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Reflections on Running Training Workshops for Research Ethics Committee Members in Spain Between 2001 and 2008

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Aim To present the experience of running workshops for members of research ethics committees (REC) in Spain from 2001-2008 by a non-profit institution.

Methods We analyzed data from 7 sessions of the course, involving 165 health professionals. Data were taken from an opinion survey conducted at the end of each seminar and a deferred questionnaire sent after the workshops.

Results Opinions of 122 participants who completed the first questionnaire (84% of the 146 attendees) on these training courses were very positive (median, ≥4.5 out of 5). The second questionnaire was administered a few months after each session, and a total of 43 participants responded (36% of 118). The participants improved their knowledge, attitude, and skills (median, 4.0 out of 5) in most of the areas evaluated. Furthermore, they believed that training for REC members should be mandatory (median, 5.0 out of 5) and carried out regularly (median, 4.0 out of 5). The lack of communication between RECs and limitations in monitoring clinical trials (median, 4.5 out of 5) were the main problems according to respondents. Training was rated as a strong necessity (median, 4.0 out of 5).

Conclusion The courses were well received, they contributed to the overall learning of the participants, and served to highlight some of the major problems faced by REC members. These results emphasize the importance of training.

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The main function of research ethics committees (REC) is to ensure the protection of human subjects in biomedical and behavioral research and to provide an adequate public guarantee in this regard, such as was ratified in the subsequent European directive (1). RECs are commonly known in Spain as *Comités Éticos de Investigación Clínica,* in the US as Institutional Review Boards, and in Canada as Research Ethics Boards. In Spain, they were established in 1990 when the Spanish Medicines Act made them compulsory for clinical research, especially drug research (2).

As outlined in the current Spanish regulations (1,3,4), RECs must comprise at least 9 members, including medical and non-medical professionals, and must ensure the independence of their decisions. They must also ensure their competence and experience in the methodological, ethical, and legal aspects of the research, and in the pharmacology and clinical practice both inside and outside of the hospital. The most recent policy change that has affected RECs came as a result of the Spanish Biomedical Research Act, which changed the name of these committees and expanded their functions (5).

Although the several Spanish regulations on RECs date back more than 20 years, it was not until 2004 that training activities for members in the various ethical, methodological, and administrative aspects were considered necessary (3). The Coordinating Center of RECs (in Spanish, *Centro Coordinador de Comités Éticos de Investigación Clínica,* CC-CEIC) was created as part of the Department of Pharmacy and Health Products of the Spanish Ministry of Health to take over the responsibility of organizing these activities for the then 127 RECs in Spain. However, two more years passed before CC-CEIC initiated training courses.

Until the CC-CEIC began its training initiative, how were the members of the RECs trained? How did they acquire the necessary skills? Many of them had to organize their own training in order to acquire the competencies needed to carry out their duties. In those areas where they lacked experience they generally learned through their daily work in the REC and especially through personal effort, which was not always sufficiently recognized (6). Furthermore, what happened when for some reason it was necessary to replace a member of the REC? It is obvious that REC members can only fulfill their statutory function through adequate training (7,8).

It was this situation that provided the catalyst for the initiative launched by two of the authors of this paper (JEB and FB), with the support of the Esteve Foundation. With the experience gained from previous initiatives (9), a series of workshops entitled "Introduction to the Functioning of RECs" was scheduled with the aim of training REC members. These courses were designed according to an interactive format similar to previous training activities organized by the Esteve Foundation (10). After 8 years of organizing such seminars for REC members between 2001-2008 (11-17), these activities eventually ceased after CC-CEIC began its training initiative in 2006.

In this article, our aim is to identify the best practices based on experience of giving these seminars over 8 years, and also to guide future efforts to ensure the efficiency of this type of training. We analyze the workshop outcomes in the following areas: the acceptability of such courses for participants; the main problems and areas for improvement in RECs and proposed solutions; and, finally, the degree of improvement in the knowledge, skills, and attitudes of those attending the seminars.

METHODS

Characteristics of the training workshops

In total, 7 sessions of the seminar "Introduction to the Functioning of RECs" were organized between 2001 and 2008 in 7 Spanish cities (Table 1). With an almost identical format and with the participation of 2 teachers in each session, these courses were also conducted in several Spanish cities in collaboration with various institutions (Table 1). With the exception of the first 2 sessions, in which Dr Inés Galende (Servicio de Regulación Sanitaria, Consejería de Sanidad, Comunidad de Madrid) also participated, all the courses were taught by two of the authors (JEB and MIL).

All courses were advertised through the Esteve Foundation mailing list, comprising mainly professionals in fields related to pharmacology, as well as through Spanish medical societies. A small fee was asked (€ 50) for every two-day seminar, and the course was also offered free to recently graduated professionals. Each course had an intensive format and ran all day on two consecutive days, with a total duration of 16 teaching hours. The themes and content of each session are detailed in Table 2. Teaching methods involved lectures, discussions of cases and an REC simulation, in which the entire group was divided into two committees to discuss a real clinical trial protocol.

TABLE 1. General information on the training workshops for Research Ethics Committee members in Spain

Date of workshop	City in Spain	Collaborating institutions*	No. of participants (women/men)†
May 2001	Bellaterra (Barcelona)		19 (9/10)
November 2001	San Lorenzo de El Escorial (Madrid)		22 (13/9)
June 2002	Antequera (Málaga)	Málaga University	21 (14/7)
December 2002	Alzira (Valencia)	La Ribera Hospital	30 (18/12)
June 2003	Donosti (Guipúzcoa)	University of the Basque Country and Donosti Hospital	26 (16/10)
January 2004	Palma de Mallorca	Son Llàtzer Hospital y Balearic Islands Department of Health	28 (16/12)
April 2008	Cáceres	School of Health Sciences Studies in Extremadura	19 (15/4)

*Apart from the first two workshops, which were organized by the Esteve Foundation, all of them were conducted in collaboration with the institutions specified.
†There were 165 participants in total (101 women, 64 men).

TABLE 2. Format and content of the training workshops for Research Ethics Committee (REC) members in Spain

Format	
1st day – morning	Lectures on general aspects of clinical research
1st day – afternoon	Discussion of a case in small groups
2nd day – morning	Discussion in two groups simulating the evaluation of a real clinical trial protocol by two RECs
2nd day – afternoon	Final joint discussion on a clinical trial protocol
Themes developed	
Lectures	Development and historical context of RECs
	Research and development process for new drugs
	Legal context of RECs and of clinical research
	Methodological basis for the evaluation of clinical trials
	Bioethical basis for the evaluation of clinical trials
	Administrative aspects of the evaluation and approval of clinical trials in Spain; the European directive and relevant Spanish legislation; Spanish Data Protection Act
Discussion of a case in small groups	Identification of potential conflicts of interest that may arise during the REC meeting Defining the main problems affecting the proper functioning of RECs
Discussion in two groups	Evaluation of the methodological and bioethical aspects of a real clinical trial protocol (in groups designed to simulate the size of actual RECs)

Difficulties faced by an REC

During the first two workshops, discussion groups were formed to consider what participants considered the main problems affecting RECs in Spain. In addition to this list of problems, a second list of suggestions of how to improve the functioning of RECs was prepared by the attendees.

Opinion questionnaire

At the end of each workshop, participants were asked to complete a voluntary opinion questionnaire about the workshop. The questionnaire consisted of several questions about the course, materials, organization, teachers, and other aspects, with the aim of improving those areas that received lower scores. Each parameter was rated on a Likert-type scale from 0 "very inadequate" to 5 "very adequate."

Deferred questionnaire

Between the fifth and sixth session of the seminar (January and February 2004) a questionnaire was sent to all participants of the 5 previous seminars, followed by at least 2 reminders by email if they did not respond. This means that the interval between the seminar and the deferred questionnaire ranged from 4 months to 3 years, depending on when the participant took the course. An introductory message was sent by email (or fax) with the questionnaire attached (in Word format). It analyzed whether participation in the courses had led to improved knowledge, attitudes, and skills in their daily work. Other questions were aimed at soliciting their opinion on the need for such courses. Those who were members of RECs were also asked about their perspectives on the future and their concerns. Drawing on the list of important issues elicited in the first two workshops, information was sought on what

issues were considered priorities. This questionnaire used a Likert-type scale of 5 options ranging from 1 "strongly disagree" to 5 "strongly agree." Instructions on the scale and how to complete the questionnaire were included in the file attached to the email containing the questionnaire.

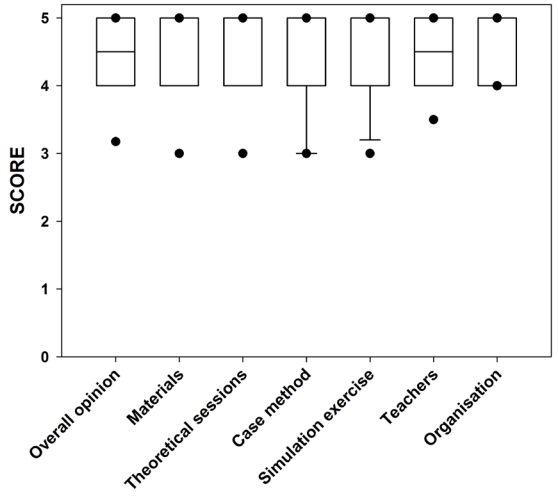
Data processing

Data were processed using the statistical package SAS® Enterprise Guide® (SAS Institute Inc., Cary, NC, USA). For the presentation of the results median and ranges were calculated. For comparison between means the Wilcoxon rank-sum test was used. Data were presented as a box-plot.

RESULTS

A total of 165 health professionals, of whom 101 (61%) were women, attended the 7 training workshops. Participants belonged to diverse disciplines: biochemistry, biology, cardiology, clinical analysis, emergency medicine, epidemiology and public health, hematology, hepatology, general practice, infectious diseases and microbiology, internal medicine, law, medical management, neurology, nursing, oncology, pharmacology, pharmacy, psychiatry, surgery, urology, and zoology.

Figure 1.



Scores obtained from the opinion questionnaires administered at the end of the workshops. Data were collected from 122 of the 146 participants (83.6%) of the first 6 workshops. Each parameter was scored on a scale of 0 (very bad) to 5 (very good). Results are represented in box plots, where the boundary of the box closest to zero indicates the 25th percentile, the line within the box marks the median (if not present, the median coincides with the 25th percentile), and the boundary of the box farthest from zero indicates the 75th percentile. The 95th and 5th percentiles are represented as whiskers (error bars) above and below the box; at least 9 data points are needed to represent each whisker. Outliers are shown as isolated dots. The box encloses 50% of the data.

A total of 122 (84%) of the 146 participants who attended the first 6 seminars completed the first questionnaire. As shown in Figure 1, the opinion on the workshops was very high, in particular in relation to the overall assessment, the work of the teachers, materials, and the organization of the seminars (median ≥4.5 out of a maximum of 5).

Deferred questionnaire was sent to a total of 118 participants of the first 5 sessions of the workshop. In this questionnaire, 43 participants (36%) gave their opinion on the usefulness of these courses, of which 27 (63%) were female and 16 (37%) men. The majority of respondents were medical doctors (51%). Of these participants, 21 (49%) said they were members of an REC at the time of completing the questionnaire.

TABLE 3. Scores for knowledge, attitudes, and skills after participating in the workshop for Research Ethics Committee (REC) members in Spain (deferred questionnaire)*

	Median score (range)
Knowledge of:	
clinical trial methodology	4.0 (1-5)
bioethical principles applied to a clinical trial	4.0 (1-5)
research and development of medicines	3.0 (1-5)
evaluation process for protocols	4.0 (2-5)
the administrative process for the approval of protocols	4.0 (1-5)
overall knowledge	4.0 (1-5)
Attitudes in relation to:	
My opinion about the usefulness of clinical trials of drugs is more favorable.	3.0 (1-5)
I understand better the difficulties involved in the clinical research of drugs.	4.0 (1-5)
I can better analyze the bioethical aspects of clinical research of drugs.	4.0 (1-5)
overall attitude	4.0 (1-5)
Skills in relation to:	
I understand better what is expected of an REC member.	4.0 (2-5)
My assessment of protocols is more efficient.	4.0 (3-5)
I feel more capable in deciding whether or not to approve a protocol.	4.0 (2-5)
I feel more capable to evaluate informed consent forms.	4.0 (3-5)
overall abilities	4.0 (2-5)

*Each parameter was scored on a scale from 1 (strongly disagree) to 5 (strongly agree). Applying the Wilcoxon rank-sum test, no significant differences between membership or not in an ethics committee was found for any of the variables.

TABLE 4. Opinion on the training workshops for Research Ethics Committee (REC) members in Spain (deferred questionnaire)*

	Median score (range)		
	total (n=43)	REC members (n=21)	not REC members (n=22)
Item "I believe this training..."			
should be obligatory for members	5.0 (1-5)	5.0 (1-5)	5.0 (3-5)
should be voluntary for members	2.0 (1-5)	2.0 (1-5)	2.0 (1-5)
should be carried out on a regular basis	4.0 (3-5)	5.0 (4-5)	4.0 (3-5)

*Each parameter was scored on a scale from 1 (strongly disagree) to 5 (strongly agree). Applying the Wilcoxon rank-sum test, no significant differences between members and non-members of an REC were found for any of the variables.

According to the questionnaire responses, health professionals considered that they had achieved an improvement in their knowledge, attitudes, and skills after completion of the course (Table 3). There were no significant differences in the opinion between members and non-members of an REC on the data obtained from the deferred questionnaire (data not shown). On the other hand, there appeared to be unanimous demand for such seminars to be mandatory training for members of RECs (median 5), and for their implementation on a regular basis (median 4) (Table 4).

From the list of problems drawn up during the first 2 workshops and included in the deferred questionnaire, 26 (60%) participants (15 women and 11 men), who had at some time been involved in an REC, scored each problem from 1 (strongly disagree) to 5 (strongly agree). The list and an assessment of each problem can be found in Table 5. During the preparation of this list, participants in the first 3 workshops engaged in group discussions and proposed some solutions to those problems that interfere with the day-to-day functioning of the REC (Table 6).

DISCUSSION

Broadly speaking, it appears that these courses were well regarded. At the same time, they yielded information about the limitations and expectations of REC members at a time when no institution had the explicit responsibility of providing training for them. These training workshops were also a challenge for the organizers since there were no such previous initiatives in Spain, and they were filling an unmet need.

The success of the courses was probably due to some of the following: a) the intensive format – although

TABLE 5. Participants' scoring of the main problems affecting the proper functioning of Research Ethics Committee (REC) members in Spain (deferred questionnaire)*

Main problems	Median (range)
1. Limitations in the adequate monitoring of studies	4.5 (2-5)
2. Lack of communication between different RECs	4.5 (2-5)
3. Excessive workload and too much bureaucracy	4.0 (2-5)
4. Lack of adequate training for REC members	4.0 (3-5)
5. Lack of consistent standards in the evaluation of protocols	4.0 (1-5)
6. Insufficient pay and recognition of REC members	4.0 (1-5)
7. Lack of resources and facilities	4.0 (1-5)
8. Impossibility of a sufficiently thorough review of protocols	4.0 (1-5)
9. The requirements imposed by European Directive 2001/20/EC	4.0 (1-5)
10. Problems of an REC in organizing itself	4.0 (1-5)
11. Need for proper economic management	3.8 (2-5)
12. Lack of consistency in administrative procedures	3.0 (1-5)
13. Conflicts with researchers	3.0 (1-5)
14. Problems related to group dynamics within the REC	3.0 (1-5)
15. Conflicts of interest with pharmaceutical companies	3.0 (1-5)
16. Selection procedures for REC members	3.0 (1-5)
17. Conflicts with hospital management	2.0 (1-5)
18. Conflicts with health authorities	2.5 (1-4)

*Each parameter was scored on a scale from 1 (strongly disagree) to 5 (strongly agree). Data were collected from deferred questionnaires completed by 26 people who had been or were currently members of an REC (61% of the 43 participants who completed the questionnaire), of which 15 (58%) were women and 11 (42%) men.

it involves losing two days of work, this may prove to be more efficient than courses of a few hours repeated during consecutive weeks (7); b) splitting up into small groups of 20 people – this facilitates interaction and learning due to the personalized attention that each attendee receives; c) the combination of participatory teaching methods (discussions) and practical case studies and role play; d) delivery of the workshops by two teachers – this facilitates the exchange of views and makes the course more entertaining; and finally e) the very small registration fee and the availability of grants to attend the workshop – the course was organized by a non-profit institution and the fees were not intended to fund the workshop, therefore it was much more feasible economically for those who wished to attend. As such, this type of collaboration between public institutions (academic, health care, training, scientific societies) and private institutions (such as the Esteve Foundation) can be highly recommended.

Courses, workshops, and other training initiatives for REC members have been used as a format in Spain (18), as well

TABLE 6. **Proposals to improve the work of Research Ethics Committee (REC) members in Spain***

1. Standardize all economic aspects of the committees, eg, hospital and investigator contracts.
2. RECs should have better access to documentation, materials, and support from Human Resources.
3. Make all official REC documents as uniform as possible, including application letters and forms, recruitment information, facilities reports, economic proposals and certificates.
4. Improve the qualifications of REC members.
5. Achieve greater professional recognition of REC members.
6. Have a monitor/auditor available – either internal or external to the REC – to be responsible for the proper monitoring of studies.
7. Include a representative of primary care as a member of the REC.
8. Publish, in electronic or print format, some kind of newsletter by or for the RECs.
9. Create a network of discussion to encourage the exchange of information between RECs.
10. Disseminate and communicate clinical research findings through RECs.

*Opinions expressed by participants and teachers after group discussion during the first three workshops, in which there were 62 participants, 36 (58%) women and 26 (50%) men.

as in other countries (7,9,19). The first described experience was specifically aimed at phase 1 volunteer studies (9), which is an important difference from the experience we describe. In 2003, the National Bioethics Committee for Medicine in Croatia held a workshop for members of hospital ethics committees (19). A survey of the 107 participants was performed following this workshop and it was found that members' level of knowledge was greater after the course. It was also found, as in our study, that most respondents felt their knowledge could be improved by additional training (19).

Although the workshop format is only one type of model, there are other alternatives such as books on bioethics training and research, teaching materials, or selections of articles that RECs can provide for the training of its members (6). Online learning systems are another option (7). Furthermore, a guide for ethics committees has been recently published that includes case studies on issues related to the REC (20).

The active participation of attendees in the workshops described in this article allowed us to gather information about their concerns and proposals regarding the work of RECs. Among the problems highlighted at the time of completing the questionnaire was the lack of training for committee members, along with other issues such as lack of communication between different RECs, overwork, excessive bureaucracy, and the problem of monitoring studies. Both the lack of communication between committees and the problem of monitoring studies could be improved with information technology initiatives, such as the Spanish databases GESTO and SIC-CEIC (21). The problems of RECs unearthed through our training workshops, along with other more diverse issues, have also arisen in publications and surveys conducted in Spain (22-24), as well as in other countries (25-30). Even though we highlighted the need for consistent standards among the different Spanish RECs, this problem is even more evident at the European level (31).

We are in agreement with the recommendations proposed by participants to improve the work of RECs. We would add our own recommendations which would be to create a central database of RECs with contact information that would be kept, updated, and disseminated periodically by one centralized Spanish organization.

The deferred questionnaire conducted after the training seminars collected data on the views of participants regarding the applicability of the knowledge, attitudes, and skills acquired during the course. The data clearly demonstrated the usefulness of the courses. This questionnaire also demonstrated the unanimous demand for compulsory courses, as well as the need for their implementation on a regular basis for REC members. This finding is in accordance with other works on this subject, which show a demand for continuing medical education and training for REC members (8). It has even been proposed that the accreditation of RECs should be linked to the training of committee members and that the nomination of a new member should necessarily be preceded by a training course (7). Regarding the contents of the training courses, it is worth mentioning that a survey was conducted in 3 African countries in which REC members were questioned about their training needs (32). It was found that among their chief concerns were fundamental ethical principles, regulatory issues, and evaluation of informed consent, all of which arose in the workshops discussed in this article.

The need to communicate findings about REC training is essential for continuous quality improvement. Although CC-CEIC has organized at least 2 basic training courses for REC members, nothing was published on how these courses were run or how they were received. Consequently, an additional advantage of the workshops discussed in this article is the effort made to publish information on what they involved, which is also what this article aims to do. Outside of Spain, there are various data on the experience of running training courses for REC members (9,19).

The data presented verify that this activity proved to be a positive experience, while at the same time indicating some limitations of this study. The first questionnaire can be considered representative of the attitude of attendees as more than 80% of them responded; however, only 36% responded to the deferred questionnaire, even though at least 2 reminders were sent. It should also be noted that both the training seminars and this study were conducted between 2001 and 2008, when there were significant changes in the world of clinical research, including the European directive (1), the Spanish Data Protection Act (33), and most importantly (34), the Biomedical Research Act (5). Another limitation of this study is that it assessed participants' self-evaluation but not their actual knowledge, skills, and attitudes after the training. That would have required a different analysis on objective measures of attendees' performance. In addition, it would have been more rigorous to have asked about their knowledge before and after the seminar, since it is possible that some participants already had good knowledge in some areas before attending the training.

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Conflict of interest: Two of the authors (JEB and MIL) were teachers at the seminars, for which they received salaries from the Esteve Foundation. The other two authors (ES and FB) are members of the Esteve Foundation.

References

1 Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Official Journal of the European Communities. 2001;L121:34-44.

2 Spanish Law 25/1990 on drugs [in Spanish]. BOE. 1990;306:38228-46.

3 Spanish Royal Decree 223/2004 through which drug clinical trials are regulated [in Spanish]. BOE. 2004;33:5429-43.

4 Spanish Law 29/2006 of guarantees and rational use of drugs and medicinal products [in Spanish]. BOE. 2006;178:28122-65.

5 Spanish Law 14/2007 of biomedical research [in Spanish]. BOE. 2007;159:28826-48.

6 Hoffmann D, Tarzian A, O'Neil JA. Are ethics committee members competent to consult? J Law Med Ethics. 2000;28:30-40, 2. Medline:11067630 doi:10.1111/j.1748-720X.2000.tb00314.x

7 Davies H, Wells F, Druml C. How can we provide effective training for research ethics committee members? A European assessment. J Med Ethics. 2008;34:301-2. Medline:18375685 doi:10.1136/jme.2007.021485

8 Ricci G, Cannovo N. The importance of the training of Ethics Committee members. Med Law. 2009;28:649-59. Medline:20157976

9 Doyle K, Tiner R. Training and development conferences for members of research ethics committees assessing clinical pharmacology studies. Br J Clin Pharmacol. 1998;46:347-9. Medline:9803982 doi:10.1046/j.1365-2125.1998.t01-1-00798.x

10 Bosch F, Baños JE, Erill S. Medical education beyond patient-physician relationship: an experience from the Esteve Foundation. Educación Médica. 2004;7:47-8.

11 Baños JE, Bosch F, Galende I, Lucena MI. Training for optimal service in Research Ethics Committees: an experience in Spain. ESRA Rapporteur. 2003;May-June:19-21.

12 Bosch F, Morales P, Lucena MI, Baños JE. Present and future of Research Ethics Committees in Spain: the challenge of the training courses. Clin Exp Pharmacol Physiol. 2004;31 Suppl 1:A81.

13 Bosch F, Morales P, Lucena MI, Baños JE. Challenge of the training courses for research ethical committees' members [in Spanish]. Revista Andaluza de Patología Digestiva. 2005;28:14-20.

14 Bosch F. Experience in continuing education from a scientific foundation. In: Algorta J, Loza M, Luque A, coordinators. Reflections on the training in drug research and development [in

Spanish/English]. Cuadernos de la Fundación Dr. Antonio Esteve. 10. Barcelona (Spain): Fundación Dr. Antonio Esteve; 2007. p. 63-75.

15 Galende I, Bosch F, Baños JE. Training for REC members. Experience of two seminars organized by the Esteve Foundation [in Spanish]. ICB Digital. 2002 August [cited 2010 June 1]; (7):2-8. Available from: http://www.icf.uab.es/icbdigital/pdf/articulo/articulo7.pdf. Accessed: November 17, 2010.

16 Lucena MI, Bosch F, Baños JE. Committees on Ethics and Clinical Research over 10 years: risks of complacency [in Spanish]. Med Clin (Barc). 2003;120:257-60. Medline:12623002

17 Morales P, Bosch F. Some training proposals for REC members [in Spanish]. ICB Digital. 2005 December [cited 2010 June 1];(37):2-5. Available from: http://www.icf.uab.es/icbdigital/pdf/articulo/articulo37.pdf. Accessed: November 17, 2010.

18 Saldaña M. Research ethics committees' meeting [in Spanish]. ICB Digital. 2008 June [cited 2010 June 1];(special number):1-4. Available from: http://www.icf.uab.es/icbdigital/pdf/noticias/noticias-2.pdf. Accessed: November 17, 2010.

19 Borovecki A, ten Have H, Oreskovic S. Education of ethics committee members: experiences from Croatia. J Med Ethics. 2006;32:138-42. Medline:16507656 doi:10.1136/jme.2005.011643

20 Karlberg JP, Speers MA. Reviewing clinical trials: a guide for the Ethics Committee. Hong Kong: Karlberg, Johan Petter Einar; 2010.

21 Research Ethics Committees of Balearic Islands. Information Systems [in Catalan]. Available from: http://www.ceicsalut.com/pag-cat/sistemes-informacio.htm. Accessed: November 11, 2010.

22 de Pablo I, Gálvez MÁ. Functions of the Research Ethics Committee: follow-up [in Spanish]. ICB Digital. 2008 January-February [cited 2010 June 1]; (51):1-6. Available from: http://www.icf.uab.es/icbdigital/pdf/articulo/articulo51.pdf. Accessed: November 17, 2010.

23 García Sáiz M, Boada Juárez JN. Adjustment of the Research Ethics Committees (REC) after the application of the new legislation on drug clinical trails. Results of a survey among the accredited RECs [in Spanish]. ICB Digital. 2005 March [cited 2010 June 1]; (29):1-8. Available from: http://www.icf.uab.es/icbdigital/pdf/articulo/articulo29.pdf Accessed: November 17, 2010.

24 Saldaña Valderas M, Quintero Sierra MJ. Resources of Spanish clinical research ethics committees [in Spanish]. Med Clin (Barc). 2009;132:476-80. Medline:19278693

25 Druml C, Wolzt M, Pleiner J, Singer EA. Research ethics committees in Europe: trials and tribulations. Intensive Care Med. 2009;35:1636-40. Medline:19543709 doi:10.1007/s00134-009-1544-y

26 Nicholl J. The ethics of research ethics committees. BMJ. 2000;320:1217. Medline:10784570 doi:10.1136/bmj.320.7243.1217

27 Russ H, Busta S, Riedel A, Zöllner G, Jost B. Evaluation of clinical trials by Ethics Committees in Germany: experience of applicants with the review of requests for opinion of the Ethics Committees – results of a survey among members of the German Association of Research-Based Pharmaceutical Companies (VFA). Ger Med Sci. 2009;7:Doc07. Medline:19675747

28 Shaul R. Reviewing the reviewers: the vague accountability of research ethics committees. Crit Care. 2002;6:121-2. Medline:11983036 doi:10.1186/cc1469

29 Jamrozik K. Research ethics paperwork: what is the plot we seem to have lost? BMJ. 2004;329:286-7. Medline:15284159 doi:10.1136/bmj.329.7460.286

30 Smajdor A, Sydes MR, Gelling L, Wilkinson M. Applying for ethical approval for research in the United Kingdom. BMJ. 2010;339:b4013. doi:10.1136/bmj.b4013

31 Hernandez R, Cooney M, Duale C, Galvez M, Gaynor S, Kardos G, et al. Harmonisation of ethics committees' practice in 10 European countries. J Med Ethics. 2009;35:696-700. Medline:19880708 doi:10.1136/jme.2009.030551

32 Ateudjieu J, Williams J, Hirtle M, Baume C, Ikingura J, Niare A, et al. Training needs assessment in research ethics evaluation among research ethics committee members in three African countries: Cameroon, Mali and Tanzania. Dev World Bioeth. 2010;10:88-98. Medline:19912281 doi:10.1111/j.1471-8847.2009.00266.x

33 Royal Decree 1720/2007 through which the Regulations of development of the Organic Law 15/1999 is approved, of personal data protection [in Spanish]. BOE. 2008;17:4103-36.

34 Ramiro Aviles MA. Impact of Spanish Law 14/2007 of biomedical research on clinical trials [in Spanish]. Med Clin (Barc). 2008;130:783-6. Medline:18579033