THE IMPACT OF PATENTS ON TRANSLATIONAL RESEARCH – NON-INVASIVE PRENATAL DIAGNOSIS IN EUROPE AND THE US

PARTICIPANT INFORMATION SHEET

I am inviting you to take part in the above research study. Before you decide whether to grant me an interview, it is important that you understand the reason why this research is being carried out, and what your participation will involve. I would be grateful if you would take time to read the following information carefully and discuss it with colleagues or other people if you wish. Please feel free to contact me if anything is unclear, and to take as much time as you need to decide whether or not to take part.

What is the purpose of the study?

This research project seeks to investigate the role that patents play in translational research in non-invasive prenatal diagnosis (NIPD). The research is socio-legal in approach, to allow a detailed and empirically grounded exploration of the law in practice. In this project, I am investigating the way that patents, as well as beliefs about patents, influence behaviour and motivations for behaviour at each point in the translational research process from research through to clinical application and wider population health impact. I am interested now not only in traditional legal constructs such as licensing or litigation, but also the ways that individuals arrange their daily practice to accommodate or avoid real or perceived legal obligations.

This research will examine the role of patents in NIPD, and explore the differences between the role of patents in single gene testing and NIPD, and analyse the reasons for those differences. Single gene testing and NIPD are two of the earliest genomic innovations to be applied clinically, and are precursors of many new technologies which are predicted to transform medicine. They therefore constitute excellent case studies to predict the impact of patents in other areas of genomic medicine.

Who is running this study?

This study is being carried out by me (Dr Naomi Hawkins) as part of a 3 year project entitled 'The Impact of Patents on Translational Research – Non-Invasive Prenatal Diagnosis in Europe and the US'. The project is funded by the UK Economic and Social Research Council (ESRC). I am based at the University of Exeter Law School, where I am a lecturer.

I obtained my undergraduate degrees in both law and science from the University of Queensland in 2002 before being admitted as a legal practitioner in Australia. Following a period of legal practice in Australia clerking for a Supreme Court Judge, and working in a large commercial law firm, I completed my Bachelor of Civil Law (a masters degree in law) at the University of Oxford in 2005. I completed my doctorate in law at the University of Oxford in 2009, supported by the Wellcome Trust. From 2009 to 2010 I was a researcher in law at HeLEX, the Centre for Health, Law and Emerging Technologies in the Department of Public Health at the University of Oxford, and continue to be a research associate of the Centre.

Who is funding this study?

This research is funded by the Economic and Social Research Council (ESRC) under the Future Research Leaders Scheme. This funding allows the project to be undertaken as a piece of independent academic research.

Why have you been chosen to take part?

The research aims to develop an understanding of how patents impact the process of translation of non-invasive prenatal testing into clinical practice. Given your involvement in this process, your insights on the impact of patents on this process would be extremely valuable.

Do you have to take part?

Your participation is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep, and you will also be asked to sign a consent form. You will still be free to withdraw at any time; this includes the right to withdraw your interview from the study after it has taken place. If you decide not to take part, or to withdraw at any stage, you will not be required to give me a reason for doing so.

What do I want you to do?

I would like you to take part in an interview lasting approximately an hour. It would take place in your workplace either face to face or by telephone at a time convenient to you. The interview will be carried out by me and will take the form of a structured conversation. There will be a discussion of a variety of relevant topics such as your experiences with patents, and your opinions with respect to them.

I will not seek information about identifiable patients, clients or colleagues, or access to files about patients or clients.

I will ask for your written permission to record the interview, to ensure that the information you give me is accurately taken down.

What will happen to the information you give in your interview?

You will be one of approximately 60 people involved in the translational research process for NIPD being interviewed as part of this research. The recording of your interview will be transcribed. I will then analyse the information and feed it into my results. Your interview will be analysed using qualitative methods, and data will be extracted for analysis using social network analysis methods. During the interview you will be asked questions about non-invasive prenatal testing you are involved with, and your experiences of intellectual property associated with this.

The interview will be audio-recorded to ensure your views and opinions are accurately reported. Anonymised transcripts of the interview will be kept for a period of no more than 5 years and then will be archived in the UK Data Archive in accordance with ESRC and

University of Exeter protocols. Audio recordings will be kept until the end of the project at which point they will be destroyed. This research is confidential and anonymous.

How will you protect my confidentiality and anonymity?

The research will be carried out in line with the Data Protection Act, and an approved research protocol. Only I, an experienced transcriber, or my academic mentors will handle the sound files, and only I, an experienced transcriber, my academic mentors or genuine researchers who gain access through the U Data Archive will handle the transcripts. Hard copies of research notes will be kept in locked filing cabinets, and electronic files will be kept on password-protected encrypted computers and hard drives.

You will not be named or otherwise identified in any publication arising from this project unless your contribution is already in the public domain (for example, if you were the named author of a published document). No unpublished opinions or information will be attributed to you, either by name or position without your consent.

It is recognised that the population from which interviewees are drawn is relatively small. As a result, extra care will be taken not to identify any specific disease or field in which you work. If it is felt that there is a heightened risk of disclosure of identity, then you will be re-contacted and asked for your express permission for the use of the data. If you wish to withhold your consent (which you are more than entitled to do) then the data will not be used in the manner causing concern.

I will exercise all possible care to ensure that you will not be identified in any research outputs.

What are the possible disadvantages and risks in taking part?

The main cost to you will be the time needed to for the interview. The main risk is that you might give me information about your current practice that suggests a conflict with the current legal framework.

However, you should note that the information is entirely for research rather than evaluation purposes. Moreover, I am confident that the arrangements described above will prevent any of the information you provide being shared either intentionally or unintentionally with anyone outside those people specifically mentioned above. For this reason, I believe that the risk of detriment to you as an interviewee is very low.

What are the possible benefits?

I hope that you will find the interview interesting, and will take satisfaction from helping to develop knowledge of this important topic. I also hope that you will find the results of the project helpful to your work.

What will happen to the results?

Following the analysis of results of the project, the opportunities for reforming the intellectual property system will be examined, and there will be consideration and formulation of potential guidelines, policies and recommendations for law and policy makers.

The project will primarily result in academic publications, and the results of the study will be disseminated via academic articles, an edited collection, conference presentations and seminars. Articles will be submitted to journals that are widely read by practitioners and policy makers.

Has anyone reviewed the study?

The in principle outline of the study was reviewed before it was funded by the ESRC. The project was approved by the University of Exeter College of Social Sciences and International Studies Ethics Committee.

Who is responsible if anything goes wrong?

This project is being conducted by me as an employee of the University of Exeter and the University of Exeter is therefore responsible for the conduct of the project. Given the nature of this study, it is highly unlikely that you will suffer harm by taking part, however, if you are harmed by participation in the study you may have grounds for legal action for compensation against the University of Exeter.

How can I find out more about this project and its results?

Please feel very welcome to contact Naomi Hawkins for further information, at the following address:

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