



The outcome of the inspection program on Institutional Review Board/ Ethics Committee in Taiwan: Preliminary results.

Authors: R.T. Cheng, Y.C. Lee, L.J. Huang, I.A. Chen

Taiwan Joint Commission on Hospital Accreditation, Taipei, Taiwan

Objectives:

To study the implementation effects for improving the performance of Institutional Review Board/ Ethics Committee (IRB/EC) inspection program in Taiwan.

Methods:

Taiwan Joint Commission on Hospital Accreditation (hereinafter referred to as TJCHA) has established an “IRB/EC Survey program” since 2005. The work items included to establish the expert task force group, hold the Survey Interpretation Conference, appoint and train professional surveyors, hold pre-survey and surveyors consensus workshops, schedule on-site inspection arrangement, and calculate and produce on-site inspection scores and comments, etc... A pilot on-site inspection was carried out in 2007, and later the formal on-site inspections were launched in 2009 and 2010.

In order to understand the process of administrative work and implementation effects, an analysis on the satisfaction questionnaires and a review on the survey results of the IRB/ECs over the years were carried out. Regarding the satisfaction questionnaires, 75 questionnaires were sent in 2009 and 38 questionnaires in 2010 to the surveyors and surveyed IRB/ECs of the correspondent year to understand their opinions on the inspection program. About the survey results of the IRB/ECs over the years, the main subjects were 22 surveyed IRB/ECs which participated in both the 2007 pilot on-site inspection and 2009 formal on-site inspections by using the t-test method ($\alpha = 0.05$) to compare the difference in the survey results in these two on-site inspection results in order to understand if there was any improvement.

Results:

- 1. The return rate of the satisfaction questionnaires was 93% in 2009 and 82% in 2010. Part of the questionnaire results were shown in Table 1. The surveyors and surveyed IRB/ECs showed satisfaction in the substantial benefits brought by the on-site inspection work, and most of them showed a positive identification on the survey design and application of survey work from TJCHA, especially on “providing the reference of improvement” and “providing the understanding of self ability to set the benchmarks.”
- 2. There were 31 IRB/ECs participated in the 2007 pilot on-site inspection, in which 22 involved again in the 2009 on-site inspections. The results found that 7 IRB/ECs showed a significant increase in the proportion of Grade C (and above); 6 IRB/ECs showed a decrease in proportion of Grade C (and above); 9 IRB/ECs did not show any significant score change (100%) of the two years with Grade C (and above), in which 6 IRB/ECs got 100% on both years. The detailed results were shown in Table 2.

Conclusions:

By the application of on-site inspection mechanism, the operation quality of Taiwan IRB/ECs is expected to promote with continuous improvement, to have the general consensus of the development and application on ethical review, and to protect the rights and privacy of the research subjects. The results can be provided to TJCHA to establish a more completed and comprehensive survey program to improve the quality of service and operation, as well as the integrity of development in biomedical researches.

Table 1. Surveyors and surveyed IRB/ECs’ opinions on the implementation of Institutional Review Board/ Ethics Committee (IRB/EC) inspection program in 2009 and 2010 (multiple choice)

Subject	Year 2009		Year 2010	
	Surveyor (N=31)	Surveyed IRB/EC (N=39)	Surveyor (N=19)	Surveyed IRB/EC (N=12)
	Percentage (%)			
Providing the reference of improvement	96.8	87.2	89.4	100
Providing the understanding of self ability and set the benchmarks	90.3	66.7	84.2	91.7
Enhancement of concerns and related IRB/EC actives	80.6	61.5	84.2	41.7
Enhancement of the communication among IRB/ECs	67.7	64.1	42.1	50
Assistance on the understanding of IRB/ECs related international trends	38.7	23.1	15.8	8.3
Assistance on the understanding of regulation and expertise for research subject protection	57.1	28.2	63.1	16.7
Gathering consensus and cohesion within the IRB/EC	58.1	46.2	47.4	33.3
Promotion on the research subject protection	74.2	48.7	63.1	25

Table 2. The percentage of scores achieving C or above of 22 IRB/ECs in both Year 2007 pilot on-site survey and Year 2009 on-site survey (C=average)

Number	Year 2007		Is there any significance?	Number	Year 2009		Is there any significance?
	The percentage of scores achieving C or above (%)	The percentage of scores achieving C or above (%)			The percentage of scores achieving C or above (%)	The percentage of scores achieving C or above (%)	
1	92	100	Significant high	12	100	100	No
2	97	95	Significant low	13	86	100	Significant high
3	91	100	Significant high	14	100	100	No
4	100	100	No	15	100	100	No
5	99	96	Significant low	16	99	100	No
6	96	100	No	17	99	96	Significant low
7	95	100	Significant high	18	88	77	Significant low
8	100	96	Significant low	19	100	93	Significant low
9	91	100	Significant high	20	100	100	No
10	88	95	Significant high	21	99	100	No
11	86	98	Significant high	22	100	100	No

