SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Ospedaliero - Universitaria di Parma

Regulation on the procedural, administrative and economic aspects of the conduction of clinical studies and trials in health care institutions of the Area Vasta Emilia Nord (AVEN)

Summary of the Regulation approved with deliberation n.192 of Managing Director on 12/03/2018

PART I – GENERAL PROVISIONS

Aims and scope

This document provides essential regulations on the procedural, administrative and economic aspects of the conduction of clinical studies and trials within facilities of the health care institutions/IRCCS of the AVEN (area comprising the Northern Provinces of the Emilia-Romagna Region).

The following provisions do not apply to retrospective or prospective data collection carried out within audits without research or publication purposes.

Principal investigator and collaborators

- In this document, the study principal investigator is an employee of the institution, on a fixed-term or indefinite-term contract;
- The Principal Investigator may rely on the collaboration of physicians and other employees of the Institution;
- Activities pertaining to research and trials (such as medical visits for patient enrolment and follow up) shall be performed during regular working hours;
- The Principal Investigator shall request in advance contribution from other facilities within or outside the Institution, if necessary;
- Participation in research in the form of patient care activities shall be restricted to professionals who hold valid and effective work contract with the Institution, and who have been included in the list of collaborators (delegation log) submitted by the principal investigator to the Ethics Committee;
- Anyone not authorized to perform patient care activities at the Institution may participate in a clinical study exclusively performing activities without this characteristic, such as data collection and management;
- Freelancers, holders of fellowships, university scholarships, PhD students, and residents may collaborate, if authorized by the director/s of the facility/ies where the research is carried out.

Research authorization

For the conduction of clinical studies and trials, authorization from the Institution is essential and integrates any other consent document required by current relevant norms.

Clinical studies and trials requiring Ethics Committee approval, according to current legislation or other norms, must receive explicit and justified clearance from the Managing Director of the institution where the research is carried out, also to rule out prejudices for patient care activities.

If the study requires patient involvement and/or collection of patient data and/or biological samples, institutional authorization shall be given only prior to:

a) Approval of the competent Ethics Committee;

b) Authorization from the Competent national Body (Ministry of Health, Istituto Superiore di Sanità, Italian Medicines Agency), when necessary.

Research integrity, conflicts of interest, publication of results, documentation, archiving, privacy protection

Research integrity, conflicts of interest

The mandate of Ethics Committees includes the protection of the rights, safety and wellbeing of study subjects and - unless attributed to specifically established bodies – the provision of opinions regarding ethical issues pertaining to research or patient care.

The principal investigator and all staff involved in research shall scrupulously comply with the principles of current norms, as well as with the Institution's code of conduct.

The principal investigator and other researchers shall not receive direct or indirect compensation or personal benefits from the Promoter.

Transparency of relationships between the Institution, the industry and the researchers must be ensured; thus, researchers are strictly forbidden to receive money or other forms of compensation from the sponsor. Contacts between researchers and the sponsor/funder may only concern technical-scientific issues.

Drafting of the study's final report is sole responsibility of the principal investigator.

The principal investigator and physicians involved in the study must adhere to the current medical deontologic code. A conflict of interest statement signed by the principal investigator shall be included in the documentation submitted to the Ethics Committee. Such statement shall also mention other interests or facts considered relevant, also related to family members.

Publication of study results

The agreement between the Promoter and the Institution shall include formal commitment of the promoter to publish study findings, also in the case of negative results, and to inform all investigators.

Data analysis and interpretation, as well as drafting of the final report, are duties of the physicians involved in the study and shall not be delegated. Researchers must make study results and conclusions publically and fully available, even when they are negative or anyway do not support the experimental treatment. Researchers shall not adhere to contracts granting the study Promoter the decision on publication and veto options.

Documentation, archiving, privacy protection

The principal investigator is responsible for ensuring compliance with the Institution's Standard Operating Procedures. Documentation recording, management and archiving must take place in compliance with current relevant norms.

The principal investigator is responsible for ensuring appropriate retention and management of archives.

The principal investigator shall retain essential documents pertaining to the study for the period required by norms enforced at the time of study completion; documents may be kept for a longer period of time if required by the agreement between the sponsor and the principal investigator.

The Promoter and the Institution are entitled, each in its own scope, to the handling of personal data of study subjects collected within the clinical trial, and must therefore comply with current provisions contained in general authorizations and in the guidelines of the Garante (Authority for privacy protection).

In particular, the Institution and the Promoter pledge to

- Maintain absolute confidentiality on all data and information they may be made aware of in the framework of this agreement, in accordance with the abovementioned norms;

- adopt all appropriate safety measures to prevent the risk of data destruction or loss, of non-authorized access or handling or not conforming to the scope of this agreement;
- identify research staff responsible for data handling, and provide them with precise, appropriate instructions.

Notification of study data from the Institution to the Promoter represents a real data "communication" and data handling by a third party; the Promoter or other subjects shall be nominally and distinctly indicated in the information sheet and informed consent forms, also concerning the right to access and other rights.

PART II COMMERCIAL RESEARCH

Reporting

Any research activities shall be reported.

The principal investigator shall ensure the scientific and financial reporting of research.

It is the specific duty of the principal investigator to report on the type and entity of presumed and actually incurred additional costs, as well as staff time burden added to usual clinical practice.

Reporting of expenses is detailed in specific institutional procedures.

Patients enrolled in interventional trials shall not bear costs for activities performed in accordance with the study protocol outside of clinical practice.

Additional activities

In this regulation, "additional activities" defines those activities not usually performed for the management of the patient's condition (or usual follow-up), but which are provided for the specific purpose of a trial. These include instrumental or laboratory tests, visits, medical or care procedures.

This definition thus does not include routine activities, i.e. those which would have been provided anyway according to clinical practice.

No additional cost related to study management and conduction shall fall upon resources of the Institution or the National Health service.

Additional provisions required by the study:

- shall not hinder regular institutional activities
- shall be agreed upon in advance by the principal investigator and the Head of the unit where they will be performed
- shall be requested, traced and monitored in such a way to ensure their reporting both by the principal investigator, and by the Head of the unit that performed them.

Practically:

a) The economic agreement signed by the Institution shall explicitly mention additional ambulatory or in-hospital activities, clarifying their nature and quantity as formally declared by the principal investigator.

b) Minimum pricing of additional activities is the one specified by the regional tariff nomenclature. If the activity is not mentioned there, cost analysis will be performed by the hospital (Controllo di Gestione service).

c) Additional activities are performed by health care professionals during regular working hours.

The principal investigator is responsible for the correct recording and attribution of additional costs, which shall correspond to what has been declared when applying for authorization and formalized in the appropriate forms.

The Promoter will reimburse patients who need to visit distant highly specialized centers. All original copies of the documentation attesting expenses incurred by the patient shall be given to the principal investigator, who will verify it and then notify the competent office, so that a money transfer can be made to the patient. Only expenses allowed by the norm will be refunded.

Funding repartition

The institution will keep a fixed proportion, established by the hospital management, of the sum paid by the Promoter to cover all indirect costs.

If after study completion funds remain available, these will be assigned to the hospital Unit where the principal investigator works and to other involved facilities of the Institution.

Goods and instrumentation

Instrumentation and any other goods not owned by the Institution that are necessary for the trial shall be supplied by the Promoter as a free loan or donation, including any consumables.

Installation may occur only prior to judgment of conformity by the competent institutional service, which is also in charge of any testing, which shall be paid by the Promoter.

The current institutional discipline provides more details in this regard.

At the end of the trial, the Promoter is in charge of retrieving the instrumentation made available as a free loan, without any costs for the Institution.

Medicinal products/medical devices

Medicinal products used within clinical trials, as well as the devices employed to administer them, any placebo or the drug used as a control, dietetics, food supplements and any other types of health goods required by the protocol and needed for the trial, shall be supplied free of charge by the Promoter.

Details on the use of medicinal products and devices are provided in the institutional discipline.

PART III non-commercial research

Non-profit studies and trials

Any additional costs related to non-profit studies, as well as any medicinal products, shall be covered by the contribution of the external non-profit Promoter or by a third party funder. The funder is not to be considered a Promoter. The funder will not own data related to the trial, its conduction and its results.

The principal investigator is responsible for the correct recording and attribution of additional costs, which shall correspond to what has been declared when applying for authorization and formalized in the financial plan.

Any use of funds, instrumentation, medicinal products, medical devices, material or services made available by third party funders (such as pharmaceutical companies) shall be notified at the time of Ethics Committee submission.

Details on conduction of expenses are provided in specific institutional procedures.

No compensation shall be paid to investigators and staff employed at the Institution participating in the study, including resident physicians. Any goods purchased with project funding are to be considered property of the Institution.

Funds must not be used for purposes different from those established in individual approved projects.

Any collaboration financed with project funding may not exceed the project‘s duration.

Patients enrolled in interventional trials shall not bear costs for activities performed in accordance with the study protocol outside of clinical practice.

Insurance

Promoters of "non-profit" studies must ensure and document insurance coverage conforming to the prerequisites specified by the current norms, protecting subjects participating in a clinical trial.

In cases different from the above, the Institution ensures "non-profit" research with institutional insurance coverage or by taking out a study-specific insurance policy.

Institutional rate financed non-profit projects

Funding allocated in the framework of competitive public calls (European Union, Ministry of Health, Region, AIFA, ISS, etc.) are assigned to the Institution, which entrusts project conduction to the principal investigators.

Allocated funds are acquired according to modalities defined in the individual calls.

For trials and studies financed by public or private bodies, recognized as *non-profit* by the Ethics Committee, the Institution may retain a proportion of the overall sum, to cover institutional costs (*overheads*).

The retained sum is entirely assigned to the institution’s Research Fund, created with specific institutional act.