**Call to apply for Ph.D./Early Career Scholars bursaries to attend/present in ESRC Seminar series:**

**Liability v innovation: unpacking key connections 2015-2017**

As part of the above ESRC seminar series (details of which provided below) the investigators seek to select six Ph.D. or Early Career Scholars with relevant research interests to attend the 4 (out of 6) taking place in the UK. Successful applicants will be awarded up to £400 to contribute towards travel, and if necessary, accommodation, for the seminars. Three of the seminars will be held at Keele University on **April 18 2016**, **4 May 2017** and **14 September 2017**. The fourth seminar will be held at Durham University on **15 September 2016.**

The call is open to Ph.D. and Early Career Scholars from any relevant discipline (including, but not limited to law, ethics, medicine, public health, economics, sociology, psychology, political science and history). Successful applicants will be expected to attend and contribute to all four seminars. Priority will be given first, to those able to present a paper in seminars 2 (**Does liability stifle innovation: economic models and anecdotal findings at Keele on 18 April 2016)** and 5 (**Thinking outside the box: Strict liability and offsetting risks at Keele on 4 May 2017)** and then to those able to make an active contribution (including by giving a paper) in any of the other UK seminars.

**Application process**

Applicants should send their CV, list of publications (if any) and a 1,000 word statement, indicating their research interests and why they believe participation in the seminar series will be beneficial to their academic development. Please also indicate if you would be willing to present a paper or otherwise to actively participate in any of the seminars, and which (for example, by acting a respondent). Applications should be sent to Professor Tsachi Keren-Paz (the PI) via email (t.keren-paz@keele.ac.uk) **by Friday, November 6 2015.**

Decisions will be communicated to applicants by the **end of December 2015**.

**Description of the Seminar series**

**Investigators:** Professor Tsachi Keren-Paz (Law, Keele, PI); Professor Alicia El Haj (Institute for Science & Technology in Medicine , Keele); Associate Professor Tina Cockburn (Law, QUT, Brisbane); Professor Richard Goldberg (Law, Durham); Dr Michael Fay (Law, Keele).

**Context:** In medico-legal literature two related claims are common: that the threat of legal liability for medical mishaps causes defensive medicine, and that in particular it stifles innovation. Both claims are supported by anecdotal experience of researchers and clinicians. However, the extent of the problem within and outside the UK is disputed. Moreover, the *Bolam-Bolitho* test determining the scope of clinical liability in England –excluding liability for clinical decisions backed as proper by a responsible body of skilled medics unless such practice is illogical – is arguably problematic in terms of the incentives given to engage in innovative and cutting edge treatment. An innovative treatment is by definition less likely to be in accordance with *accepted* practice. So while policy-makers encourage and pay considerable lip service to innovation, tort law might give the opposite incentive to clinicians.

The seminar series intends to fill some significant gaps in our knowledge about the extent of the problems of defensive medicine and stifled innovation and the possible solutions to these (real or perceived) problems. These gaps include *empirical* questions (the extent of defensive medicine and of stifled innovation); *methodological* questions (how to define and measure innovation; the extent to which changes in legal rules affect levels of defensive medicine and innovation; the relative weight of tort liability and of disciplinary proceedings in causing defensive medicine and stifled innovation); and *normative* questions (how to balance the interests of clinicians, patients and society; how best to encourage responsible innovation; whether the regulation of innovative treatments and research should change and whether it should be unified).

**Objectives:**

Academic

The series' objectives are to explore the relationships between tort liability, disciplinary proceedings, defensive medicine and the effect on innovation. In particular, to explore:

1) the extent to which the combined effect of tort liability and disciplinary proceedings creates defensive medicine, and in particular negatively affects innovation (Seminars 1,2 and 4);

2) the relative contribution of changes in the tests governing the determination of negligence on levels of defensive medicine and innovation, including the likely effect of the proposals in the Medical Innovation Bill (currently, the Access to Medical Treatments (Innovation) Bill (Seminars 2, 3);

3) whether a law reform is warranted in order to encourage innovation while at the same time protecting patients' interests in security and compensation and discouraging excessive risk-taking by clinicians (Seminars 2,3 and 5);

4) the relationship between research and innovative treatments, the justification for the different regulatory frameworks applicable to both contexts, and whether the regulation of research unduly stifles innovation (Seminar 6).

Dialogue between academics and stakeholders

The debate about the effects of liability on defensive medicine and innovation is topical in terms of policy making. In the UK, the Access to Medical Treatments (Innovation) Bill (introducing pre-treatment peer approval 'defence' to protect responsible innovation) is being deliberated; in Australia, legislation inspired by the English Bolam-Bolitho common law solution (basically excluding liability for clinical decision backed as proper by a responsible body of skilled medics unless such expert testimony is illogical) was enacted, contrary to Australian courts' reluctance to adopt Bolam's deferring 'common professional practice' test; and a review of the regulation applied to some autologous cells by the Therapeutic Goods Administration (TGA) is underway; in the US, a spate of "right to try" new drugs legislation has been enacted.

The seminars will bring together the main stakeholders in the debate: physicians, researchers, policy makers, regulators, solicitors and barristers specialising in medical malpractice, insurers and patients' advocacy groups. The format of the series will be interactive so that stakeholders' experience and beliefs will inform academics' research agenda, and the findings from the academic literature will be disseminated and explained to stakeholders. In particular, we will focus attention—based on CIs expertise—on regenerative medicine and on medicinal products in which the stakes in terms of decreased innovation are especially high.

Capacity building

The seminars will include presentations by a) internationally leading academics in the fields of law, economics and ethics; b) early career academics and c) Ph.D students in these areas. Our aims are: to provide early career researchers and Ph.D. students with an opportunity to exchange ideas and to collaborate with established researchers, stakeholders and other early career researchers and Ph.D. students; and to further cross disciplinary collaborations.

**Format:** Two seminars will be held in Brisbane to benefit from and foster collaborations between the UK and the ACHLR and AusHSI research networks. All seminars will include early career and senior academics from different disciplines, regulators, policy makers, and other stakeholders. The basic format will include presentations by stakeholder first (which might be in a round table format), then 4-6 academic papers (which might be accompanied by discussants), and finally a session in which academic and non-academic presenters and the floor interact, with one or two of the applicants moderating the discussion. Each seminar will be attended by c. 20-30 people (including presenters).

**Seminar 1: The defensive medicine debate (Brisbane, 17 December 2015; Cockburn and Keren-Paz moderators)**

This seminar will set the ground to the inquiry by examining the broader question of whether tort liability causes defensive medicine. The findings in the literature are inconclusive, and broadly speaking, are US focused. Participants will include both academics researching medical malpractice and defensive medicine and stakeholders, including medical and legal practitioners.

**Seminar 2: Does liability stifle innovation: economic models and anecdotal findings (Keele, 18 April 2016; Keren-Paz and El-Haj moderators)**

This seminar has four related aims. First, to learn from anecdotal evidence brought forward by regenerative medicine and other clinicians and researchers suggesting that the problem exists. Second, to examine conflicting findings in the literature of whether liability stifles innovation or not. Third, to explore, mainly from a health economics perspective, the methodological difficulties involved in defining and measuring levels of innovation. Finally, to scrutinise assumptions, methodologies and findings on the effect of changes in malpractice liability rules on level of innovation.

**Seminar 3:** **The medical innovation Bill (currently, the [Access to Medical Treatments (Innovation) Bill](http://www.heatonharris.com/sites/www.heatonharris.com/files/9_9_15_book.pdf%22%20%5Ct%20%22_blank)): significant change, or much ado about nothing? (Durham, 15 September 2016; Fay and Goldberg moderators)**

A major policy oriented response to the fear from stifled innovation is the introduction of the Medical Innovation Bill by Lord Saatchi. In its latest form the[Access to Medical Treatments (Innovation) Bill](http://www.heatonharris.com/sites/www.heatonharris.com/files/9_9_15_book.pdf%22%20%5Ct%20%22_blank) would add to the common law Bolam's common professional practice 'defence' a statutory defence which hinges on a pre treatment peer review of the benefits and risks of the proposed treatment, alternative treatments, and no treatment. The seminar will explore the significance and desirability of the Bill, and the best wat forward, by bringing together academics, representatives of the Bill's team, clinicians, patient rights' advocates and legal practitioners.

**Seminar 4: The effect of disciplinary proceedings (Brisbane, 22 February 2017; Cockburn moderator)**

Clinicians are likely to be more wary of disciplinary proceedings than of malpractice suits. Yet, curiously, much of the defensive medicine research focuses solely on tort liability to the neglect of disciplinary proceedings. Seminar 4 will begin to fill this void by looking into disciplinary proceedings in the context of innovative treatments and their supposed consequences, drawing on the experience of academics, clinicians, legal practitioners and regulators.

**Seminar 5: Thinking outside the box: Strict liability and offsetting risks (Keele, 4 May 2017; Fay and Goldberg moderators)**

The Medical Innovation Bill's solution in its various iterations still works within the confines of received wisdom: (a) fault-based liability, (b) full compensation and (c) the patient's best interest as a governing principle to determine whether offering the innovative treatment is negligent. Seminar 5 will question this received wisdom. It will examine, first, the case for strict liability towards patients injured from innovative treatments; and then, the case for and against determining (= standard of care) and reducing (= compensation) the physician's liability based on benefits to others.

**Seminar 6: The regulation of research (Keele, September 2017; Keren-Paz and El-Haj moderators)**

This seminar will examine the relationship between the regulation of research, and of innovative treatments and the effects on innovation. Issues to be addressed include the distinction between innovative treatment and research; the relative threat of tort law and regulation on innovation in research; and whether the level of compensation to research subjects stifles innovation.