## CLINICAL RISK AND PATIENT SAFETY

### Patient safety plan

The programming Document on managing clinical risks and patient safety sets out the objectives pursued by the Hospital Company in conformity with regional provisions on the issue of risk prevention and patient safety.

**CARMINA** (Clinical Assessment of Risk Management: an Integrated Approach)

"Carmina" represents the result of the project headed "*Management of the clinical risk through an integrated approach: definition of minimum standards for Italian health care organisations*", of the project area of Ccm's (National Centre for the prevention and Control of Diseases) schedule of activity for the year 2010, approved by ministerial decree of 2.3.2010.

The said project has realized a self-assessment and comparison tool applied to seven areas of interest in clinical risk management, measured through a questionnaire formulated in the light of 52 weighted standards, according to a progressive logic reflecting the level of organisational maturity, as regards the different aspects and areas under examination.

It is an assessment system based on objective elements of utter flexibility, in terms of scope of application, being in fact used across an entire health care organisation (company, institute or other body), regardless of the number of hospital facilities or differences between single Operating Units; alternatively, it may be referred to single Hospitals or Operating Units.

In respect of some standards, in fact, the measurement of the relevant level of diffusion is required.

### PROCEDURE Reporting events and near misses

This document aims at detailing the operating methods on how to report adverse events or near misses to the patients' detriment with a view to providing a basis for analyses, drawing up improvement strategies and actions in order to prevent their future recurrence.

The procedure does **NOT**concern the reporting of adverse reactions to drugs and medicines plagued by defects or extraneous bodies, concerning which reference should be made to the specific procedure headed: Management of the pharmacological process.

### OPERATING INSTRUCTION: Reporting a suspected adverse drug reaction

The purpose of the instruction is to describe the methods for reporting a suspected adverse drug reaction (ADR).

The detailed objectives are:

- standardizing the conduct of health care operators Pharmacovigilance procedures;
- standardizing the methods of using the ADR reporting card.

All the health care operators(doctors, nurses, chemists and trainee doctors) must report the suspected adverse drug reactions they come to know within the scope of their own activity.

## INFORMED CONSENT PROCEDURE

### Purpose and scope

The purpose of this procedure is to identify the methods to be used for communicating information required for diagnostic and curative actions and the tools for obtaining/refusing consent to the healthcare act, based on the legal and ethical premises, by means of Company forms relating to the obtaining or refusal of consent,in writing, to the prosed healthcare act.

This procedure applies to all facilities of the *AziendaOspedalieraPadova* (Padua Hospital).

### About consent

The aim of consent is to create conditions in which the patient may participate in informed decision-making regarding the healthcare acts being performed.

The information process must be tailored to the patient's desire for knowledge and must take place at appropriate times and locations, using suitable language and with gradual provision of information, taking into account the people who the patient wishes to participate.

Indeed, it is not possible for a patient to give specific consent if he/she has not been provided with adequate information, in the absence of which no signed consent form is legally valid.

The process leading to a patient’s acceptance/refusal of a healthcare act is, therefore, made up of three key stages, in logical and chronological order:

1. the patient being given important information regarding diagnosis and treatment
2. assurance that he/she has understood the meaning of the said information
3. the patient making a definitive decision on the matter.

It should be noted that the consent that the patient expresses regarding a healthcare act, after being thoroughly informed, is also valid with regard to all the other components (including the nurse) that contribute to performance of the said act.

For further details, please refer to page 12 of Notebook 13 (*Quaderno 13*): “Guidelines on informing the patient and consent to the healthcare act” (“*Linee di indirizzo per l’informazione del pazienteedilconsensoall’attosanitario”*).

**Information sheet instructions**

**Purpose and scope**

The aim of these Operating Instructions is to provide directions on how to draw up information sheets regarding the proposed healthcare act for invasive and/or risky diagnosis/treatment procedures for which written consent or refusal by the patient is required to be obtained in accordance with the "Procedure for informing the patient and obtaining consent to/refusal of the healthcare act" ("*Procedura per l'informazione al paziente e acquisizione del consenso/rifiutoall'attosanitario*").

The information sheet does not substitute an interview between the Doctor and patient but contributes to ensuring completeness and traceability, regarding both the content of and the scientific references to the information provided during the said interview, thus permitting informed and active participation by the patient in his/her care path.
This document applies to all Departments of the *Azienda Ospedaliera di Padova* (Padua Hospital).