Planning for Translational Research in Genomics

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Outline

1. What is translational research in genomics?
2. Role of commercialisation in genomics
3. Intellectual Property Rights
4. Collaboration Agreements
5. Consent and Commerce – what are participants told?
6. Recommendations

Translation in Genomics

Potential outcomes:

- Better understanding of physiology and disease
- Diagnostic tools
- Therapeutics

Commercialisation

- Commercial parties play an important role in the development of biomedical innovations
- The process of developing a product and taking it through the regulatory approval process is difficult and expensive
  - Not the role of a university
- The relative importance of commercialisation may depend on the translational outcome in question

Commercialisation

- Intellectual property rights are important in commercialisation

- Commercial parties rely on IP to protect their investment

What is Intellectual Property?

- Patents
- Trademarks
- Copyright and Related Rights
- Design Rights
- Confidential Information

Patents

Patents

- Novel
- Inventive/non-obvious
- Industrially applicable
- Sufficient
- Not a discovery ‘as such’

Other IP Rights?

- Copyright
  - In software
  - In images
  - In some databases
- Database Right

IP Myths

IP ≠ Evil

IP Myths

IP ≠ $$$

IP Issues

- Publishing
  - You cannot publish before you apply for a patent
  - But patent applications can be done quickly and need not delay publication unduly

Collaboration Agreements

- Formalise informal relationships
- Articulate the nature and aims of a project
- Benefits:
  - Full consideration of possibly problematic areas
    - Recognise and avoid pitfalls
  - Basis and mechanism for resolving later disputes

Consent and Commerce

- Participants want to know about commercial involvement in research
- Context is important:
  - Commercial partner in research – participants have some idea of commercial involvement.
  - Research by the NHS or a university – participants may think of as 'pure' research
- What are participants told?

Consent and Commerce

- Huge variation in consent forms:

- *'I consent to participate in the genetic component of the [study]. DNA will be prepared from my blood cells for the study of genetic influences which may be relevant to diabetes, heart disease, stroke and cognitive function, and their risk factors. DNA will be stored for use in projects undertaken by the [study] and its collaborators. I understand that no information found from the DNA will be given to me and that the information will be treated in the strictest confidence. I understand that the samples and information will be coded and used anonymously for research purposes only.'*

Consent and Commerce

- Huge variation in consent forms:

'I understand that the [university], and its academic and commercial partners in the study, will use the results to try to improve the diagnosis and treatment of patients (including, for example, patenting and developing new drugs), and that I shall not benefit financially from my participation.'

Consent and Commerce

'I understand that all information provided by me will be treated confidentially, and that the [universities] that are responsible for the whole project will use the results to try to improve the prevention and treatment of common disease, and that I shall not benefit financially from my participation.
The information and blood samples collected will not be used for any commercial purposes.'

Checklist

1. Make sure appropriate and effective agreements are in place before commencement of research.

2. Address research participant concerns about commercialization, and ensure that research participants are fully informed through informed consent procedures about the potential commercial outcomes of research.

Acknowledgements

Based on a paper:

Naomi Hawkins, Jantina de Vries, Paula Boddington, Jane Kaye and Catherine Heeney

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Genome Medicine 2009 **1**: 87