Ministério da Saúde

CEIC
Comissão de Ética para a Investigação Clínica
National Ethics Committee for Clinical Investigation

Note on Procedures for issuing CEIC´s single opinion to carrying out Clinical Trials with medicinal products for human use

Background

Created in January 2005, CEIC is endowed with independent technical and scientific experts who work in the dependence of the Minister of Health. During these seven years, CEIC evaluated about 840 requests for an opinion relating to new trials and 2640 relating to requests for substantial amendments to the previously approved trials.

CEIC is a multidisciplinary ethics committee, consisting of about three dozen individuals with recognized expertise and experience in clinical trials and ethics, which meet monthly in plenary sessions under the direction of its Chairman or his Vice-chair. The Executive Committee is composed of the Chairman, the Vice-Chair and five to seven members selected from among other members of the CEIC; the Executive Committee meets weekly. The experts who evaluate clinical trials are chosen from the members of the CEIC, according to their area of expertise. CEIC has a secretariat composed by specialized technicians and administrative staff, whose procedures are properly defined.

CEIC issues this note on procedures for obtaining the single opinion for clinical trials, having in mind a clarification of the procedures.

Procedures of CEIC for issuing the single opinion:

The request for authorization to conduct a clinical trial is submitted to CEIC, with an application form, proof of payment of fees to Infarmed and with the required documentation. CEIC then triggers a number of procedures for issuing the single opinion, with a final decision taken in the plenary session.

1. VALIDATION

After submission, the request for an opinion for the conduction of clinical trials, begins with the validation by the secretariat, in charge of checking whether the process satisfied all legal requirements, according to a checklist. Where these are not met, the Secretariat shall invalidate the submission process or, when only minor elements are missing, they are requested from the applicant.

(An exception to this validation procedure is the final financial agreement established between sponsor and the clinical trial site, which is submitted after the emission of the favourable opinion by the Ethics Committee).

This step ends with the validation or invalidation of the process. If the process is invalidated, it has to be resubmitted, and a new validation process will be launched.

The legal deadlines start from the day of the entry of each process. If the process is resubmitted because of invalidation, the time -clock is restarted.

2. DISTRIBUTION TO THE EXPERTS

Once validated, the proposals for clinical trials are distributed to the experts according to their area of specialty. After confirming their availability to evaluate the process, the counting time starts. The experts have 15 days for the evaluation of new trials and 10 days for the requests to amendments to previously approved trials.

3. EVALUATION BY EXPERTS

a) The expert makes an assessment of the trial and issues an initial opinion in accordance with a CEIC´s form. Usually, the initial assessment requires some clarifications concerning different issues in the protocol or in the informed consent document.
b) This initial assessment - favourable / unfavourable or questions - is discussed by the Executive Committee, and whenever justified, the secretariat issues a letter of request for additional information.
c) Once the responses are received from the applicant, these are sent to the expert for further evaluation.
d) The expert issues a final opinion which is brought back to the discussion by the Executive Board

   When there are some remaining questions, the Executive Committee and the expert schedule a "prior audience" with the sponsor, the coordinating investigator and who-never else of interest involved in the trial, as a last attempt to clarify the outstanding issues.
e) After the responses to the “prior audience”, the expert prepares a new version of his final opinion.
f) When there are no questions in the expert's initial opinion and after discussion by the Executive Committee, the process proceeds to discussion and voting at the plenary session

4. DISCUSSION AND VOTING

The Plenary session begins with the declaration of conflicts of interest by those present, after the approval of the agenda. Requests for opinions are discussed and voted by all elements, except by those which had declared conflict of interest for the process under discussion.

5. ISSUING THE OPINION

After the deliberation of the plenary session concerning each clinical trial proposal, an opinion letter is issued for each process (favourable, unfavourable or favourable with conditions) together with the nature of the resolution (number of votes against and abstentions). For all proposals of new clinical trials or substantial amendments with unfavourable opinions a statement of reasons is issued.

6. APPROVAL OF FINANCIAL CONTRACTS

The favourable single opinion is effective only after evaluation and approval by the Ethics Committee of the final financial agreement signed by the parties involved. The secretariat then sends a letter to the applicant.

Additional clarification

i. CEIC requests for additional information only once, as provided by law
ii. CEIC asks the applicant via e-mail to solve some remaining issues that were raised in the request of additional information, or because of small details that were not sufficiently clarified or corrected
iii. CEIC is always available to respond via email or phone to any question asked by the applicant in order to clarifying any question that was raised
iv. The CEIC proposes to carry out a "prior audience", giving the applicant a second chance to answer questions that have not been sufficiently answered when requesting additional information. Thus, the "prior audience" is not a new round of questions, or requests for further information.

- 27th July of 2012 -