1. **General Principles**

The Clinical Indemnity Scheme has been established on the basis of “enterprise liability”. The fundamental principle underlying enterprise liability is that “the enterprise” will assume liability for all its employees’ alleged clinical negligence or medical malpractice arising out of the performance of their duties under their contract of employment.

An “enterprise”, for the purposes of the Scheme, (referred to hereinafter as an “agency”) may be a health board or other statutory body, a public voluntary hospital or other agency commissioned to provide clinical services to eligible patients.

Each agency covered by the Scheme will be designated as a “State authority” under Section 7.1 (i) or Section 7.1 (j) of the National Treasury Management Agency (Amendment) Act, 2000 as appropriate.

The most significant change that has resulted from the introduction of enterprise liability is that doctors and dentists are incorporated into the liability borne by each agency.

2. **Scope of Cover of the Clinical Indemnity Scheme**

**General**

- The Clinical Indemnity Scheme will cover all claims alleging medical malpractice or clinical negligence against an agency and/or its staff arising from the diagnosis and treatment of patients by those employed by the agency. This will include services provided at hospitals, clinics, other facilities owned or operated by the agency as well as in patients’ homes and other community based facilities.

- It will cover doctors, dentists, nurses and other clinical staff employed by each agency, whether permanent, locum or temporary. It will cover the clinical activities of public health doctors, health board dentists, nurses and other community-based clinical staff.

- It will cover Good Samaritan acts occurring within an agency covered by the scheme.
• The Scheme will also cover non-clinical staff working under the direction of clinical staff who owe a duty of care to patients and other users of clinical services.

• The scheme will cover all aspects of a doctor’s or dentist’s public practice i.e. the diagnosis, treatment and care of public patients irrespective of location at a hospital, clinic or other facility operated by a health board, voluntary hospital or other body delivering services to eligible patients.

• The scheme will cover all work connected with the diagnosis, treatment and care of a hospital consultant’s private patients in a public hospital or at another facility used by the public hospital to provide services to private patients of the hospital. This cover will apply where the consultant has a contractual right to treat private patients in the public hospital and is practicing within the terms of that contract.

• The scheme will cover corporate liability in areas such as corporate clinical governance, including the work of committees.

• The scheme will also cover contracts to provide clinical services such as pathology and radiology to third parties.

• The scheme will cover needlestick injuries arising from the direct negligence of clinical staff. It will not cover injuries arising from the unsafe disposal of sharps, as these are covered by other insurance/indemnity arrangements that agencies have in place.

• The scheme will cover injuries arising from patient falls where these arise from a lack of supervision by clinical staff. It will not cover slips, trips and falls attributed to non-clinical environmental hazards.

The scope of the scheme is limited to care provided in the Republic of Ireland. However the scheme will cover staff accompanying patients outside the jurisdiction up to the point where clinical responsibility for the patient is transferred to staff at the receiving hospital in another country. The reverse will apply where clinical staff accompany a patient back to this country.

The scheme will cover agencies in circumstances where they arrange for volunteers, whether paid or unpaid, to provide services to charitable agencies. Agencies wishing to offer their services, whether paid or unpaid, to charity events and wishing to be covered by the scheme must seek the prior approval of the scheme. Individuals who are employed by agencies covered by the scheme and who wish to offer their services, whether paid or unpaid, to charity events and who wish to be covered by the scheme must seek the prior approval of the agency.

**Contractors**

• The scheme will not cover the activities of contractors employed by agencies. Individual contractors or corporate contractors may be required to provide their own insurance/indemnity cover. Agencies, which have contracts for the supply of
services with private hospitals or with consultants who are not employees of that agency, will need to have explicit agreements with these contractors on insurance/indemnity cover before contracts are agreed.

**Research**

- The scheme will cover claims arising 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, the cover under this scheme extends to treatment only and does not cover product liability or claims arising from trial design or protocol. Coverage against such claims will remain the responsibility of the body conducting the trial or research project and an appropriate indemnity must be secured from external sponsors.

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

- In all trials (whether sponsored or agency/investigator led) it is a condition precedent to cover under the scheme that the relevant agency’s Ethics Committee has approved the trial.

3. **Services to be provided by the Medical Defence Organisations and/or Insurers**

- The medical defence organisations will provide services to members in accordance with the terms of their individual Memoranda and Articles of Association.

- Doctors and dentists employed by agencies covered by the Clinical Indemnity Scheme will need to provide themselves with indemnity cover for professional activities not covered by the scheme. These will include:
  - non-indemnified private practice and other professional activities undertaken by them in a private capacity, whether paid or unpaid;
  - Cover for Good Samaritan acts, other than those covered by the scheme.
  - Cover for treatment of persons (i.e. relatives/friends) who are not patients of the agency.

- The medical defence organisations will continue to provide advice, assistance and representation on non-indemnity matters.
• The medical defence organisations will continue to provide representation for their members at disciplinary hearings and before the Fitness to Practice Committees of the Medical Council and the Dental Council.

• The medical defence organisations will continue to represent their members at inquiries, whether of a statutory or non-statutory nature. The Clinical Indemnity Scheme will be responsible for managing and settling any claims for personal injury arising from the events being inquired into where the practice of the professional/professionals involved falls within the coverage of the scheme.

• The Clinical Indemnity Scheme will provide representation at Coroner’s Inquests for agencies and practitioners covered by the scheme. Where a doctor or dentist wishes to be separately represented at an inquest he/she will be entitled to request his/her defence organisation to provide separate representation.

• The medical defence organisations will continue to represent their members in criminal matters arising from the practice of medicine. The Clinical Indemnity Scheme will manage and resolve claims for personal injury arising from such cases in circumstances where the allegations of criminal behaviour arise from the delivery of clinical care. The scheme will not cover claims arising from criminal activity which does not fall within the accepted definition of clinical care.

• Nothing in this section should be taken to suggest that these services will be exclusively provided by the medical defence organisations. Doctors and dentists may choose to purchase these services from other providers.

4. Exclusions

• The Clinical Indemnity Scheme will not cover General Practitioner Services

• The Clinical Indemnity Scheme will not cover claims in respect of which an agency has the right to seek an indemnity from other sources.

• The scheme will not cover claims that are the subject of such policies held by the agency as Administrative Negligence, Directors and Officers Liability, General Professional Indemnity.

5. Relationships with Medical Indemnity Organisations/Insurers

The scope of the Clinical Indemnity Scheme will be as comprehensive as possible. Coverage wordings will be explicit and clear. The scope for conflict with insurers and the medical indemnity organisations will be kept to a minimum so as to avoid creating new problems over establishing liability, or apportioning shares of liability. Close attention will be paid to areas where there is scope for conflict e.g. health and safety, needlestick injuries, product liability, administrative negligence etc.
**Operation**

1. **Organisation**

The Clinical Indemnity Scheme will be operated by the State Claims Agency at the National Treasury Management Agency on behalf of the Government. Each agency covered by the Scheme will be designated as a “State authority” for the purpose of the scheme. Agencies will be obliged to report incidents and claims to the State Claims Agency through the IT system to be provided to each agency. Agencies and their staff will be required to cooperate with the State Claims Agency and any lawyers appointed by it to investigate and manage claims arising under the scheme. The State Claims Agency will provide regular reports to each agency on claims against them.

2. **Confidentiality**

Incidents which are not yet claims will be reported to the State Claims Agency without patient identification details. They will not contain the names of the medical or other clinical staff involved in the incident. If an incident develops into a claim the agency concerned will then be obliged to disclose the identities of the patient and staff involved to the State Claims Agency. Access to information on incidents and claims reported under the scheme will be restricted to the staff of the Clinical Indemnity Scheme. The database holding data generated by the scheme will be hosted on dedicated secure servers at the State Claims Agency.

3. **Claims Management**

Claims and incidents likely to give rise to claims will be investigated and managed by the State Claims Agency. These tasks may be undertaken by the staff of the State Claims Agency or by lawyers appointed by the Agency. The Clinical Indemnity Scheme will establish the general policy parameters within which claims will be handled. Within these parameters it will facilitate maximum involvement in the claims management process by the agency against which the claims is made. The scheme will provide support to staff of the agency who may be required to give evidence in cases which proceed to hearing.

The scheme will encourage the use of mediation and other dispute resolution procedures to dispose of claims.

4. **Clinical Indemnity Scheme Consultative Group**

The objective of the Clinical Indemnity Scheme is to settle valid claims for compensation as quickly, and at least cost, as possible. It is as equally determined to resist the payment of claims for compensation where it believes that the plaintiff has no valid grounds to seek compensation. The scheme will vigorously defend the reputations of agencies covered by the scheme and their employees. In order to
ensure that it can achieve these objectives the State Claims Agency will establish the Clinical Indemnity Scheme Consultative Group. The role of this group is to ensure that the State Claims Agency, as the operator of the Clinical Indemnity Scheme has access to the views and expertise of those most directly affected by the Scheme.

The CIS Consultative Group will be chaired by the Head of the Clinical Indemnity Scheme. It will include representatives of:

- The Department of Health and Children
- The Department of Finance
- The State Claims Agency
- Agencies covered by the Scheme
- The medical and other clinical professions
- Patients’ groups

The CIS Consultative Group will be presented with regular reports on the operation of the scheme. It will be consulted on the general policies covering the operation of the scheme.

It is the intention of the Clinical Indemnity Scheme that claims should be resolved as speedily as possible to the satisfaction of all parties concerned. This includes the agency against whom the claims is made and the staff involved in the incident giving rise to the claim. Ultimate responsibility for the decision on whether a claim is defended or settled must rest with the State Claims Agency which is responsible to the Government for the funds expended on the scheme. Subject to this constraint the State Claims Agency will have regard to the views of the agency concerned and the staff involved.

Where a serious conflict of opinion exists as to the claims management strategy to be adopted in relation to a particular claim, arrangements will be put in place to have the matter in dispute referred for peer review by an agreed panel of specialists in the clinical discipline concerned. The parties to the dispute will agree to be bound by the recommendation of the peer review panel.

In exceptional circumstances an application may be made to the Clinical Indemnity Scheme to have a separate claims manager and separate legal representation provided to a practitioner involved in a claim against an agency covered by the scheme. The decision on whether to grant such separate representation will be at the discretion of the State Claims Agency.

**Funding**
The Clinical Indemnity Scheme will be funded on a “pay as you go” basis. At the appropriate point in each year an estimate will be made of the funding requirements of the scheme for the following and subsequent years. Provision will then be made in the Estimate of the Department of Health and Children for the following years. This sum will be drawn down by the State Claims Agency from the Department of Health and Children as required.

**Risk Management**

1. **National Risk Management Strategy**

   The Department of Health and Children will work with the Clinical Indemnity Scheme on the development of a National Risk Management Strategy for the health service. This will include an evaluation of existing risk management structures and processes. It will examine the scope for integrating clinical risk management with other quality and patient safety initiatives. Included in the strategy will be the development of risk management standards. The objective of the strategy is to ensure that risk management is delivered to a consistent level throughout the country and across all care sectors.

2. **Risk Management at Agency Level**

   Within the context of the National Risk Management Strategy the Department of Health and Children and the Clinical Indemnity Scheme will continue to support the development of risk management at agency level.

Risk Management Project Office  
Department of Health and Children  
January 2003