27 Novembre 2014

Trento

RICERC@

Gaia Marsico

Comitato Etico per la sperimentazione con l'essere umano, Università di Trento

Comitato Etico Locale, Az.U.S.L. 6 Livorno

RICERC@

Rete Italiana

Un'identità condivisa di rete per riaffermare la scelta di essere rappresentanti più che controllori di tante e diverse realtà sanitarie che devono essere protagoniste collettive della generazione di ricerche e di conoscenze utili per la cura e l'assistenza.

Comitati Etici

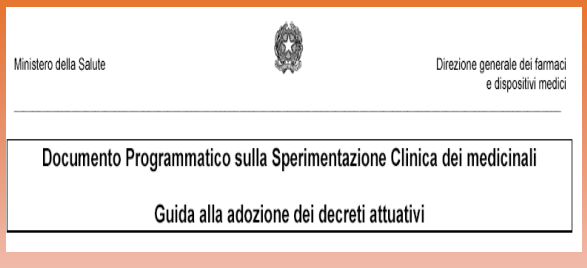
Come strumenti di sviluppo di una cultura diffusa sui ruoli e sugli stili della ricerca, consapevoli che la correttezza esecutiva e formale dei protocolli è uno strumento e non un fine.

Ricercatori

Perché questo ruolo sia pienamente integrato nell'attività di cura ed assistenza a la ricerca sia uno dei modi per dare risposta alle necessità dei propri assistiti.

Cittadini

Per trovare modi innovativi di una loro espressione nell'ambito dei Comitati etici, per meglio riflettere interessi e punti di vista della società, rispetto ai ruoli oggi prevalentemente formali, spesso irrilevanti, e resi ancora più marginalizzati dalla legislazione europea.



I COMITATI ETICI

Rappresentano la struttura di garanzia locale

dei cittadini-pazienti di cui è prevista la partecipazione cosciente ed informata alla sperimentazione

I Comitati etici "normalmente" incrociano problemi e devono prendere decisioni che rimandano a "ruoli" e "competenze" «etiche» e/o di diritto:

- ✓**In quali occasioni?**
- ✓**con quale frequenza?**
- ✓**solo per questioni legate al consenso?**
- ✓**quali sono i loro contenuti più rilevanti/interessanti?**
- ✓**Come vengono gestite, da chi, con quali risultati?**

Quanti di queste problematiche possono essere trasformate in progetti di ricerca?

- **L'informazione al paziente?**

…non solo…!

- **Gli studi che coinvolgono persone con bassa aspettativa di vita**
- **Gli studi di fase I-II**
- **Percezione/gestione della rilevanza nei comitati etici**
- **Il ruolo dei rappresentanti della cittadinanza-comunità**
- **Rapporti alla cittadinanza**
- **Il problema degli end-point**
- **La variabilità (e la trasparenza?) nella valutazione dei protocolli**
- **La capacità di fare «rete»**

….

….

Che cosa sappiamo dell'attività svolta dai COMITATI ETICI?

Published in final edited form as:
J Empir Res Hum Res Ethics. 2011 March ; 6(1): 3–19. doi:10.1525/jer.2011.6.1.3.

A Systematic Review of the Empirical Literature Evaluating IRBs: What We Know and What We Still Need to Learn

Lura Abbott and **Christine Grady**
National Institutes of Health

Abstract

institutional review boards (IRBs) are integral to the U.S. system of protection of human research participants. Evaluation of IRBs, although difficult, is essential. To date, no systematic review of IRB studies has been published. We conducted a systematic review of empirical studies of U.S. IRBs to determine what is known about the function of IRBs and to identify gaps in knowledge. A structured search in PubMed identified forty-three empirical studies evaluating U.S. IRBs. Studies were included if they reported an empirical investigation of the structure, process, outcomes, effectiveness, or variation of U.S. IRBs. The authors reviewed each study to extract information about study objectives, sample and methods, study results, and conclusions. Empirical evidence collected in forty-three published studies shows that for review of a wide range of types of research, U.S. IRBs differ in their application of the federal regulations, in the time they take to review studies, and in the decisions made. Existing studies show evidence of variation in multicenter review, inconsistent or ambiguous interpretation of the federal regulations, and inefficiencies in review. De
identified published study is
the structure, process, and o
inconsistencies and inefficie
research is needed to unders
important, what quality IRB
participants.

Ann Epidemiol. 2014 Oct;24(10):734-40. doi: 10.1016/j.annepidem.2014.06.100. Epub 2014 Jul 10.

Uncertainty about effects is a key factor influencing institutional review boards' approval of clinical studies.

Wao H[1], Mhaskar R[2], Kumar A[2], Miladinovic B[2], Guterbock T[3], Hozo I[4], Djulbegovic B[2].

⊕ Author information

Abstract

PURPOSE: To investigate factors, which influence institutional review boards' (IRBs') decision to approve or not approve clinical studies, a nationwide vignette-based online survey of IRB members was conducted.

METHODS: A factorial design was used, whereby seven aspects of each hypothetical study were randomly varied in 15 phrases in each vignette to produce unique vignettes. Participants indicated the degree of study approval and described factors influencing approval decision. Qualitative responses were thematically content analyzed.

RESULTS: Sixteen themes were obtained from 208 participants from 42 institutions. Uncertainty, adherence, study design, and harms were frequently and intensely cited to influence study approval. Analysis of two extreme subgroups (approvers vs. nonapprovers) showed that uncertainty influenced approval decisions, odds ratios (OR) = 3.5 (95% confidence interval [CI], 1.3-9.8) and OR = 3.2 (95% CI, 1.1-8.9), respectively, based on theme frequency and theme intensity, ignoring multiple observations per person. Taking into consideration multiple observations per person, similar results were obtained for uncertainty: OR = 8.9 (95% CI, 0.93-85.4).

CONCLUSIONS: Perceived uncertainty about benefits and harms of a proposed intervention is a key driver in IRB members' approval of clinical trials. This, in turn, calls for improved standardization in the communications of information on benefits and harms in the research protocols considered by the IRBs.

Published by Elsevier Inc.

KEYWORDS: Benefit risk assessment; Clinical ethics committee; Clinical protocols; Decision-making; Empirical research; Institutional review board;

Clin Trials. 2013 Aug;10(4):560-7. doi: 10.1177/1740774513484393. Epub 2013 May 10.

Use of central institutional review boards for multicenter clinical trials in the United States: a review of the literature.

Check DK[1], Weinfurt KP, Dombeck CB, Kramer JM, Flynn KE.

⊕ Author information

Abstract

BACKGROUND: To improve the efficiency of conducting multicenter clinical trials, the Food and Drug Administration, the Office of Human Research Protections, and the Department of Health and Human Services have expressed support for using a centralized institutional review board (IRB) process. However, research institutions differ in their willingness to defer to central IRBs.

PURPOSE: We aimed to review and describe peer-reviewed journal articles on the use of central IRBs for multicenter clinical trials in the United States in an effort to inform the policy discussion about central IRBs.

METHODS: We used a PubMed search and consulted IRB experts and the bibliographies of other reviews to identify relevant commentaries and empirical studies.

RESULTS: Our search identified 33 articles related to the use of central IRBs for multicenter trials in the United States. Of these, 22 were commentary pieces and 11 were empirical studies.

LIMITATIONS: Our review was restricted to journal articles about the use of central IRBs for multicenter clinical trials in the United States.

CONCLUSIONS: There is limited empirical work on the use of central IRBs for multicenter trials in the United States. Most published studies focused on problems in efficiency associated with redundant local reviews of multicenter studies and the potential benefits of a centralized system. Because the absence of studies on the use of central IRBs may be due to their infrequent use, additional work is needed to generate data on the use of central IRBs and to elucidate and address the concerns that research institutions have about deferring ethical review to a central IRB.

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J Empir Res Hum Res Ethics. 2011 March ; 6(1): 3–19. doi:10.1525/jer.2011.6.1.3.

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Abstract

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> The IRB process is too important not to undergo periodic evaluation. Evaluations can help an IRB to determine whether it is effectively protecting human subjects, whether it is operating efficiently, and whether it has adequate authority (Office of the Inspector General, 1998a, p. 20).

Institutional review boards (IRBs), a fixture in the U.S. research firmament (McCarthy, 1996), review most research involving human participants before it is initiated and at least annually until it is complete. IRBs review research proposals to assure they adhere to federal regulations (Department of Health and Human Services; Federal Drug Administration), include adequate protections of study participants' rights and welfare, and are ethically sound. But, little is known about how well IRBs accomplish these goals.

In occasione dell'avvio del progetto RICERC@ abbiamo pensato di ri-proporre la Dichiarazione di Helsinki, nella sua ultima revisione perché

è il documento di riferimento per qualunque riflessione etica sulla ricerca e per creare una "rete" di riflessione sulle criticità e i possibili progetti da intraprendere.

I documenti di riferimento sulla sperimentazione clinica (locali, regionali, nazionali, sopranazionali o universali) mostrano in modo esplicito che ci troviamo di fronte a due diverse culture:

DICHIARAZIONE DI HELSINKI
CONVENZIONE DI OVIEDO

→ requisiti sostanziali,

il diritto-dovere della collettività di cercare risposte autentiche a bisogni inevasi, i diritti dei cittadini-pazienti e le responsabilità dei clinici e di quanti si trovano coinvolti nella ricerca a vario titolo

GCP/REGOLAMENTO (UE) N.536/2014 DEL PARL. EUROPEO

→ requisiti procedurali necessari per le esigenze di registrazione.

Due culture, due linguaggi diversi, lontanissimi tra loro

RICERC@

Sarebbe importante e significativo se quanti entreranno
a vario titolo
a far parte di questo progetto,
provassero, a partire dalla
DICHIARAZIONE di HELSINKI,
ad individuare AREE sulle quali investire energie e creatività
per avviare
progetti di confronto

"**epidemiologie dei diritti**"

in un ambito ancora tanto controverso come quello della ricerca.

…Anni fa…i comitati etici erano:

Agenzia Italiana del Farmaco

Componenti dei Comitati Etici per qualifica

Nr. totale componenti: 3062 (su 212 CE che hanno inserito almeno un componente)

Qualifica	Nr. compon.	%
Clinico	778	25.4
Farmacista	257	8.4
Esperto in materia giuridica	230	7.5
Direttore Sanitario	218	7.1
Volontario	193	6.3
Farmacologo	190	6.2
Infermiere	188	6.1
Medico di medicina generale territoriale	181	5.9
Biostatistico	159	5.2
Bioeticista	144	4.7
Altro	135	4.4
Medico Legale	131	4.3
Personale Amministrativo	79	2.6
Teologo/Religioso	73	2.4
Psicologo	35	1.1
Direttore scientifico di IRCCS	29	0.9
Sociologo/Filosofo	23	0.8
Biologo	16	0.5
Veterinario	3	0.1
Fisico	1	0.0
Totale	**3062**	**100.0**

Milano, 20 maggio 2006

LA MASSA CRITICA

E’ ancora possibile?