The EFGCP Report on
The Procedure for the Ethical Review of Protocols for
Clinical Research Projects in Europe and Beyond

Question 10

How are RECs funded in the country? Do they charge fees? If yes, what is their scale of fees?

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece

Hungary
Iceland
Ireland
Italy
Latvia
Lithuania
Luxemburg
Malta
Netherlands
Norway
Poland
Portugal

Romania
Russia
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Turkey
United Kingdom
**Austria**

They are permitted by law to charge fees. Usually fees are waived for applications academic research.

The fee agreed to by the Forum of Austrian Ethics Committees, an association of Austrian Ethics Committees founded on a voluntary basis in 1997 on the initiative of the Ethics Committee of the Vienna Medical University is currently (June 2007):

a) For single site clinical trials, as well as for multi-site clinical trials with only one centre in Austria: €1.500.

b) For multi-site clinical trials submitted to an Ethics Committee authorized to review multi-site trials (“one single national opinion”): €4.000.

c) For the administration of a multi-site clinical trial at each “local” Ethics Committee: €500.

For academic applications (without industrial sponsor) the fees may be waived. Fees include the assessment and evaluation of any follow-up documents (amendments, reports, etc.).

**Belgium**

RECs charge fees for trials with a commercial sponsor as follows:

1. For interventional studies:
   - *Initial evaluation*: single opinion committee €1000; other committees €300 (local advice only).
   - *Amendments*: €250 to the ethics committee that gave the single advice.

2. For non-interventional studies:
   - *Initial evaluation*: single opinion committee €400; other committees €100 (local advice only).
   - *Amendments*: €100 to the ethics committee that gave the single advice.

The fees are fixed by the Royal Decree of July 15, 2004, but they are subject to an indexation each year. Correct fees can be found on the Agency’s website. The committees do not charge fees for academic (non-commercial) trials.

Moreover, the committees receive each year a certain amount of money from the competent authority (which has a direct fee of €2850 for initial dossiers and €250 for amendments): indeed, 75% of the fees paid by commercial sponsors to the competent authority, should be redistributed to the ethics committees. This redistribution is done on the basis of the number of trial protocols evaluated by each committee.
Bulgaria

Ethics Committees are funded by their local fees. Fees range around 500-1,200 BNG (250-600 €).

Croatia

Fees for the Central EC review are paid to the Agency for Medicinal Products and Medical Devices of Croatia (HALMED), which gives administrative support to the Central EC. The fees are scaled according to the type of study, e.g., the fee for the review of a new study sponsored by Industry is 25,000 Kunas or ~ Euro 3,400. No fees are required for local ECs.

Cyprus

The National Bioethics Committee in Cyprus is funded by a budget assigned to it by the Ministry of Health covering the operational expenses of the Committee.

For bioethical assessment a fee of €600 for each protocol is charged by CNBC. This fee is collected by the Ministry of Health.

Czech Republic

Fees are paid to the institution where the REC is located, and are not paid directly to the REC. The MREC fee is charged in the range of 40,000-100,000 - CZK (1,600 – 4,000 Euros) depending on the number of sites. Local RECs usually charge around 10,000 - CZK. The fee for Amendment negotiation is usually 5,000 - CZK.

Denmark

The regions finance the operation of the regional committees and they lay down a fee per project notified by the research institutions, etc. and by private undertakings and hospitals.

It has been agreed that the fee for notifying a project shall be DKK 4,000 and for a supplementary protocol, DKK 1,500.

Estonia

Ethics committees are not funded by the state.

The fee charged for assessing the protocol for a clinical trial is 383 euros.

For protocol variations there is no fee.
Finland

They are funded by hospital districts that collect fees from opinions based on a Decree issued by the Ministry of Social Affairs and Health (46/2012).

France

The Ministry of Health offers allocations to the committees in relation to their activity.

Germany

All RECs charge fees for their work in the range €1000 – 6000 for clinical trial assessments and €200–1000 for substantial amendments. For trials initiated by investigators requests for reduction of fee are possible.

The amounts of the fees are not fixed by the RECs but by their establishing institution or by State law.

Greece

The NEC is funded by Ministerial Decision. No fees are charged.

Hungary

There are civil service procedure fees.

Clinical trials with IMPs

The fee to be paid in connection with clinical trials with IMPs has been determined by the 95th Act of 2005. At present (April 2010) the fee for an application is 450,000 Hungarian Forints (HUF), while for protocol variations 90,000 HUF (in April 2010, 265 HUF was worth €1).

This fee is distributed between the authority (the NIP) and its co-authorities (including the KFEB). The exact amounts will be specified by law that what is expected to be issued in the first half of 2010.

For the authorisation of non-commercial trials, no fee should be paid.

Non-interventional clinical trials with IMPs

The fee is 200,000 HUF.
Clinical trials with medical devices

The fee is 374,000 HUF. It will be distributed among the EEEKH and the co-authorities. The exact amounts will be specified by law that what is expected to be issued in the first half of 2010.

Other biomedical research

Both the original authorisation and its variation cost the same fees.

<table>
<thead>
<tr>
<th>Ethics Committee</th>
<th>Authority</th>
<th>Fee (HUF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TUKEB</td>
<td>114,000</td>
<td>320,000</td>
</tr>
<tr>
<td>HRB</td>
<td>114,000</td>
<td>315,000</td>
</tr>
<tr>
<td>Regional EC</td>
<td>98,700</td>
<td>15,300</td>
</tr>
</tbody>
</table>

Authorisation of special trials by the Minister of Health is free of charge.

The local committees may not charge fees, if necessary; their remuneration should be part of the contract between the sponsor and the trial site.

**Iceland**

EC’s are publicly funded, no fees are charged.

**Ireland**

Funding is provided by the appointing authority augmented by fees that are payable to the appointing authority as follows:

a) For industry-sponsored trials a fee of €1000.00 in connection with each application and a fee of €150.00 in respect of each trial site to which the application relates.

b) For non-industry-sponsored trials, the application fee is reduced to €150.00.

c) Notification of amendments attracts a fee of €200 (industry) or €50 (non-industry).

**Italy**

The Ethics Committees are funded by the institution or health facility in which they are funded. The Ethics Committees usually charge fees to the sponsors for the performance of their tasks according to the directives of the Regional Authorities with a range between €1,500 and €4,000 per trial. There is also a Ministerial Decree 17-12-2004 on non-for-profit experimentations judged to be relevant for the NHS where it is possible to obtain several waivers:
The EFGCP Report on
The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe
(Update: April 2012)

1) REC fee.
2) Insurances.
3) Drugs.
4) Additional expenses.

**Latvia**

CMEC is funded from the state budget.

The other four committees charge fees (500-1000 EUR for review of application; 200 EUR for review of amendments).

**Lithuania**

Ethics committees are funded from the state budget in Lithuania. Following the Law on Pharmacy (Article 18, Paragraph 6), a state fee shall be paid for examining and issuing a favourable opinion to conduct a clinical trial on medicinal products. The state fee shall be paid to an account of Vilnius District State Tax Inspectorate. According to the Decree of the Government of the Republic of Lithuania, the state fee ranges from approximately 2000 to 3000 LTL depending on the number of research ethics committees involved.

**Luxemburg**

The functioning and logistics CNER is partly financed by public funds it receives from the Ministry of Health, and, since January 2010, partly through submission fees which are applied when studies are submitted for ethical review. Scale of fees: information available on the website [www.cner.lu](http://www.cner.lu).

**Malta**

The HEC is self-funding and fees charged for the review of clinical trials are used for administrative purposes. For example, office supplies, subscription to medical journals and the cost of obtaining the opinion of external experts during the assessment of clinical trials are paid for in this way. Members of the HEC receive no remuneration. Academic research without financial support from industry and clinical trials on orphan drugs may apply for reduced fees. Other clinical trials may also apply for reduced fees and will be evaluated on a case by case basis.

**Netherlands**

Research ethics committees are funded by fees and, in case of research committees in an institute or hospital, also by the parent body. Section 20 of the WMO allows an METC to cover the costs of its protocol review activities by charging fees to the parties submitting protocols for review. The fees charged may not exceed the reasonable cost for conducting the review. The fees can be found on the CCMO-website: [http://www.ccmo-online.nl/main.asp?home=1&pid=14&sid=16&ssid=33&def=22](http://www.ccmo-online.nl/main.asp?home=1&pid=14&sid=16&ssid=33&def=22).
The EFGCP Report on
The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe
(Update: April 2012)

Norway

They are funded by the State. No fees are charged.

Poland

There is no central funding for Bioethics Committees in Poland. The committees established by the universities and the medical/scientific institutes are funded by their parent bodies, but they rely on fees from sponsors for the assessment of sponsored studies. Un-sponsored studies are assessed free of charge. The committees established by the Regional Chambers of Physicians and Dentists also rely on fees from sponsored studies for their funding, but whereas they will also assess unsponsored studies free of charge, they will not give a decision on such studies, as their opinion has to be referred back to the Regional Council of Physicians for a final decision. In these cases the Regional Chamber of Physicians and Dentists must cover all expenses connected with the evaluation of unsponsored studies.

The level of fees charged depends on a number of factors, including the location of the clinical trial; some committees charge a single fee for the complete assessment of a study, whilst some charge a lower fee for the initial assessment followed by additional fees for any subsequent assessment. There is no fixed tariff, each regional committee setting its own level of fees and each university or institute committee having its fees determined by the parent body. Thus in Warsaw, for example, the Regional Chamber of Physicians and Dentists charges 8,500 zlotys (= 1,800 euros) for the total ethical review process of a clinical trial submission.

Portugal

No fee is directly charged by CEIC. The National Ethics Committee for Clinical Research which is otherwise independent is funded by the National Medicines Agency (INFARMED). INFARMED charge sponsors according to a scale of fees. Local committees are financed by local health institutions and do not charge fees.

Romania

NECCT is funded in Romania by a NGO which charges the fees from the CRO’s and with this money assures the logistics of the NECCT. The scale of fees is between 170 and 670 €.

Russia

Usually RECs are funded by the organisation under what they are established, but they do also charge fees, which are variable.
Serbia

Four useful websites may be found at:

www.klinicki-centar.rs (website of Clinical centre of Serbia)
www.kcv.rs (website of Clinical centre of Vojvodina)
www.kcnis.co.rs (website of Clinical centre of Nis)
www.kc-kg.co.rs (website of Clinical centre of Kragujevac)

Slovakia

Ethics committees usually do not have their own budget. Health care facilities/research institutions/regional state authorities should provide necessary means for ECs’ activities (office space, secretarial support, etc.). Usually, a tentative budget for the EC is set within the budget of the health care facility/research institution/regional state authority, but the EC usually has no direct control over this budget.

ECs do charge fees but these go to the budget of their appointing health care facility, research institution, or regional state authority. There is no official regulation for ECs’ fees (it is pending, however), the range is about €300 – €900. For non-commercial studies, the fees are usually waived.

Slovenia

No fees are charged for review of any (type of) application.

The NMEC has no office or administration of its own. The administrative work is done mainly by its President at the Institute of Clinical Neurophysiology of the Ljubljana Medical Centre. The members of the NMEC are volunteers.

Spain

Institutions responsible for the CEICs provide funding (i.e. Regional Governments and Public Hospitals) at different levels. Most of the CEICs charge fees for reviewing protocols. Fees vary, ranging from 300 € to 1200€ per protocol.

Sweden

They are funded by fees ranging from 2,000 SEK (approximately 200€) for an amendment to 16,000 SEK (approximately 1,600€) for pharmaceutical trials, or multicentre studies.

Switzerland

REC requires a fee (between CHF 1000 and CHF 5,000-) for reviewing industry-sponsored projects. Projects that are only sponsored by the investigator or by non-profit
organisations are charged with a fee between 0 and 500 CHF. In addition the Cantons guarantee that REC’s are properly funded.

**Turkey**

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 $\rightarrow 1 \text{ €} = 2,35 \text{ TL})*

**United Kingdom**

Funding is provided by the Health Departments in each of the four UK countries and channelled through the NHS in England, Scotland and Wales and the Health and Social Care service in Northern Ireland. No fees are charged.

*April 2012*

© 2012 EFGCP aisbl – all rights reserved