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NEWSLETTER

The Newsletter of the International Academy of Legal Medicine



Dear Members,

When you read this, summertime in Europe will be over and you will hopefully have had time to relax during your holiday. In this newsletter we will give you a short introduction to the Guidelines and Recommendations for European Ethics Committees. This document has been published by the European Forum for Good Clinical Practice (EFGCP), which is a non-profit organisation chartered under Belgian law. The chairman of the Ethics Working Party of the EFGCP is Francis Crawley.

The following review has been written by Dr. B. Karger from the Institute of Legal Medicine, University of Münster.

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Please note, that as of 12 October 1996, new area codes will come into being in Finland and the above numbers will be changed as follows: Tel.: +358 (2) 333 7543; FAX: +358 (2) 333 7600

Guidelines and Recommendations for European Ethics Committees

The European Forum for Good Clinical Practice (EFGCP) is an independent organisation established to promote the harmonious implementation of good clinical practice in Europe. The Ethics Working Party of the EFGCP has recently published Guidelines and Recommendations for European Ethics Committees, which represent an effort to provide a system of organising a more efficient review of proposed studies and to open a distinct area of discourse in biomedical ethics. The document is intended as a basis upon which ethics committees (EC) can develop their own specific procedures. Although the guidelines and recommendations focus on clinical trials involving medicinal products and substances, they are also intended to be useful in other areas of biomedical research.

The procedure for constituting an EC should comprise general membership requirements, the terms of appointment (duration of an appointment, disqualification and replacement procedure), the conditions of appointment (voluntary withdrawal if there is a conflict of interest, all reimbursement related to an EC must be made known to the chairman and public upon request, confidentiality covering information regarding applications and subjects), officers, and quorum requirements (minimum and maximum numbers of EC members, professional qualifications, sex and age distribution). Concerning the latter, a minimum of 5 persons including 2 physicians, one layperson, one lawyer and one paramedical are recommended to be required to compose a quorum. Furthermore, the quorum should represent the cultural make-up of the local community.

The procedure for submitting an application should be well defined and established in detail including formal, technical and timewise factors. The documentation required for a review should include an application form, a protocol of the proposed research, a summary of the scientific state of the art, the investigator(s)'s curriculum vitae, the material used for subject recruitment and information, an informed consent form, indemnity agreements for liability, all significant previous decisions by other ECs for the proposed study and compensations made to subjects. A statement certifying that investigators have no vested interest in the outcome of the study and disclosure of a potential conflict of

interests is recommended, but full disclosure of payments to investigators is not required. A detailed registration procedure for all incoming applications should be established.

ECs are to meet in accordance with published meeting dates following a previously scheduled agenda. It is recommended that ECs meet every 4 weeks and never less than 6 times per year. When appropriate, the applicant, outside experts or special interest groups are to be invited to assist the meeting. The elements of the review should comprise all the information submitted, the suitability of the protocol and the data collection forms, the statistical analysis and the scientific efficiency, the suitability of the investigator, the adequacy of the site (staff, facilities) and of provisions made for monitoring the conduct, the adequacy of the recruitment and information of the subjects, the insurance and indemnity agreements covering the liability of the investigator and the measures taken to insure the confidentiality of personal subject information.

An EC's decision may only be taken when sufficient time has been made for review and discussion following the removal of all third parties. An EC is to follow a predefined method for arriving at a decision. It is recommended that a decision be arrived at through consensus or, when a consensus appears unlikely, that the chairperson calls for a vote with a two-thirds majority. In the latter case, all dissenting members are to be given an opportunity to append an opinion to the EC's decision. An EC may append advice to the decision which is not constraining or it may make a conditional decision. A decision is to be communicated within 2 weeks time of the meeting and should include, among other things, a clear statement of the decision, any advice, opinion or requirement adjoined to the decision, a statement of the responsibilities of the applicant and, in case of a negative decision, the clearly defined reasons for this decision.

ECs are responsible for establishing a review procedure for following the progress of all studies until termination. A follow-up review should be conducted at least once a year. Any amendment to the protocol likely to affect the safety of the subjects, serious adverse events in human subjects or any event or new information that may effect the benefits/risks ratio. It is recommended that ECs require a copy of the final report of a study. A documentation and archiving procedure is to be established in detail, including authorised persons having access to the archives. It is recommended that all archived material be maintained for a minimum of 15 years.

Altogether, there are no major collisions with most of the existing regulations governing the work of ECs. The guidelines provide a general framework that has to be put in concrete terms. The recommendations represent a first step in this direction. In April 1995, the Swiss Department medical, Office intercantonal de controle des medicaments used the guidelines and recommendations as a basis for a guideline of standard procedures for ethics committees in Switzerland by adopting them to the Swiss legal and medical research environment.

B. Karger

DIARY OF FORTHCOMING MEETINGS

OSAKA, JAPAN, 2-4 September 1996

The 3rd International Symposium. Advances in Legal Medicine (ISALM).

Organized by The Medico-Legal Society of Japan. Deutsche Gesellschaft für Rechtsmedizin

Further information: Secretariat for the 3rd International Symposium, Advances in Legal Medicine (ISALM)
c/o Conference and Event Department, Simul International, Inc. Kowa Bldg. No. 9, 1-8-10,
Akasaka, Minato-ku, Tokyo 107, Japan; Tel.: +81 (3) 3586 8691, FAX: +81 (3) 3586 4531

SYDNEY, AUSTRALIA, 8-13 September 1996

13th International Symposium on the Forensic Sciences

Further information: Mr. Graham Cook, ANZFSS Symposium Secretary, Locked Bag 4,
Lidcombe NSW 2141, Australia; Tel.: +61 (2) 646 0311, FAX: +61 (2) 646 0333

DUBLIN, IRELAND, 25-27 September 1996

Advances in Forensic Science

Further information: Dr. S McDermott, The Forensic Science Laboratory,
Garda HQ, Phoenix Park, Dublin 8, Republic of Ireland;
Tel.: +353 / 677 156, FAX: +353 / 679 4667, shechane@10L.IE

ALICANTE, SPAIN, 22–25 September 1996

EUROTOX'96 in collaboration with the Spanish Association of Toxicology

Further information: Congress Secretariat: VIAJES HISPANIA, S.A. EUROTOX'96 Congress, Maisonnave, 11-7°, E-03003 Alicante (Spain); Tel.: +34 (9) 6522 8393, FAX: +34 (9) 6522 9888

BUDAPEST, HUNGARY, 20–25 October 1996

XXI International Congress of the International Academy of Pathology and 12th World Congress of Academic and Environmental Pathology

Further information: XII International Congress of The International Academy of Pathology and 12th World Congress of Academic and Environmental Pathology, 2nd Department of Pathology, Semmelweis University of Medicine, Üllői út 93., H-1091 Budapest, Hungary; Tel./FAX: +36 (1) 215 -7591 and -6921

LÜBECK, GERMANY, 6–7 December 1996

VII. Lübeck Workshop of Legal Medicine: "Neurotraumatology"

Language: English

Further information: Professor M. Oehmichen, Department of Legal Medicine, Medical University of Lübeck, Kahlhorstrasse 31-35, 23562 Lübeck, Germany; Tel.: +49 (451) 500 2750, FAX: +49 (451) 500 2760

STOCKHOLM, SWEDEN, 28 June – July 1997

6th Congress of ESBRA, European Society of Biomedical Research on Alcoholism

Further information: Chairman of the 6th Congress: Associate Professor Stefan Borg, Karolinska Institute, Department of Neuroscience, St Görans Hospital, Address: Psykiatriska Beroendekliniken, St Görans Sjukhus, Box 12557, S-102 29 Stockholm, Sweden; Tel.: +46 (8) 672 1451, FAX: +46 (8) 672 1904

OSLO, NORWAY, 2–5 July 1997

Meeting of the European Association of Poisons Centres and Clinical Toxicologists

Further information: Congress Secretariate EAPCCT Scientific meeting Oslo 1977
c/o Help Arrangement-Service AS, P.O. Box 527, N-1301 Sandvika, Norway

ODENSE, DENMARK, 13–16 August 1997

The XIII Nordic Congress of Forensic Medicine

Further information: Institute of Forensic Medicine, Winsløwparken 17, DK-5000 Odense C, Denmark

DUBLIN, IRELAND, 20–23 August 1997

The XVII Congress of the International Academy of Legal Medicine (IALM)

Further Information: Prof. J.F.A. Harbison, Office of the State Pathologist and T.C.D./R.C.S.I. Department of Forensic Medicine, 188 Pearse Street, Trinity College, Dublin 2, Ireland;

Tel.: +353 (1) 671 9835; FAX: +353 (1) 677 2694

or Ms. Louise Loughran, Confrence Secretary, Royal College of Surgeons in Ireland, 123 Stephen's Green, Dublin 2, Ireland, where the Congress will be held

COPENHAGEN, DENMARK, 26 June – 2 July 1998

The 9th Congress of the International Society for Biomedical Research on Alcoholisms (ISBRA)

Further information: Prof. Christer Alling, Department of Medical Neurochemistry, Institute of Laboratory Medicine, University Hospital, S-221 85 Lund, Sweden



ACADÉMIE INTERNATIONALE DE MÉDECINE LÉGALE
INTERNATIONAL ACADEMY OF LEGAL MEDICINE

CANDIDATURE

APPLICATION FOR MEMBERSHIP

Name.....First Name(s).....Title.....

Address for correspondence.....

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Tel..... Fax..... E-mail:.....

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Brief Curriculum Vitae:.....

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Date:..... Signature:.....