We have prepared this booklet to introduce you to the Clinical Indemnity Scheme and to answer some preliminary questions you may have about the Scheme and its operation.

If you require more detailed information, please contact the State Claims Agency at 01 664 0900
Q. **What is the CIS?**

A. Under the CIS, the State has assumed responsibility for the indemnification and management of clinical negligence claims arising from the diagnosis, treatment and care of patients. The Scheme, which is managed by the State Claims Agency (SCA), was established in July 2002 in order to rationalise the medical indemnity arrangements which had applied up to that point. The CIS means that each enterprise (hospital, HSE area, etc.) assumes legal liability for its employees’ alleged clinical negligence. The Scheme does not cover General Practitioner Services, except where such services are provided on behalf of a participating enterprise.

Q. **Why the CIS?**

A. The CIS was established because commercial insurers either withdrew from offering insurance cover to obstetricians/gynaecologists and to obstetric units or were not in a position to provide cover at affordable rates. This was due to the escalation in the size of court awards and associated costs in cases of birth-related cerebral injury. Up to July 2002, diverse insurance and indemnity arrangements had meant that each defendant to a claim – hospital, health board, consultant, hospital doctor or nurse – was represented by a separate legal team. This led to an unduly adversarial approach to the resolution of claims and added significantly to claims’ costs.

Q. **Does the Scheme cover all claims?**

A. No. The Scheme covers only claims alleging medical malpractice or clinical negligence. The Scheme does not cover Employer’s Liability (EL) or Public Liability (PL) claims against health agencies. Such claims are covered under existing policies of insurance with insurance providers.

Q. **How is the CIS funded?**

A. The CIS is funded directly by the Exchequer on a ‘pay-as-you-go’ basis.
Q. Who is covered under CIS?
A. – HSE hospitals and other agencies, as set out in schedules I and II.
– Non-consultant hospital doctors, nurses and other clinical staff employed by health agencies, whether permanent, locum or temporary. Consultants are covered with effect from 1 February 2004 in respect of alleged clinical negligence incidents on or after that date.
– The clinical activities of public health doctors, nurses and other community-based clinical staff.
– Dentists providing public practice.
– Certain other ancillary healthcare providers.

Q. Are private hospitals covered?
A. The CIS does not cover private hospitals with the exception of obstetric/gynaecological practices in Mount Carmel Hospital, Dublin and the Bons Secours Hospital, Cork. A special indemnity arrangement applies in respect of these institutions.

Q. Does the CIS provide representation for practitioners at disciplinary hearings or at statutory or other inquiries?
A. The Scheme does not provide representation at disciplinary proceedings or before professional regulatory bodies. Nor does it provide representation for agencies or individual practitioners at inquiries.

Q. Does the CIS provide representation at Coroner’s Inquests?
A. The Scheme provides representation at Coroner’s Inquests for agencies and individual practitioners where this is requested.

Q. Are Good Samaritan acts covered?
A. Yes. The CIS covers personal injury claims against staff employed by agencies, covered by the Scheme, who provide care or treatment in emergencies in the Republic of Ireland.

The above cover does not extend to informal non-emergency diagnosis, treatment or prescribing for families, friends, or colleagues other than in the context of a formal attendance for treatment at an agency covered by the Scheme.
Q. Are hospital committees and committee members covered?
A. The CIS will cover ethics, drugs and therapeutic committees etc., where there is a risk that decisions taken by such groups, or guidance issued by them, could be considered to have resulted in an injury to a patient.

Q. Does CIS cover clinical trials and research?
A. The CIS will cover claims from patients whose treatment was part of a clinical trial or other approved research project. In trials sponsored by external organisations such as pharmaceutical companies, CIS cover extends to treatment only and does not cover product liability or claims arising from trial design or protocol. Coverage against such claims remains the responsibility of the body conducting the trial or research product, thus, an appropriate indemnity should be secured from the external sponsor(s).

Where the trial is designed by an agency covered by the Scheme or any of its employees (including investigator-led where the investigator is an employee) the cover under the Scheme will extend to claims arising from trial design or protocol.

In all trials, it is a condition precedent to CIS cover that the relevant agency’s Ethics Committee has approved the trial.

Q. What is the State Claims Agency (SCA)?
A. In December 2001, the Government delegated the management of personal injury claims against the State and associated risk management functions to the National Treasury Management Agency (NTMA). When carrying out these functions, the NTMA is known as the State Claims Agency (SCA).

In February 2003, the Agency’s functions were extended to include clinical risk management and the management of clinical negligence claims against CIS enterprises.

Q. How are CIS claims managed?
A. The SCA employs a specialist team of Clinical Claims Managers who have considerable legal expertise and experience in the management of clinical claims. The ultimate decision as to whether a claim should be settled or contested is a matter for this specialist team.
Q. How are such decisions made?
A. Following rigorous examination of medical records and detailed consultation with practitioners, decisions are made on the basis of relevant case law, expert peer review and the opinion of counsel. The SCA is particularly sensitive to the issue of practitioner reputation in determining its legal strategy.

Q. Does the CIS incorporate clinical risk management?
A. The CIS has responsibility for developing and implementing a National Clinical Risk Management Strategy, including the development of clinical risk management standards. The CIS advises and assists participating enterprises on the adoption of effective risk management. This includes assistance in the development of policies, procedures and guidelines which promote good clinical practice. Risk management advice is informed by analysis conducted on a central national database of adverse clinical incidents reported to the CIS by healthcare enterprises.

Q. How are adverse incidents reported?
A. As of early 2004, adverse clinical incidents are reported to the CIS by healthcare enterprises through a new web-based IT system called STARSWeb. The system links hospitals and other healthcare enterprises, via a secure web link, to a national database and enables them to access, analyse and report on their own incident and claims data.

Q. What data does the system record?
A. The STARSWeb system enables healthcare enterprises to record adverse clinical incidents and near misses, clinical negligence claims and anticipated claims, Employer’s Liability (EL) and Public Liability (PL) incidents and claims. Clinical incidents are reported to the CIS without patient identification details. The identity of patients and of any staff involved in incidents is revealed to the CIS only if litigation ensues.

Q. Who will have access to data?
A. Each participating enterprise will have reporting access only to its own data. The SCA will have access to aggregate national data on clinical incidents and claims but will have not have access to data on EL and PL incidents and claims.
Q. What is to be gained from incident reporting?

A. Within healthcare enterprises, the system will provide the comprehensive data necessary to inform and support risk management initiatives and to encourage the development of a culture of continuous improvement. There will be a strong emphasis on using data for purposes of systemic learning rather than the attribution of blame to individuals.

Nationally, comprehensive incident reporting will help to identify areas of significant risk e.g. trends or clusters suggestive of system failures. Lessons absorbed at individual enterprises can be disseminated throughout the whole of the healthcare sector. Over time, through risk management initiatives based on sound data and analysis, the aim is to reduce error rates, avoidable harm and litigation.

The ultimate impact should be to achieve significant improvements in patient safety and increased public confidence in the healthcare system.