KLH-11 version 1 Ethics Committees

This Guideline supersedes guideline KLH-11 with the effect from 10 June 2011

Translation of Chapter 3. of ICH Guideline for Good Clinical Practice (E6, May 1, 1996), which defines principles of work of ethics committees. Text of the guideline is not modified or changed.
There is added four explanatory notes:

1) to part 3.1.2.:
According to the Act No. 378/2007 Coll., Act on Pharmaceuticals , the ethics committee must within 60 days of the delivery date of the application give its reasoned opinion on the relevant clinical trial to the sponsor.

2) to part 3.1.6.:
The conduct of a clinical trial in vulnerable subjects is permissible only if expected to provide preventive or therapeutic benefits for these persons.

3) to part 3.1.7.:
In acute cases when it is impossible to obtain the trial subject's informed consent prior to the inclusion in the clinical trial, the consent shall be requested from the subject's guardian. Where such guardian has not been assigned or is unavailable, the trial subject may only be included in the clinical trial if the inclusion procedure is specified in the protocol and the investigator has obtained a written favourable opinion from the trial's ethics committee which contains an explicit position on the procedure of including trial subjects. The opinion of the ethics committee may include a condition according to which the inclusion of each single trial subject must be approved by the ethics committee. The investigator shall obtain the consent of the trial subject or, where applicable, his or her guardian, with the trial subject's continued participation in the clinical trial as soon as practicable with respect to the condition of the trial subject or the availability of the guardian.

4) to part 3.4.: Records, specifying situation in the Czech Republic:
In the CR the regulatory authority according to the Act No. 378/2007 Coll., Act on Pharmaceuticals the State Institute for Drug Control.