payments. These payments may be based only on a percentage of the value sales made (royalties) or may contain other sums, such as annual fees, or payments triggered by commercial milestones. The IPR may also be assigned or sold for a single agreed sum to a third party. Where IPR is at an early stage of commercial development and not ready for licensing, commercialisation might include a strategic research partnership to co-develop the technology on the basis that a license will be issued in the future. In recent years, there has been increased interest in the creation of new companies (Spin-outs) to take forward commercial development of IPR. This has the advantage of the owner and the inventor being able to have greater control of the IPR and the way in which it is developed. The knowledge transfer teams can provide specialist advice and support for Spin-out companies, including allocation of shares, attracting investment and preparing business plans.

The knowledge transfer teams will bring professional expertise to ensure that, whatever the commercialisation process, it is one which the originating scientists are comfortable with and is appropriate for the technology in question and its stage of development.



Project Management

The complexity and diversity of external funding mechanisms for research, coupled with higher levels of direct accountability, is placing an increasing burden on scientists to manage research projects, leaving less time for the research itself. The knowledge transfer teams can provide assistance in the post-award administration of research and related agreements. This will typically include financial management, but can be extended to include co-ordination of all administrative aspects of projects, including timesheets and project meetings.



When Should I Consult Them?

As we have seen earlier in this guide the area of intellectual property is one which is complex. Balancing the rights to publish results with successful commercial development is one which requires careful consideration and it is essential that these issues are considered as early as possible.

The knowledge transfer teams are there to help scientific staff to make research submissions and to help them make informed decisions about how best to protect their interests. Contacting the team at an early stage will help them to help you. Negotiations always take longer than expected and leaving too little time may lead to an agreement that seriously affects the technical and financial viability of a project and prejudices the long term freedom to conduct research in that area or publish results.



Further information

There are a number of other sources for further reading. These include:

The Biological Technology and Biological Sciences Research Council publishes two useful guides entitled 'Intellectual Property' and 'the BBSRC Bioscience Exploitation Guide'. Each is available from the Business and Innovation Unit, BBSRC, Polaris House, North Star Avenue, Swindon SN2 1UH. Details are also available on their Website: www.bbsrc.ac.uk

The general guidelines for IPR management adopted by the Rowett can be found in the BBSRC Employment Code, available from local knowledge transfer teams or personnel officers. It is also available on the BBSRC Website: www.bbsrc.ac.uk

The British Technology Group has produced two leaflets, 'Publish and be damned' and 'Keeping a Laboratory Notebook', available from The British Technology Group plc, 10 Fleet Place, London, EC4M 7SB. Website: www.btgplc.com



The European Commission has an Intellectual Property Rights Helpdesk which covers frequently asked questions concerning IPR and latest news. It covers in particular issues arising from research collaborations particularly where these are multi-national. The help desk is accessed via the EU CORDIS Website: www.cordis.lu

Technology Ventures produced a useful booklet 'Intellectual Property Guidelines' available from their Website: www.theros.co.uk

The Patent Office produces an extensive list of publications on all aspects of intellectual property. These are best accessed via the Website, which also gives details of the UK Patents system. www.patent.gov.uk

The Association for University Research and Industry (AURIL) has produced a number of guides. Jointly with the CBI they produced 'Research partnerships between Industry and Universities: a guide to better practice', with the Patent Office they produced the 'AURIL Handbook of Intellectual Property Management' and with Universities UK 'Optimising Consultancy: A Good Practice Guide for Management of Consultancy'. These are extensive guides clearly aimed at the Higher Education sector but they each contain useful general information. These are best obtained via your knowledge transfer teams.

In recent years there have been a number of reports and publications highlighting the important role that good management of intellectual property has in developing economic growth. These are detailed publications but for background reading they do give an insight into the increased importance place by government on the role of research establishments in the economy. Two of these are:

-  Creating Knowledge, Creating Wealth: realising the Potential of Public Sector Research Establishments, HM Treasury, August 1999
-  Delivering the Commercialisation of Public Sector Science, National Audit Office, February 2002



Main Features of Intellectual Property Rights (IPR)

	Subject Matter	Exclusions	Registration	First Owner	Term	Infringement
Patents (Patents Act 1977)	Inventions which are new, involve an inventive step, and are capable of industrial application	Discoveries; Scientific theories; mathematical methods; Copyright works; schemes, rules and methods for performing mental acts; games or business computer programs as such; methods of medical treatment & diagnosis; immoral inventions; any variety of animal or plant or biological process (not including micro-biological processes)	Yes (note law relating to confidentiality)	Applicant (usually inventor or inventor's employer)	20 years from date of application	Making, disposing of, altering to dispose of, importing, using or keeping patented produce without licence
Copyright (Copyright Designs & Patents Act 1988 Part 1)	Original literary (including computer programs), dramatic, musical, artistic works; records, films; broadcasts, cable programmes	Immoral works; industrial designs	No	Author/maker; when made in course of employment, the employer	Author's life + 70 years The former 70 year period still applies for some works eg sound recordings	Copying, issuing copies to the public, performing, broadcasting, cable transmission, adapting, authorising any of the foregoing, dealing in infringing copies, without licence
Registered Trade Marks (Trade Marks Act 1994)	Any distinctive sign used with goods or services		Yes	Applicant	Indefinite, Renewable every 10 years	Using identical or similar sign on same or similar goods or services
Registered Designs (Registered Designs Act 1949)	New exterior features of shape, configuration, pattern or ornament which are material to the eye of the purchaser	Designs dictated solely by functions of article; must-match designs; designs having no aesthetic appeal	Yes	Applicant (usually designer or designer's employer)	25 years maximum 5x5 year periods	Use of design by way of commercial manufacture, import or dealing
Unregistered Design Rights (Copyright Designs & Patents Act 1988 Part 3)	Any original aspect of shape or configuration of the whole or part of an article interior or exterior; topography of semiconductor chips	Must-fit and must-match designs; commonplace designs, surface decoration	No	Designer (unless of course of employment or commission, or computer generated)	15 years from creating or 10 years from first marketing, which ever is less	copying the design exactly or substantially for commercial purposes by making an article to the design or by creating a design document for purposes of manufacture

Type & Subject of IPR (table)

Type of IPR	Subject matter
Patents	New Technical Concepts, Innovations
Confidential information/ know-how	Ideas, information
Copyright	Text, Graphics, Software, Data Compilations, Art, Music
Trade Marks	Brands (Product or Service), Image and Reputation
Registered Design/Design rights	Form and Appearance, Decoration

Activity (table)

Activity	Patents	Confidential Information	Copyright	Design Rights	Trade Marks
Using others' research papers publications etc			X	X	
Research information. Preparing and collating research or experimental results			X	X	
Publishing or presenting research, academic or technical papers	X	X	X	X	
Contract research	X	X	X	X	
Consultancy projects	X	X	X	X	X
Discussions on a collaborative project or contract research	X	X			
Receiving important confidential information		X			
Giving out confidential information	X	X			
Using computer software		X	X		X
Preparing notes for lectures		X	X		
Responding to telephone queries of a technical nature		X			

General Stages in a Patent Application (table)

Timescale	Activity	Costs
0	Patent Application files in the UK	£0 - £2000
1 year	Updated Application filed in the UK (New technical material can be added up to at this stage, but no later) Plus any overseas Applications required	£1000 - £5000
1 year 6 months	Application published with Search Report (at this stage anyone can obtain copies of the Patent specification)	£500 - £2000
2 to 4 years (depending on country)	Examination report received, Patent Agent and Examiner correspond and negotiate on wording of Patent claim	£500 - £8000 per country
3 to 5 years (typically)	Patent granted (or refused)	£400 - £2000 per country
4 to 20 years	Annual renewal fees due	£400 - £1000 per country per year



Management of Confidential Information: A Short Guide

Key information should be kept confidential until such time as it is protected

Non-confidential disclosure can be reduced by:-

- (a) relatively simple internal housekeeping and discipline: and
- (b) the use of Confidentiality Agreements where appropriate

Beware of 'casual' visitors and ensure that security arrangements for key information are appropriate

Check for obligations placed on you by a third party

Consider confidentiality before publishing information and starting discussions on collaborative projects or contract research

Copyright: A Short Guide

Copyright applies to literary, musical or artistic works in their very widest sense

Written text, graphics, artwork, drawings and sketches, data compilations and software are Copyright works

Copyright protection exists automatically

Protects against actual copying of works.
Will not protect against independent creation of identical or closely similar works

Protection usually exists for life of author plus 70 years*

*(The former 50 year period still applies for some works)

If not established by a legally-binding written contract,
Copyright ownership may end up with someone who was never intended to own it

Trade Marks: A Short Guide

A Trade Mark can be any form of distinctive 'sign' such as a word, logo, a type of artwork, a particular colour combination or a container of unusual shape

In the UK, rights are primarily acquired through registration

Trade Marks are registered for specific classes of goods or services. Similar Trade Marks may therefore be used by different proprietors for different applications

Trade Marks are very valuable means of differentiating products and services from those of competitors, eg software, laboratory testing services etc

When developing new Trade Marks, a clearance search should be carried out to avoid possible infringement of the Trade Mark rights of others



Tailpiece

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