Research Protocol Template

Main Investigator

Name

Address

Phone/fax

E-mail

Number of involved centers (for multi-centric studies)

Indicate the reference center

Title of the study

Protocol ID (acronym)

Keywords (up to 7 specific keywords)

Rationale

Study design

Mono-centric/multi-centric

Perspective/retrospective

Controlled/uncontrolled

Open-label/single-blinded or double-blinded

Randomized/nonrandomized

n parallel branches/n overlapped branches

Experimental/observational

Objectives

Endpoints (main primary and secondary endpoints to be listed)

Expected Results

Analyzed Criteria

Main variables/endpoints of the primary analysis

Main variables/endpoints of the secondary analysis

Safety variables

Health Economy (if applicable)

Visits and Examinations

Therapeutic plan and goals

Visits/controls schedule (also with graphics)

Comparison to treatment products (if applicable)

Dose and dosage for the study duration (if applicable)

Formulation and power of the studied drugs (if applicable)

Method of administration of the studied drugs (if applicable)

Informed Consent

Study Population

Short description of the main inclusion, exclusion, and withdrawal criteria

Sample Size

Estimated Duration of the Study

Safety Advisory

Classification Needed

Requested Funds

Additional Features (based on study objectives)

References