The EFGCP Report on
The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe
(Update: April 2012)

Turkey

Question 1: What laws or regulations apply to an application for conducting a clinical trial in Turkey?

Laws (in Turkish):

- Sağlık Hizmetleri Temel Kanunu "Ek Madde 10" (6 April 2011)
- Araştırma ve Geliştirme Faaliyetlerinin Desteklenmesi Hakkında Kanun (2008)
- Türk Ceza Kanunu (2005)
- Sağlık Bakanlığının Teşkilat ve Görevleri Hakkında Kanun (13 December 1983)
- İspençiyari ve Tıbbi Müstahzarlar Kanunu (1928)

Regulation:

Regulation On Clinical Trials (19 Aug 2011):
http://www.iegm.gov.tr/Default.aspx?sayfa=regulations&lang=en&thelawtype=14&thelawId=398

Question 2: Which government, legal or authoritative body or bodies is or are responsible for the establishment and/or accreditation of (research) ethics committees for IMPs, and for their supervision and quality? Are there different (research) ethics committees reviewing other projects?

Ministry of Health (MoH) is the responsible authority for the accreditation of Ethics Committees (ECs).

Question 3: What is the process for achieving clinical trial authorisation from the competent authority in Turkey?

Questions 3 and 4 are most appropriately answered together for Turkey.

Question 4: What is the process for obtaining ethical review of a clinical trial protocol by a competent (research) ethics committee in Turkey?

1) The application dossier for a clinical trial will be prepared according to the Guideline for Good Clinical Practice and other applicable guidelines, using the application form and its relevant annexes posted on the Ministry's website, and will be reviewed for Ministry permission and ethics committee approval according to this Regulation and the guidelines to be issued by the Ministry.
2) In multi-center clinical trials, the scientific and ethical approval will be obtained of the ethics committee in the locality where the coordinating center is located. Notifications will be made to ethics committees in places where the other sites are located.
3) The application for a clinical trial will be made to the relevant ethics committee or general directorate by the sponsor, consisting of natural/juristic person(s), or by a contract research organization domiciled in Turkey appointed by the sponsor. If the sponsor has no representative domiciled in Turkey, the application for a clinical trial must be submitted through a contract research organization domiciled in Turkey.
4) Applications to obtain Ministry approval for conducting a clinical trial that have been granted ethical and scientific approval with any substances or products which and which may involve investigation in human beings, including clinical trials with medical devices, BA/BE trials, comparability studies for biosimilar products, Phase I, Phase II, Phase III and Phase IV drug clinical trials, clinical trials with advanced therapy medicinal products, observational studies with drugs, observational studies with medical devices, clinical trials with traditional herbal medicinal products and cosmetic products or raw materials, will be made to the General Directorate of Pharmaceuticals and Pharmacy. a) For clinical trials with Class III medical devices or with implants or long-term invasive devices in Class IIa or Class IIb, the study sponsor or a contract research organization delegated by the sponsor will, upon the approval of the ethics committee concerned, make an application to the General Directorate of Pharmaceuticals and Pharmacy, and the application will be evaluated within sixty days after the notification date. b) For all clinical trials with medical devices, excluding the ones mentioned in subparagraph (a), and all other drug clinical trials will be evaluated within not more than thirty days by the relevant general directorate.
5) Applications to obtain Ministry approval for conducting clinical trials with industrial advanced medicinal products or non-industrial advanced medicinal products, gene therapy clinical trials, stem cell transplantation trials, organ or tissue transplantation trials and clinical trials with a novel surgical procedure which have been given scientific and ethical approval will be made to the General Directorate of Health Services. These applications will be evaluated within not more than sixty days.
6) If the general directorate concerned adopts an unfavorable decision regarding the request for conducting the clinical trial, this decision will be notified to the applicant, together with the rationale for the decision. The sponsor will be granted a single opportunity to resubmit the application after making amendments to address the issues raised in the decision, or to file a reasoned objection against the decision. If the requested changes are not fulfilled or an acceptable justification cannot be offered, the general directorate concerned may reject the clinical trial.

7) In the case of clinical trials with cellular therapies using products containing genetically modified organisms or products involving gene therapy, the thirty days specified for Ministry approval may be extended for an additional thirty days. However, in cases where it becomes necessary to hold detailed deliberations or to consult non-Ministerial third party experts, the timeline may be extended further by an additional ninety days, depending on the subject matter of the study.

Question 5: Is there a single organisation to which to apply for ethical review of a clinical trial for an investigational medicinal product, regardless of whether this is for a single site or multiple sites?

No. As of today, there are 52 different Ethics Committees in 26 different cities.
In multi-center clinical trials, the scientific and ethical approval will be obtained of the ethics committee in the locality where the coordinating center is located. Notifications will be made to ethics committees in places where the other sites are located.

Question 6: What is the website for the organisation that issues guidelines on the ethical review of a clinical trial for an investigational medicinal product?

The websites of the MoH General Directorate of Pharmaceuticals and Pharmacy:

Turkish: http://www.iegm.gov.tr/Default.aspx?sayfa=klinik&lang=tr-TR
English: http://www.iegm.gov.tr/Default.aspx?sayfa=clinical_dep&lang=en

The website of the Clinical Research Association:
http://www.klinikarastirmalar.org.tr/en/index.php

Question 7: Is there a procedural interaction between the national or local competent authority and the (research) ethics committee during the approval process?

No. Ethics committees are independent in their function of reviewing and approving clinical trial applications from a scientific and ethical perspective. The decisions of an ethics committee shall not be approved separately by the President of Refik Saydam Hıfzısıhha Center, the rector, the dean, or the chief physician.

Permission of the Ministry is required to commence a clinical trial that has been approved by ethics committee.

Question 8: Does the application to the REC and to the competent authority have to be submitted in parallel, or, if not, in which order?

No. Sequential. First EC and then Regulatory Authority (MoH) application is performed.

Question 9: How many (research) ethics committees are there in Turkey?

N/A

Question 10: How are RECs funded in Turkey? Do they charge fees? If yes, what is their scale of fees?

During the application below listed fees should be paid to the bank account of the institution of related EC/MoH:

- Phase I: 2.045,32 TL (870 €)
- Phase II: 2.045,32 TL (870 €)
- Phase III: 2.045,32 TL (870 €)
- Phase IV: 1.025,42 TL (436 €)
- Registry: 1.025,42 TL (436 €)

(Indicative Exchange Rates Announced on 16-Mar-2012 by the Central Bank of Turkey ->1 € = 2,35 TL)

Question 11: Who is responsible for submitting the request for ethical review to the competent (research) ethics committee for single-site and for multi-site clinical trials?

The application for a clinical trial will be made to the relevant ethics committee or general directorate by the sponsor, consisting of natural/juristic person(s), or by a contract research organization domiciled in Turkey appointed by the sponsor. If the sponsor has no representative domiciled in Turkey, the application for a clinical trial must be submitted through a contract research organization domiciled in Turkey. If there is no sponsor application is made by principal investigator or by coordinator in multi-center trials.

Question 12: How is a "single opinion" achieved for multi-site studies?

First step: EC approval
Application is made to the related Ethics Committee for the purpose of receiving approval scientifically and ethically for clinical trials.
According to kind of clinical trial, application is made to the related Ethics Committee with the application form and cover letter samples prepared considering the appropriate application form and application cover letter samples published at the website of General Directorate for Pharmaceuticals and Pharmacy (www.iegm.gov.tr).

Second step: MoH permission
Permission of the Ministry is required to commence a clinical trial that has been approved by an ethics committee. The study sponsor will make an application to the

General Directorate of Pharmaceuticals and Pharmacy to obtain permission of the Ministry.

In order to receive Ministry permission after the received scientific and ethical approval application is made to General Directorate for Pharmaceuticals and Pharmacy for clinical trials to be conducted with medical devices, for bioavailability/bioequivalence (BA/BE) studies, for comparability studies of bio-similar products, for Phase I, Phase II, Phase III, and Phase IV drug clinical trials, for clinical trials to be conducted with advanced treatment medicinal products, for observational drug studies, for observational medical device studies, for efficacy and safety studies to be conducted with cosmetic raw materials or products, and for clinical trials to be conducted with traditional herbal medicinal products.
In order to receive Ministry permission following scientific and ethical approval, for clinical trials to be conducted with non-industrial advanced medicinal products application is made to General Directorate of Treatment Services for clinical trials to be conducted with industrial advanced medicinal products, for gene treatment clinical trials, for stem-cell transplantation trials, for organ and tissue transplantation trials, and for new surgery method trials.

Question 13: How many members serve on a REC?

Ethics committees, comprised of not less than seven (7) and not more than fifteen (15) members with at least one (1) of them a non-health care professional and one (1) a jurist, and the majority consisting of health care professionals holding a doctorate or medical residency degree.

Question 14: How many members constitute a quorum?

Ethics committee members will convene with the two thirds majority of total number of members, and adopt decisions by the favorable vote of a simple majority of its full membership.

Question 15: How are REC members appointed?

Ethics committees will be established with Ministry approval within universities upon the proposal of the rector, within Refik Saydam National Public Health Agency upon the proposal of the President of Refik Saydam National Public Health Agency, or at teaching and research hospitals upon the proposal of the chief physician, and commence functioning as of the approval date by the Ministry.

Question 16: How is the independence of members ensured?

In “Regulation On Clinical Trials” it states:
ARTICLE 11 – b) Ethics committees are independent in their function of reviewing and approving clinical trial applications from a scientific and ethical perspective. The decisions of an ethics committee need not be ratified by the President of Refik Saydam National Public Health Agency, the rector, the dean, or the chief physician.

Question 17: How are conflicts of interest of REC members avoided?

Ethics committee members who are affiliated with the study sponsor or have a role in the study being reviewed may not take part in ethics committee discussions and nor in the voting on the study concerned, nor may they have their signature under the committee decision. [In "Regulation On Clinical Trials", ARTICLE 11 – e].

Question 18: What backgrounds and/or qualifications of members are actively sought?

In "Regulation On Clinical Trials" it states in ARTICLE 10:

(10) An Ethics Committee for Drug Clinical Trials will consist of members that have at least the following qualifications:

a) Specialist physicians, at least one of whom with experience as an investigator in a clinical trial that was organized according to the guidelines for good clinical practice;
b) A pharmacist or doctor of medicine holding a doctorate or medical residency degree in pharmacology;
c) A biostatistician or physician holding a doctorate or medical residency degree in public health;
ç) A person holding a doctorate, medical residency or master's degree in medical ethics (deontology), if available;
d) A jurist;
e) A non-health care professional.

(11) An Ethics Committee for Bioavailability/Bioequivalence Trials will consist of members that have at least the following qualifications:

a) Specialist physicians, at least one of whom with experience as an investigator in a clinical trial that was organized according to the guidelines for good clinical practice;
b) A pharmacist or doctor of medicine holding a doctorate or medical residency degree in pharmacology;
c) A biostatistician or physician holding a doctorate or medical residency degree in public health;
ç) A pharmacist holding a doctorate degree in pharmaceutical technology;
d) A pharmacist or chemist holding a doctorate degree in pharmaceutical chemistry or analytical chemistry;
e) A person holding a doctorate, medical residency or master's degree in medical, ethics (deontology), if available;
f) A jurist;
g) A non-health care professional.

(12) An Ethics Committee for Non-drug Clinical Trials will consist of members that have at least the following qualifications:

a) Persons holding a doctorate or medical residency degree, at least one of whom with experience as an investigator in a clinical trial that was organized according to the guidelines for good clinical practice;
b) A biostatistician or physician holding a doctorate or medical residency degree in public health;
c) An engineer or expert in the field of biomedicine, or, if unavailable, a biophysicist or physiologist who is preferably a medical graduate;
ç) A person holding a doctorate, medical residency or master's degree in medical ethics (deontology), if available;
d) A jurist;
e) A non-health care professional.

(13) An Ethics Committee for Clinical Trials will consist of members that have at least the following qualifications:

a) Persons holding a doctorate or medical residency degree, at least one of whom with experience as an investigator in a
b) A pharmacist or doctor of medicine holding a doctorate or medical residency degree in pharmacology;
c) A biostatistician or physician holding a doctorate or medical residency degree in public health;
ç) An engineer or expert in the field of biomedicine, or, if unavailable, a biophysicist or physiologist who is a preferably medical graduate;
d) A person holding a doctorate, medical residency or master's degree in medical ethics (deontology), if available;
e) A jurist;
f) A non-health care professional.

Question 19: How do RECs obtain specialist expertise?

Where necessary, ethics committees may solicit the written opinion of experts in a relevant field or subfield, and invite them to attend meetings in capacity of an advisor. [In "Regulation On Clinical Trials", ARTICLE 11 – ğ].

Question 20: What are the training requirements for members of RECs?

From the EC members at least one Specialist physician, should have experience as an investigator in a clinical trial that was organized according to the guidelines for good clinical practice.

Question 21: What training programmes are available for REC members in Turkey?

Some of the pharmaceutical companies organize ICH-GCP trainings for investigators and EC members.

On the other hand, starting from mid 2009 the MoH also conducts ICH-GCP training programmes for ECs.

Question 22: What are the timelines for the assessment of single- and multi-site studies?

For ECs: Ethics committees will form their opinion and communicate it to the applicant within thirty days after the application date. Should additional information or clarifications become necessary during the ethics committee review, all of the requests will be communicated to the applicant in a single request. A second request will not be made to the applicant. The review process will be frozen until the required data and documents are submitted to the ethics committee.

For MoH: All drug clinical trials will be evaluated within not more than thirty days by the relevant general directorate.

Question 23: How are substantial amendments submitted during the review process dealt with?

If, after the commencement of a clinical trial, the need arises to make any of the amendments described in the Guideline for Good Clinical Practice, such amendment(s) will be notified to the ethics committee concerned, to be approved by the sponsor, and to the relevant general directorate. Should the amendments be found acceptable, the ethics committee will approve them within fifteen days, and the general directorate concerned within thirty days, to the extent they find the amendments acceptable.

Question 24: How does a REC assess the suitability of investigators and of sites?

In the application dossier, the CVs of principal investigators are included and ECs assess the suitability of investigators according to their CVs.

In "Regulation On Clinical Trials" it states the suitability of study sites are defined as follows:

Clinical trial sites, standards, and applications for authorization - ARTICLE 16

1) Clinical trials may only be conducted at centers for health practice and research established within universities, including Gülhane Military Medical Academy (GATA), approved centers for research and development subordinate to universities, Refik Saydam National Public Health Agency and the Ministry's teaching and research hospitals which are suitable for and possess appropriate staff, equipment and laboratory means that enable ensuring the safety of research subjects and proper conduct and monitoring of a clinical trial, and appropriate emergency care should it be necessary.
2) Clinical trials conducted at centers mentioned above may be supplemented with other health institutions or organizations meeting the criteria specified herein, provided it will be under coordination and responsibility of these centers.

3) Phase I drug trials, BA/BE trials and comparability studies for biosimilars:

a) These studies will be conducted at health institutions or organizations subordinate to the Ministry or universities or at centers for research and development approved by the Ministry which possess the necessary means to provide emergency care.
b) Centers established for conducting these studies may not commence operating without obtaining approval of the Ministry. Applications to obtain Ministry approval will be made to the General Directorate of Pharmaceuticals and Pharmacy, using the application form posted on the Ministry's website and relevant annexes, in accordance with applicable guidelines. The Ministry will give its approval for the trial site within ninety days after the application, provided that during the inspection of proposed trial sites by the General Directorate of Pharmaceuticals and Pharmacy the accuracy of the data and documents submitted with the application is demonstrated, and the trial site is shown to meet the necessary requirements. The Ministry will conduct subsequent inspections of these sites every three years, or in shorter intervals as may be deemed necessary, and may either renew its previous approval or suspend the site's operations depending on the inspection outcome.
c) Centers that obtain approval from the Ministry for the trial site may commence the activities described in this paragraph, to the extent that such centers will be obligated to obtain the approval of relevant ethics committee and permission of the Ministry for each study that they will conduct.

4) Sites where clinical trials will be conducted on the basis of the Guideline for Good Clinical Practice must minimally have:

a) the necessary staff and equipment at an adequate level, appropriate to the nature of the study,
b) the facilities and means necessary for storing and dispensing the investigational product in a manner appropriate to its nature,
c) the means and equipment to provide appropriate care to subjects, including cases requiring emergency care,
ç) the sufficient means and equipment to enable transferring subjects to a more advanced health institution/organization, where necessary, and
d) the sufficient means and equipment to retain the data and documents relating to the clinical trial and subjects, for the period prescribed in the Guideline for Good Clinical Practice, after the study is completed.

Question 25: How are the requirements for (research) ethics committees to review the contractual or financial arrangements in clinical trials for both investigators and hospitals handled?

The application dossier includes the overall study budget, plus any special budgets and financial contracts that are signed between the institution, the sponsor and the investigator.

Question 26: How are the requirements for (research) ethics committees to review the compensation arrangements for study subjects handled?

Insurance coverage shall be provided against any bodily injury or death of a volunteer taking part in a clinical trial due to the investigational medicinal product or any procedures applied at the time of the clinical trial. It must be documented, therefore, by the sponsor of the trial that all patients and healthy volunteers taking part in a clinical trial have been provided insurance coverage by the sponsor of the clinical trial against any injury associated with taking part in the clinical trial concerned.

Accordingly, the relevant ethics committee and the Ministry must be presented with an insurance policy or, in the case an insurance policy cannot be submitted, a certified authentic copy of the insurance policy or certificates of insurance clearly indicating the terms and conditions of insurance in reference to the insurance policy concerned.

Question 27: Is there an ongoing quality assurance process (e.g. audits, inspections, internal SOP) for (research) ethics committees in Turkey?

For ethics committees to function in a standardized manner, the Ministry will establish an Ethics Committee Standard Operating Procedure and post it on the Ministry website, updating it as necessary. Ethics committees will carry out their functions according to these set of standards.

Ethics committees who fail to operate in line with the ethical guidelines, or fail to meet the requirements laid down in the Ethics Committee Standard Operating Procedure, or found in a Ministry audit to be lacking the space, secretarial services, archiving services or equipment essential to fulfilling the function of an ethics committee will be issued a warning by the Ministry. The approval may be withdrawn if the ethics committee fails to address the issues that gave rise to the warning within the prescribed timeframe.

Clinical trials being conducted, trial sites, sponsors and contract research organizations, manufacturing sites of investigational products, laboratories where analyses relevant to the trial are being performed, and ethics committees may be inspected in and/or outside of the country by the Ministry, with or without advance notice, to determine compliance with this Regulation and other applicable regulatory provisions.

Question 28: Is there an appeal mechanism?

Appeal mechanisms are mentioned in the guidelines of Ministry of Health:

http://www.iegm.gov.tr/Default.aspx?sayfa=regulations&lang=en&thelawtype=12&thelawId=236

http://www.iegm.gov.tr/Default.aspx?sayfa=regulations&lang=en&thelawtype=12&PageNo=2&thelawId=420

Question 29: How do RECs deal with SUSAR reports and Annual Safety Reports?

According to attached guideline:
http://www.iegm.gov.tr/Default.aspx?sayfa=regulations&lang=en&thelawtype=12&thelawId=235

Question 30: How are 'substantial amendments' defined?

Examples Regarding Matters That Might Require Significant Amendment in Clinical Trials.

The amendments indicated below are examples and amendments are not limited to these.

Samples of Basic Significant Amendment
- Physical and mental health of the volunteers,
- Scientific value of the trial,
- System and method on conducting the trial,
- Quality and safety of the investigational product used in the trial.

Amendments Regarding Trial Protocol/Plan
- Purpose of the trial,
- Design of the trial,
- Volunteer informed consent form (SICF),
- Method/methods of volunteer recruitment for the trial,
- Efficacy measurements,
- Addition or omitting of tests or measurements,
- Number of volunteers,
- Age interval of volunteers,
- Inclusion criteria for the trial,
- Exclusion criteria for the trial,
- Monitoring of volunteer safety,
- Duration of exposure to investigational product,
- Change in dosage of investigational product,
- Change of comparator drug,
- Statistical analysis.

Amendments Regarding Administrative Structuring
- Change of principal investigator,
- Change of coordinating investigator,
- Change of trial site and/or addition of new trial sites,
- Change of sponsor or legal representative,
- Change of contract research organization,

Amendments Regarding Investigational Product
- Change in quality data of investigational product,
- Change in title or code of investigational product,
- Change in internal package material,
- Change in producer of active substance,
- Change in manufacturing process of active substance,
- Change in specifications of active substance,
- Change(s) in information related to Manufacturing of medical product,
- Change in specifications of medical product,
- Change(s) in specifications of excipients in cases the performance of investigational product is affected,
- Change in shelf life of investigational product,
- Basic change made in formulation,
- Change in storage conditions,
- Change in test methods of active substance,
- Change in test methods of medical product,
- Change in test methods of excipients not related to pharmacopeia.

Amendments Made Related to Pre-clinical Pharmacology and Toxicology Data for Ongoing Trials
- Results of newly made pharmacology tests,
- New interpretation of available pharmacology tests,
- Results of newly performed toxicity tests,
- New interpretation of available toxicity tests,
- Results of new interaction studies.

Amendments Made in Data Regarding Usage During Clinical Trial and in Humans for Ongoing Trials
- Change pertaining to safety information occurring in the clinical trial process of the investigational product or during its usage in human,
- Results of new clinical pharmacology tests,
- New interpretation of available clinical pharmacology tests,
- Results of new clinical trials,
- New interpretation of available clinical trial data,
- New data obtained from the usage of investigational product in human,
- New interpretation of available data regarding the usage of investigational product in human.

Question 31: What are the indemnity insurance requirements for research projects?

It was defined in the attached "Guidance On Insuring Subjects in a Clinical Trial" and "Guidance On Insuring Volunteers in a Clinical Trial" guidelines of MoH:

http://www.iegm.gov.tr/Default.aspx?sayfa=regulations&lang=en&thelawtype=12&thelawId=233

http://www.iegm.gov.tr/Default.aspx?sayfa=regulations&lang=en&thelawtype=12&thelawId=402

Question 32: What are the indemnity insurance requirements for (research) ethics committee members themselves?

No mandatory requirement exists.

Question 33: How is informed consent obtained from vulnerable subjects who are potentially to be involved in a clinical trial?

a) After the subjects are given information sufficiently and in a manner comprehensible to them on the clinical trial, their written consent will be obtained and documented on the Subject's Informed Consent Form. In cases when a witness is necessary, persons affiliated with the trial may not act as a witness.
b) In the event that the study involves conducting genetic and/or pharmacogenetic investigation of samples collected from subjects, or collecting germ cells such as sperms or ovules, the subject's consent must be obtained separately for each study.
c) The legal representative is competent in cases where the subject is unable to consent.
ç) No samples or similar data obtained from individuals, including during non invasive studies, may be used without permission of the individual or that of his or her legal representative.
d) Signed consent of the donors or of their legal representatives must be obtained for using collected blood, urine, tissue, radiological images or similar materials for purposes of clinical research. However, in the event that it is no longer possible to contact a material's donor or his or her legal representative, the collection will be regarded anonymous, provided that the ethics committee establishes that this is the case and gives its permission.
The data collected from a collection may be used for purposes of clinical research, provided that the owner's identification details are kept confidential.

Question 34: How do RECs assess the progress and outcome of research projects that they have approved?

With the annual reports and final report.

An ethics committee may monitor a clinical trial approved by it, with or without prior notice. Moreover, the Ministry may ask an ethics committee to monitor a clinical trial. The ethics committee submits its monitoring report to the relevant general directorate at the latest within ten days. The reports will be evaluated by the general directorate concerned.

Question 35: How does the REC ensure reception of the Annual Safety Report and the Summary of the Final Report of a research project that it has approved?

ECs follow-up the studies according to timelines. The first annual report should be

submitted one year after the approval date of MoH and then yearly submission should be done until the end of study. After all the study patients have completed the study in all sites in Turkey, then the Final Report should be submitted.

The responsibility to ensure regular submission of the reports to the relevant general directorate rests with the sponsor.

Question 36: Do national regulations in Turkey allow research on healthy volunteer children (subjects under 16)?

No trial may be conducted in children. However, where the subject of research is directly related to children or is a clinical condition that can be investigated only in children, or it is necessary to verify the applicability of adult data to children, it may be permitted to conduct a study in children within the below premise, provided that the study carries no foreseeable serious risk to subjects' well-being and it is expected that the study will directly benefit the subjects:

a) If the child is capable to assess the information provided to him or her and reach a conclusion on the matter, all information relevant to the trial will be communicated to the child in an appropriate manner. If the child refuses to participate in the trial or requests to withdraw from the trial at any phase, he or she will be removed from the study.
b) The ethics committee will not approve a clinical trial in children unless a favorable view for conducting the study in children has been given by a pediatric psychiatrist or a pediatrician, or, in the case of a clinical trial in children related to pediatric dentistry, by a dental practitioner who holds a doctorate or medical residency degree in pediatric dentistry.
c) A common medical view must exist that the investigational product carries no known risk to children.
ç) The written consent of the legal representatives will be obtained after informing them. The legal representatives may withdraw their written consent at their discretion, even if the study causes no unfavorable effect on the children.
d) The ethics committee concerned will be informed on the clinical, ethical, psychological and social issues associated with the trial, by a pediatric psychiatrist or a pediatrician, or, in the case of a clinical trial in children related to pediatric dentistry, by a dental practitioner who holds a doctorate or medical residency degree in pediatric dentistry, and give consideration to the protocol accordingly.
e) No compelling incentive and/or financial benefit may be offered in connection with a clinical trial in children, other than the covering of necessary expenses arising from children's participation in the trial.

Question 37: Do national regulations in Turkey allow payment, (other than expenses), to children taking part in research?

No.

Question 38: Do RECs invite or allow a) applicants or b) observers to attend committee meetings?

No, but occasionally a sponsor or an investigator may be invited for questions about their own study..

Question 39: Are the minutes of (research) ethics committee meetings made public?

No, they are not made public.

Question 40: Is there any scope for Chairman's actions in between meetings?

No.

Question 41: Do (research) ethics committees ever appoint subcommittees for any specific purpose?

Where necessary, ethics committees may solicit the written opinion of experts in a relevant field or subfield, and invite them to attend meetings in capacity of an advisor.

Question 42: Is there a national policy on the registration of clinical trials before they start?

No.

Question 43: If the answer to Question 42 is 'yes', do (research) ethics committees have any role to play in reviewing such registration?

Information not available.

Question 44: If the answer to Question 42 is 'yes', is this register of clinical trials made available to the public?

Information not available.

Question 45: With regard to Clinical Trial Insurance, do research ethics committees in Turkey work to a set template of requirements?

Information not available.

Question 46: If the answer to Q45 is 'yes', how are these requirements
a) Decided upon?
b) Cross referenced to statutory requirements?

c) Updated?

Information not available.

EFGCP April 2012