CHECKLIST FOR FULFILLING THE CONDITIONS OF THE SCIENTIFIC RESEARCH ETHICS COMMISSION – human subjects

CHECKLIST– human subjects	Yes	Observations
a) Clinical protocol/amendments;		
1. General information		
The general information that a protocol must contain is:		
a) protocol title, protocol identification number and date; any amendment must also bear a number and a date;		
b) the name and address of the sponsor and monitor (if it is someone other than the sponsor);		
c) the name and title of the person/persons authorized by the sponsor to sign the protocol and its amendment/amendments;		
d) the name, title, address and telephone number(s) of the medical expert for the sponsor's study;		
e) the name and title of the investigator(s) who is/are responsible for conducting the study and the address and telephone number of the study site(s);		
f) the name, title, address and telephone number(s) of the qualified physician who is responsible (if any other than the investigator) for medical decisions at all study sites;		
g) the name and address(es) of the clinical laboratory(s) and/or other medical and/or technical departments and/or institutions involved in the study.		
2. Background information		
The basic information that the protocol must contain are:		
a) the name and description of the drug/drugs for clinical investigation;		
b) a summary of findings from non-clinical studies that have potential clinical significance and from clinical studies that are relevant to the clinical study in question;		
c) summary of potential risks and benefits, if any, for subjects;		
d) description and justification of the route of administration, the doses, the method of administration and the period/periods of treatment;		
e) a statement regarding the fact that the study will be conducted in accordance with the protocol, the rules of good practice in the clinical study and the legal regulations in the field;		
f) description of the population to be studied;		
g) references to literature and data that are relevant to the study and that present basic information for the study.		
3. The objectives and purpose of the study		
The protocol must contain a detailed description of the objectives and purpose of the study.		
4. Direct access to source documents		
The sponsor must ensure that it is specified in the protocol or other written conventions that the investigator/institution must allow monitor control, audit, EC verification and National Medicines Agency inspection, ensuring direct access to source data/documents.		
5. Quality assurance and quality control		
In the protocol there must be provisions regarding quality assurance and quality control.		
6. Ethics		
The protocol must describe the ethical considerations related to the study.		
7. Data handling and record keeping		
In the protocol there must be provisions regarding data handling and record keeping.		

CHECKLIST– human subjects	Yes	Observations
8. Financing and insurance		
Financing and insurance must be described in the protocol, if not provided for in a separate convention.		
9. Publication Policy		
The measures for publication must be described in the protocol, if they have not been provided for in a separate convention.10. Date suplimentare		
În protocol pot să fie prezentate date suplimentare, dacă este cazul.		
b) The informed consent form and the updated form if the investigator proposes it for use in the study;		
1. Quantitative elements:		
Both the informed consent discussion and the written informed consent form, as well as all other written information presented to the subject, must include an explanation of the following:		
a) that the study constitutes research;		
b) the objective of the study;		
c) the treatment during the study and the possibility of randomization of each treatment;		
d) study procedures that must be followed, including all invasive procedures;		
e) responsibilities of the subject;		
f) those aspects of the study that are experimental;		
g) foreseeable risks or inconveniences for the subjects and when applicable for the embryo, fetus, newborn, infant;		
h) the provided benefits; when it is not intended to provide benefits for the subject, attention must be paid to this aspect;		
i) the alternatives of procedures or treatment that can be used for the subject and their potential risks and benefits;		
j) compensation and/or treatment available to the subject in the event of a study-related injury;		
k) the scheduling of the reward provided, if any, for the subject participating in the study;		
l) the expected expenditure, if any, for the subject's participation in the study;		
m) that the subject's participation in the study is voluntary and that the subject can refuse to participate in the study or can withdraw at any time, without suffering repercussions or losing the benefits with which he is invested;		
n) that the monitor/monitors, the auditor/auditors, the EC and the National Medicines Agency will have guaranteed direct access to the subject's original medical records for verifying the procedures in the clinical study and/or the data, without violating the confidentiality of the subject, in compliance with the legislation in force and regulations and that by signing the written informed consent form, the subject or his legal representative authorizes this access;		
o) that the records identifying the subject will be kept confidential and that, in accordance with the legislation/regulations in force, they are not made publicly known; if the study results are published, the identity of the subject will remain confidential;		
p) that the subject or his legal representative will be informed in time if any information appears that is important for his decision to continue participating in the study;		
q) the person/persons to be contacted for other information regarding the study and the rights of the study subject and who must be notified in the event of an event affecting the subject, in connection with the study;		

CHECKLIST– human subjects	Yes	Observations
r) the circumstances provided for and/or the reasons why the subject's participation can be stopped;		
s) estimation of the duration of the subject's participation in the study;		
t) assessment of the approximate number of subjects included in the study.		
2. Qualitative elements:		
- must not contain language that allows the inference of the waiver of legal rights or that implies the exemption of liability in case of negligence		
- complete information about all aspects of the study including written information and the approval/favorable opinion of the CECS.		
- non-technical, practical and understandable language		
- time for thinking, possibility of written and verbal information		
- the form must be dated and signed by the subject and the person who provided the information		
- if a subject/legal representative is not able to read - impartial witness		
- copy for the subject, signed and dated for. any form/information/update		
- the preference for subjects expressing their personal consent - conditions in other cases		
- if it includes subjects who can be enrolled in the study only based on the consent of the subject's legal representative - information compatible with the ability to understand		
- foreseen emergency situations (if applicable)		
c) procedures for recruiting subjects		
- detailing the recruitment methods		
- demonstration of the possibility of recruitment		
d) the written information that will be given to the subjects;		
a) name of all drugs, doses, dosing schedule, route/mode of administration and treatment period, including post-treatment follow-up period, for each investigational drug treatment/study treatment group/treatment arm ;		
b) medication/treatment allowed (including emergency medication) and not allowed before and/or during the study;		
c) procedures for monitoring the subject's compliance with the study conditions.		
e) the investigator's brochure;		
1. COVER PAGE		
2. PRIVACY STATEMENT		
3. Contents of the investigator's brochure		
4. CONTENTS		
f) available information regarding the safety of drug administration;		
g) information about the payments and compensations available to the subjects; (insurance?)		
h) updated curriculum vitae of the investigator and/or other documents proving his qualification;		
i) any other documents necessary for CECS to fulfill its responsibilities.		

Date Examinator

CHECKLIST FOR FULFILLING THE CONDITIONS OF THE SCIENTIFIC RESEARCH ETHICS COMMISSION - experimental animals

CHECKLIST– experimental animals	Yes	Observations
Administrative data:		
Project manager (surname, surname, contact details, e-mail, telephone), beneficiary/institutional affiliation		
Project title		
Source of funding.		
Summary		
Details were provided regarding the description of the background, the research objectives, including details about the species or animal strain used, methods, intended results.		
Introduction		
Background		
Details of the scientific background to support the working hypothesis(es) have been provided and the experimental approach and rationale explained.		
It was explained how and why the species and animal models used can address the scientific objectives and, if applicable, the relevance of the study to human biology.		
objection		
Details of the primary and secondary objectives of the study or the specific hypotheses being tested were provided.		
Methods		
Ethics		
Details were provided regarding the accreditation of the institution/laboratory where the study is conducted.		
Details were provided regarding the accommodation conditions of experimental animals (cages, temperature, humidity, light, etc.), access to food and water. Dietary restrictions were justified.		
Details were provided regarding the necessity of the procedures used in the context of the "3R" principle		
Study design		
Details of the number of experimental and control lots were provided.		
Details were provided on the method of batch formation (including the number of animals allocated per batch).		
Details of the experimental unit (eg, single animal, group or animal cage) were provided.		
Details were given on a diagram graphically describing the experiment (if possible).		
Details were provided regarding the degree of severity of the procedure.		
Details were provided regarding the method of euthanasia.		
Experimental procedures		
Details were provided regarding each experiment and experimental batch (including the control batches), all the procedures to be performed were detailed/justified (for example: doses, route of administration, use of anesthesia techniques, administration of analgesia, equipment, etc).		
Details were provided regarding the order in which animals in the different experimental groups would be treated and evaluated		

CHECKLIST– experimental animals	**Yes**	**Observations**
Experimental animals		
Details of the animals used were provided, including species, sex, developmental stage (eg mean or mean age plus age range).		
Details of additional relevant information such as animal source, international strain nomenclature, genetic modification status, genotype, health/immune status, test drug or naïve, previous procedures, etc., were provided.		
Details of well-being interventions to be carried out before, during or after the experiment were provided.		
Estimated experimental results		
Details of estimated primary and secondary experimental outcomes (eg, molecular markers, behavioral changes) were provided.		
Statistical methods		
Details of the statistical methods used for each analysis were provided.		
Details were provided regarding the unit of analysis for each data set (eg, single animal, group of animals, single neuron).		
Details were provided on the methods used to assess whether the data met the assumptions of the statistical approach.		
Other relevant information		
Details were provided regarding the competence of the people involved in the project		

Data Examinator