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**REQUEST FOR PROPOSALS ON**  
**THE USE AND IMPACTS OF SCIENTIFIC EVIDENCE IN THE COURTS**  
**For Grants Supporting Pilot Studies and Small Studies**

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**BACKGROUND**

The past several decades have seen continuing conflict over the use of scientific evidence in both regulation and litigation. One manifestation of these conflicts is the trilogy of Supreme Court rulings that set forth new criteria regarding the admissibility of expert testimony in federal courts. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the Court established legal rules for the exclusion and evaluation of scientific evidence. Specifically, the *Daubert* decision obligated trial judges to act as “gatekeepers” of proffered expertise by determining whether the scientific evidence is both relevant and reliable. In *General Electric v. Joiner*, the Court ruled that appellate courts should not overturn the admissibility decision of a trial court unless the trial court abused its discretion. In *Kumho Tire Co. v. Carmichael*, the Court extended *Daubert’s* gatekeeping function to include all expert testimony, including non-scientific expert testimony.

Admissibility is only one issue of concern related to the use and impacts of scientific evidence in the courts. In 2004, the Project on Scientific Knowledge and Public Policy (SKAPP)<sup>1</sup> sponsored a conference addressing secrecy in science and its potential impacts on public health and safety. Sequestered science is by no means a new phenomenon: documents classified as secret or restrictive, trade secrets, non-disclosure agreements, claims of confidential business information and court-sealed documents have been present for decades and are a reflection of other societal priorities, especially national security and the protection of private interests. However with the recent emphasis on homeland security, changes in information technology and a trend towards greater involvement by private interests in academic research and science policy, openness and transparency in science is becoming increasingly elusive.

In early 2006, SKAPP sponsored another conference, this time dealing with research conducted for litigation or designed to support or discourage regulatory action. Among other issues, participants discussed the possible impacts of the conflict of interest often present in such studies and potential sources of bias in study design. They also discussed how the presentation of scientific results can affect their value in litigation or regulation.

These and other issues highlight the importance for public health and safety of understanding how science interacts with the law.

Considerable anecdotal evidence has emerged regarding science as it is used in the law. Yet there is little rigorous empirical research to document even the most basic aspects of the law-science interface. Moreover, the ability to conduct quantitative research is limited by the difficulty of identifying cases that are randomly selected from an identified case population. The Project on Scientific Knowledge

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<sup>1</sup> The Project is housed at George Washington University’s School of Public Health and Health Services and guided by a planning committee of public health scientists. Major support for the Project is provided by the Common Benefit Trust, a fund established pursuant to a court order in the Silicone Gel Breast Implant Products Liability litigation. The Project’s funding is unrestricted; we do not provide our funders—or anyone working on their behalf—advance notice or opportunity to review or approve any project activity.

and Public Policy requests proposals from interested researchers to conduct pilot studies that assess the feasibility of research that empirically examines the use of scientific evidence in regulation or litigation or develops databases capable of supporting such research.

### **FUNDS AVAILABLE**

The project will fund up to four pilot studies at an average of \$25,000 each (including indirect costs, which are not to exceed 10%). The project reserves the right not to issue grants or to issue fewer than four grants if proposals submitted are determined to be of insufficient quality. Pilot studies are to be conducted over a period of not more than eight months. We expect that successful pilot studies will put the investigators in a good position to secure funding of full proposals from a variety of sources. If pilot studies are successful, project staff and advisors will support investigators in seeking additional funding for more comprehensive research.

### **EXAMPLES OF PRIORITY ISSUES**

Research areas of interest include, but are not limited to:

1. The impact of conflict of interest on research findings.
2. Factors affecting the evaluation of scientific evidence by judges and/or juries.
3. Empirical analysis of court-generated scientific knowledge
4. Trial documents as a source of new scientific information.
5. Sources of disparities in public health risk assessments.
6. The cost of *Daubert* challenges and the distribution of the burden of these costs
7. The impact of *Daubert* hearings and decisions on case outcomes
8. Development of a database of cases randomly selected from an appropriate population with data elements that would support future research on scientific evidence in the courts.

### **ELIGIBILITY**

Grants will be made to qualified researchers at not-for-profit institutions.

### **DELIVERABLES**

Funded projects will be required to submit a final report at the end of the project period. The progress report must include (1) description of work accomplished and problems encountered, and (2) description of work remaining. The final report must follow a standard report format (introduction, methods, results, discussion and conclusion) and outline implications of the pilot study results for the feasibility of full-scale studies.

## **PILOT PROJECT SUBMISSION TIMELINE**

<b>Date</b>	<b>Event</b>
Friday, September 15, 2006	Initial contact letter deadline
Friday, October 6, 2006	Notification of outcome of initial review and invitation for full proposals
Friday, December 29, 2006	Full proposal deadline
Friday, February 9, 2007	Notification of awards

## **INITIAL CONTACT LETTER**

The initial contact letter should be no more than two pages in length and include the following:

1. Project title
2. List of investigators
3. Contact information for the principal investigator
4. Specific aims
5. Brief description of data and methods
6. Preliminary budget

Biographical sketches of the principal investigator and co-investigators should be attached to the initial contact letter. A panel of reviewers will review each initial contact letter. All applicants will be notified regarding the decision of the review. We will request full proposals for the initial contact letters that are most favorably reviewed. We expect that at least 1/3 of the full proposals will be funded.

## **PILOT STUDY PROPOSAL**

The combined length of the Research Plan, Sections 1-3 of the proposal, should be no more than ten-pages in length. The proposals will follow the outline below:

<b>Proposal Outline</b>	<b>Suggested Length</b>
0. Cover page	1 page
– Complete Form A	
1. Goals and Specific aims	1 page or less
– Describe the overall goals of the full study that this pilot study will test the feasibility of	
– Describe the feasibility questions that the pilot study will address	
2. Background and significance	1-2 pages
– Describe the importance of questions addressed by the full study	
– Indicate how the pilot study will demonstrate the feasibility and usefulness of the full study	
– Describe preliminary studies if any	
3. Research design methods	5-7 pages
– Characterize study sample(s) under investigation	
– Describe the project's sources of data, data collection methods, and analysis plan/methods	

<ul style="list-style-type: none"> <li>– Address possible study limitations and how limitations are minimized by the study design</li> <li>– Provide evidence that you will have timely access to needed data</li> <li>– If you plan to rely on another organization for the data, include a letter of cooperation from that organization</li> </ul>	
4. Biographical sketches on key personnel	2-3 pages
5. Conflicts of interest disclosure (do key personnel have any financial interests that could directly and significantly affect the design, conduct or reporting of the project?)	1/2 page or less
6. Budget and budget justification	1-2 pages
7. References	1-2 pages
8. Appendix- letters of cooperation (if appropriate)	1 page or less for each
9. Proof of tax exempt status and Federal Tax ID number	

**PROPOSAL REVIEW**

Within 30 days following the proposal deadline, a panel of reviewers will convene and apply the following criteria to assess the merit of each application:

1. **Significance:** Does the eventual full study address an important problem/question? If the aims of the proposal are achieved, how will knowledge be advanced? Is the proposal relevant to the areas described in this request for proposals? How will the knowledge gained help formulate a full-scale research proposal?
2. **Approach:** Are the conceptual framework, design (including the composition of the study population), methods and analyses developed, well integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Is there an emphasis on demonstrating the feasibility of techniques/approaches rather than on preliminary results? Is there potential for further grant support?
3. **Investigator:** Is the investigator appropriately trained and well suited to carry out this work?
4. **Environment:** Does the environment in which the work will be done contribute to the probability of success? Does the proposed project take advantage of unique features of the environment or employ useful collaborative arrangements? Is there evidence of institutional support?
5. **Budget:** Is the budget within the parameters of the pilot study program? Is there appropriate justification of budget items?

**SUBMISSION INFORMATION**

All questions regarding this RFP, as well as the Initial Contact Letters, should be sent electronically to Celeste Monforton: [eohcnm@gwumc.edu](mailto:eohcnm@gwumc.edu)

Proposal Cover Page (Form A)

<b>1. Project Title</b>	
<b>2. Funding Amount Requested</b>	
<b>3. Start and End Dates</b>	
<b>4. Principal Investigator</b>	Name: Institution: Address: Zip: Phone: Fax: Email:
<b>5. Contact Person (if different from Principal Investigator)</b>	Name: Institution: Address: Zip: Phone: Fax: Email:
<b>6. Abstract (150 words or less)</b>	