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Bridging the gap between researchers and patients: The role of the Institutional Review Boards in the informed consent process

ABSTRACT

Background: The Institutional-Review-Boards (IRB) frequently give unfavorable opinions to evaluated studies due to deficiencies in informed consent forms (ICFs), which delays the ethical *approval* of the study and increases waste in research. **Objective:** To analyze the extent to which IRB in our center gives unfavorable opinions due to documents deficiencies and to evaluate types of objection. **Material and methods:** Retrospective observational study of decisions during the first review by the IRB in our center (2012-2015). We carried out a systematic review of minutes when decisions on approval of studies are collected. If not approval, we analyzed appealed objections. **Results:** 1858 clinical studies were evaluated by the IRB. 1558 required informed consent for participating (83.9%, CI95%:82.1-85.5), 987 were not approved during the first review due to deficiencies in ICFs (63.3%, CI95%:60.9-65.7). The main causes of objections for non-approval were unreadability (11.7%, CI95%:10.6-12.9), inadequate information given about access to personal data rights (9.2%, CI95%:8.1-10.2), biological samples management (7.8%, IC95%:6.9-8.8), and expected benefits (7.6%, IC95%:6.7-8.6).

Conclusions: Deficiencies in ICFs are an important reason for non-approval of protocols evaluated by an IRB. There are three fundamental weaknesses on which the IRB plays a key role: 1) improving readability; 2) adapting them to regulations concerning data protection and biological materials management; 3) avoiding misleading information towards enrollment.

Keywords: Informed consent forms; institutional review boards; objection; approval.

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Introduction

The informed consent process is an essential part of clinical research, which main aims are to respect and promote participants autonomy and protect them from potential harm. For participants, signing of the informed consent forms (ICFs) is meant to indicate their agreement to participate in a study and confirm that they understand them. According to an international guidelines[1-4], consent documents must contain detailed information regarding different legal and ethical aspects. Before being enrolled in a medical investigation, patients have to be aware of certain aspects such as the nature and purpose of the study, available alternatives, risks and benefits, or the voluntary nature of their decision to participate.

However, in recent years, ICFs have become increasingly complex and difficult for patients to understand[6-14]. In many cases, sponsors and institutions use them as a legal document and an instrument to protect themselves against litigation[14], which further increases their complexity. Thus, obtaining informed consent for participation in a clinical study requires a high level of literacy skills. In fact, published studies support the fact that the language used in ICF is not comprehensible for most potential participants[15-17].

In this context, the Institutional Review Boards (IRBs), when reviewing a proposed clinical research for approval, play a key role in safeguarding the rights, safety, and well-being of all trial subjects, as well as ensuring that any written material given to potential participants is understandable. The IRBs members make a comprehensive review of ICFs to guarantee these documents are in accordance with international guidelines and ethical standards. They ensure that these documents are free of mistakes, including missing information, avoiding the biased information with some information about risks or adverse events before giving favourable ethical opinion of the research. Other relevant aspects, such as potential risks of participation, the use and collection of biological samples, research data maintenance, and confidentiality protection are also reviewed by the IRBs. They also verify that patient´s expectations are not inappropriately raised due to exaggerated or overemphasized benefits in the ICF.

It is known that most applications do not receive the IRB´s favourable opinion during the first review, and further clarifications and modifications are required before the final decision[18].

In an agreement with other authors[19], we observed a lack of published information concerning the objections and recommendations from experts on the informed consent issues. Taking this into account, we conducted the following study to test

the hypothesis that one of the main causes for the IRB´s non-approval is related to deficiencies found in the informed consent documents.

Our main objective was to analyse the extent to which our centre's IRB gives unfavourable opinions during the first review of applications due to the deficiencies detected in the informed consent forms. Secondary objectives were to evaluate the type of objections raised by the IRB regarding aspects such as readability (assessed by an IRB member who is not a healthcare professional and represents patients), ICF length (the IRB at our hospital agreed that the document of more than 15 pages would be considered excessive), the purpose of the study, goals and designs of the study, treatments a patient will receive, expected benefits and foreseeable risks, potential adverse events, and available alternatives as standard treatments in clinical practice. Other aspects, such as voluntary nature of the decision to participate, right to withdraw, data confidentiality, or sponsor and investigator contact information for possible questions, were also evaluated.

Material and methods

We conducted a four year retrospective observational study (from 2012 to 2015) of the decisions during the first review by the IRB in our centre. The IRB in our hospital (1350 beds) is one of the most important in our country in terms of number of applications for evaluation. The committee meetings take place twice a month, and after each of them, the minutes are recorded. We carried out a retrospective study of the minutes when the decisions on the approval of the study or non-approval are collected. In case of non-approval, we analysed the appealed objections.

Primary outcome

The primary endpoint was the number of clinical studies evaluated by the IRB in our hospital that were not approved during the first revision due to the deficiencies detected in the informed consent documents.

Secondary outcomes

Following the current international guidelines[1-5] that set out the principles and details of informed consent, we created a standardized form to extract secondary variables form eligible minutes. The data were tabulated and categorized according to the type of objection (table 1).

Table1. Secondary measured outcomes were objections related to information deficiencies found in the informed consent forms.

• Identification data of the study (title, sponsor and principal investigator)
• Goals and study design
• Readability
• Excessive length of the ICFs
• Expected therapeutic benefits (induction to get involved, misunderstandings or misinterpretations)
• Personal data protection law reference (European Parliament 2001)
• Foreseeable risks
• Data confidentiality (handling, and record keeping) (European Parliament 2001)
• Information provided about the rights that the data owner has to access his personal information, rectify it, cancel it or oppose to his data being treated according to the Spanish data protection law (ARCO rights) (Spanish Data Protection Agency 2014)
• Voluntary nature of the participation
• Potential adverse effects
• Alternative treatments
• Communication of results of tests performed and procedures
• Information provided about biological materials that are going to be used for genetic testing (use, storage and property rights of the samples according to the Spanish regulation (Official Spanish Gazette 2007)
• Information provided to the mature- minor, a parent or legal guardian in studies in children
• Publication of the results
• Information about new evidence that may influence decision to participate
• Information provided to potential pregnant partner
• Name and contact information for questions
• Availability of liability insurance

We also assessed whether the study received unfavourable opinions due to other reasons different from informed consent issues (objections associated with design or local aspects), and whether the application corresponded to a multicentre study or to a local research project. Medical specialties involved in the research studies were also evaluated.

Eligibility criteria

We evaluated the IRB resolutions of all clinical studies, including interventional (clinical trials) and non-interventional researches, assessed by the IRB whose decision on approval during the first review has been registered in the meetings' minutes during four years (from 2012 to 2015).

La Paz University Hospital IRB, which oversees all clinical research at the institution, approved the study protocol.

Statistical Analysis

Data management

A database was designed to reflect the Case Report Form's content, in which a data entry matrix with possible ranges or values was established, along with the various consistency rules between the variables. The quality of information received through exploratory analysis aimed at detecting discrepancies in the values, out-of-range values or missing values. Exploratory analysis also provided information on the distribution of the main variables to be studied and provided guidance on possible transformations.

General considerations

The information included was: the mean, standard deviation, median, maximum, minimum and 25% and 75% quartiles. For categorical data, the frequency distributions (absolute and relative) were presented. In addition, the 95% confidence intervals were calculated, where appropriate. The statistical analysis was carried out using SAS 9.1 (SAS Institute Inc., Cary, NC, USA).

Sample size considerations

According to the available data on the activity of the IRB in our hospital, two meetings are held every month, except in August. Given that there could have been meetings out of the scheduled dates, it was estimated that around 20 to 23 meetings a year would have been held. In the study period (2012-2015) the IRB would have hold a total of 80 to 92 meetings. Considering that the committee evaluates about 20 initial study applications during each meeting, we would analyse 1600-1840 IRB´s initial resolutions. In a pilot study in which 10 minutes were assessed, we found a

15% of studies' applications for evaluation did not require informed consent because of its design. According to this result, it was estimated that 1360-1564 ICFs would have been analysed by the IRB in the study period.

Results

Table 2. Distribution of clinical studies evaluated by the IRB according to the medical specialty involved.

Medical specialty	N of Clinical researches applications to the IRB	Percentage
Oncology	214	11,5%
Haematology	142	7,6%
Neurology	132	7,1%
Cardiology	106	5,7%
Rheumatology	84	4,5%
Gastroenterology	78	4,2%
Intrenal Medicine	79	4,2%
HIV unit	67	3,6%
Pharmacology	66	3,5%
Pneumology	59	3,2%
Nefrology	55	3%
Neonatology	43	2,3%
Gynecology	41	2,2%
Alergy	37	1,9%
Dermatology	35	1,9%
Psychiatry	36	1,9%
Intensive care unit	35	1,9%
Ophthalmology	32	1,7%
Genetic unit	26	1,4%
Urology	26	1,4%
Nutrition and dietetic	24	1,3%
Paediatrics	23	1,2%
Emergency	20	1,1%
General surgery	18	1%
Clinical pharmacy	18	1%
Traumatology	19	1%
Other	**343**	**18,5%**

A total of 91 minutes corresponding to the IRB meetings over four years (2012-2015) were analysed. In these meetings 1858 clinical studies were evaluated (1057 clinical trials and 801 non-interventional studies). There was a similar number of studies evaluated a year (mean 464.5, SD±51.6). The main specialties that conducted clinical studies are shown in table 2.

Out of the 1858 studies evaluated, 1558 (83.9%; CI95%: 82.1%-85.5%, which indicates the probability that the true value will fall between these two percentages) required a signed informed consent for subject's participation. These analysed consent forms corresponded more to clinical trials (1038, 66.6%) than to non-interventional studies (520, 33.3%).

Global results

Total studies evaluated: 1858
Number of evaluated studies that required informed consent: 1558/1858 (83.9%, CI95%:82.1%-85.5%)
Studies with objections to the informed consent documents: 987/1558(63.3%, CI95%:60.9-65.7)

The objections leading to the IRB´s non-approval of a proposed study were mainly related to inaccuracies in the ICFs (53.1%) and to a lesser extent to design inaccuracies (27.4%) and local issues (30.5%).

Inaccuracies in the informed consent forms were primarily due to unreadability 354/3012 (11.7%,CI95%:10.6-12.9), (251/354, 70.9% because of poor writing, and 103/354, 29.1% IRB members considered that the text was unintelligible to the potential participant), followed by inadequate information provided about the rights that the data owner has, for example to access his personal information, rectify it, cancel it, or oppose to the data being treated according to the Spanish data protection law (ARCO rights) 276/3012 (9.2%,CI95%:8.1-10.2), biological samples management according to our country regulations 236/3012 (7.8%,IC95%:6.9-8.8), expected benefits (induction to get involved, misunderstandings or misinterpretations) 230/3012 (7.6%,CI95%:6.7-8.6), and excessive length 198/3012 (6.6%,CI95%:5.7-7.5) (table 3).

Table 3. Type of objections raised by the IRB to informed consent documents.

Type of objection	N	%
Unreadability	354	11,7%
ARCO rights*	276	9,2%
Information of biological materials management (genetic testing, use, storage and property rights)	236	7,8%
Expected benefits (induction to get involved, misunderstandings or misinterpretations)	230	7,6%
Excessive length	198	6,6%
Study identification data (title, sponsor or principal investigator)	150	5%
Purpose and design of the research	142	4,7%
Personal data protection law reference	126	4,2%
Alternative Treatments	122	4%
ICFs for the parents or guardians poor writing	116	3,8%
ICFs for mature minors poor writing	112	3,7%
Procedures and tests explanation (risks, whether they were routine or experimental, etc)	86	2,8%
Foreseeable risks	85	2,8%
Personal data confidentiality	85	2,8%
Name and contact information for questions	81	2.7%
Availability of liability insurance	81	2,7%
Information provided to potential partner pregnant	79	2,6%
Information of new evidence that may influence decision to participate	66	2,2%
Potential adverse effects	66	2,2%
Request of a new ICF by major flaws that invalidate the submitted	58	1,9%
Publication of the results	42	1,4%
Voluntary nature of the participation	37	1,2%
Other	**184**	**6.1%**

*ARCO rights: rights that the data owner has to access his personal information, rectify it, cancel it or oppose to his data being treated according to the Spanish data protection law.

Secondary endpoints were assessed according to whether they were omitted in the ICFs or were included but needed modifications prior approval (table 3). Regarding omissions, we observed that frequently omitted requirements were related to our country's regulations on personal data protection and on investigation on biomedical materials, specifically about information provided to the patients of the ARCO rights (94%, 262 of the 276 objections related to ARCO rights were due to information omissions in the ICFs), and of the patient biological material management of samples taken because of their participation in the study (91,1%, 215 objections of the 236 related to biological material management). When analysing these 215 objections due to omissions associated with samples management, we observed that 112 (52%) were because there were no mention about the patient´s rights to be informed of the results of analysis, in 51 (23.7%) there were no mention about the inability to use them for another purposes not related to the research, in 48 cases (22.5%) there were no mention about how it should be stored, and finally in 4 cases (1, 9%) there were no information at all about these samples management. The second most frequently omitted aspect was the availability of alternative treatments (111 objections out of 122 related to alternatives to participating, 91%).

To a lesser extent the claims were due to aspects that were covered by the ICFs but required modifications. These text modifications were mainly related to poor writing of documents that were addressed to mature-minors (in the *range* of 12 to 17 in our country) in paediatric studies (77.7% of all objections rose to the ICFs for mature-minors), patient information about data confidentiality (77.6%), and information about benefits (misunderstandings due to false expectations) (176 objections out of 230 related to benefits, 76.5%). Table 4 shows modifications required by the IRB.

When we look at the top ten specialties involved in clinical researches, these accounted for 55.3% of applications for approval. Of all objections registered in the minutes evaluated, 36.4% (1098/3012) were related to applications of these top ten specialties. However, we observed that, only 18.1% of all objections registered to the ICFs were due to inaccuracies found in the consent forms of these top ten research specialities. Figure 1 shows objections during the first review concerning the top ten specialties involved in the researches.

As table 5 shows, objections during the first review to the clinical studies of these top ten specialties were related more to the ICF than to the design or the local aspects.

Table 4. Distribution of objections based on the changes required by the IRB for approval (additions to the informed consent forms or modifications of the information contained).

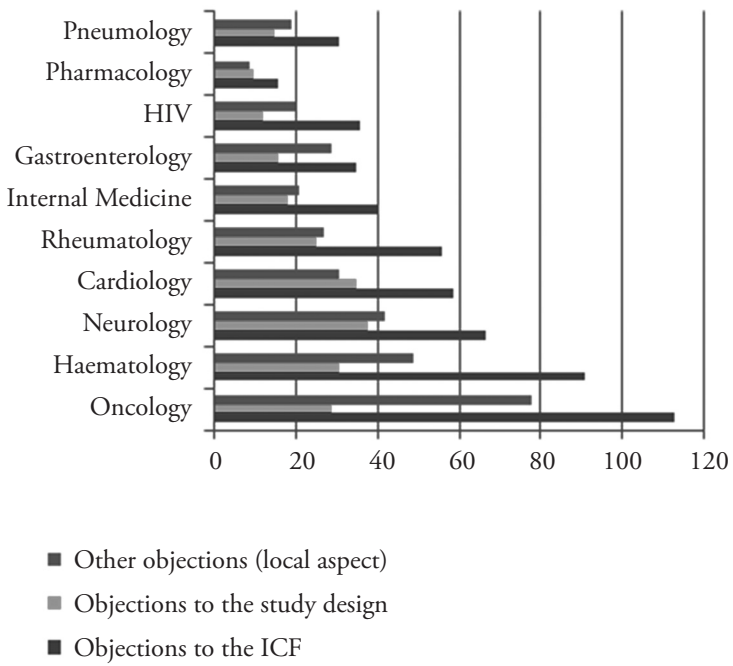
Type of objection	N	IRB requested modifications of the ICFs	Item omitted (addition to the ICF was required)
Unreadability	354	354 (100%)	-
ARCO rights*	276	14 (5.1%)	262 (94.%)
Information of biological materials management (genetic studies)	236	21 (8.9%)	215 (91%)
Expected benefits	230	176 (76.5%)	54 (23.5%)
Excessive length	198	198 (100%)	-
Study identification data (title, sponsor or principal investigator)	150	58 (38,7%)	92 (61,3%)
Purpose and design of the research	142	142 (100%)	-
Personal data protection regulation law	126	12 (9,5%)	114 (90,5%)
Alternative Treatments	122	11 (9%)	111 (91%)
ICFs for the parents or guardians poor writing	116	77(66,4%)	39(33,6%)
ICFs for mature minors poor writing	112	87 (77,7%)	25 (22,3%)
Procedures and tests explanation (risks, whether they are routine or experimental, etc)	86	41 (47,7%)	45 (52,3%)
Foreseeable risks	85	42 (49,4%)	43 (50,6%)
Personal data confidentiality	85	66 (77,6%)	19 (22,3%)
Name and contact information for questions	82	6 (7,4%)	76 (92,7%)
Availability of liability insurance	81	52 (64,2%)	29 (35,8%)
Information provided to potential pregnant partner	79	12 (15,2%)	67 (84,8%)
Potential adverse effects	66	41 (62,1%)	25 (37,9%)
Information of new evidence that may influence decision to participate	66	3 (4,5%)	63 (95,4%)
Request of a new ICF by major flaws that invalidate the submitted one	58	58 (100%)	-
Publication of the results	42	6 (14,3%)	36 (85,7%)
Voluntary nature of the participation	37	19 (51,3%)	18 (48,6%)
Other	**183**	**-**	**-**

*ARCO rights: rights that the data owner has to access his personal information, rectify it, cancel it or oppose to his data being treated according to the Spanish data protection law.

Table 5. Reasons for non approval by the IRB at first review to clinical trials applications of the first ten specialties involved in researches.

TopTen specialties involved in reseraches	**Objections to the ICFs**	**Objections to the study design**	**Other objections (local requirements)**
1ºOncology	113(51,4%)	29 (13,2%)	78(35,4%)
2ºHaematology	91(53,2%)	31(18,1%)	49(28,6%)
3ºNeurology	67(45,6%)	38(25,8%)	42(28,6%)
4ºCardiology	59(47,2%)	35(28%)	31(24,8%)
5ºRheumatology	56(51,8%)	25(23,1%)	27(25%)
6ºInternal Medicine	40(50,6%)	18(22,8%)	21(26,6%)
7ºGastroenterology	35(43,7%)	16(20%)	29(36,2%)
8ºHIV	36(52,9%)	12(17,6%)	20(29,4%)
9ºPharmacology	16(74,3%)	10(28,6%)	9(25,7%)
10ºPneumology	31(47,7%)	15(23,1%)	19(29,2%)

Figure 1



Discussion

Written consent is needed for almost all clinical researches. In agreement with other authors[9,18], we found that a high proportion of the studies evaluated by the IRB in our centre included informed consent documents for assessment (83.3% of all applications). When evaluating the process of obtaining informed consent and the written information for prospective participants, the IRBs must not only ensure that all these documents are written appropriately in a language understandable to the subject, but also make sure that the guidelines[1-5] are followed and all information required is contained.

Our results suggest that many non-approvals during the first review were due to deficiencies found in the ICFs. Thus, we observed that more than a half of them (53.1%) failed to meet the IRB´s standards and further response and modifications were needed before approval. Even though there are not many data about the success rates of applications to the IRBs concerning the evaluated ICFs, some authors previously identified deficiencies in applications associated with these documents. They observed, as we do in our work, that the ethical issue most frequently raised by the IRBs while reviewing protocols was related to the informed consent forms[18].

In our study, we detected that the main reason of the IRB´s unfavourable opinions and non-approval on an initial assessment was unreadability. A 11.7% of the ICFs evaluated were not written appropriately, most frequently because of a poor quality translation into Spanish. Other authors previously[9,23-29] have proved that ICFs given to the patients, in many cases are unreadable, providing them with incomplete or incorrect information of relevant aspects.

According to the most of those authors, although consent documents often included all the required information, participants do not understand what it was written. Published research shows that most of these forms are written for a grade reading level above 17 years[30-33], which is higher than the reading level of the majority of the population in Europe or EEUU[34,35]. Falagas et al.[36], in a review of ICFs from 1961 to 2006 found that only 54% of patients properly understood the purpose of the study, only a 50% understood what it means to randomization, 47% voluntarism of participation, 50% the risks undertaken, and 57% the expected benefits.

In 2003 the Eastern Cooperative Oncology Group conducted a randomized study[37]comparing the use of an easy to read version of the ICFs versus standard consent statement. The authors observed lower consent anxiety and higher satisfaction in patients who were randomized to the intervention arm (easy to read ICFs) compared with the control arm (standard ICFs) but patient comprehension was not affected. Similarly, Davis et al.[38] found that the degree of patient´s understanding of two

versions of the ICFs, one of university student´s level compared with other simplified corresponding to an educational level between 12-13 years were essentially the same (56% *vs* 58%) although patients preferred the simplified version. Taken this into account, other authors have investigated complementary strategies to help improve the understanding of the ICF. Flory et al.[39] found that the interaction and feedback person- person is the most effective way to achieve a proper understanding of the information transmitted to the patient. Other strategies such as the use of media, or the involvement of a neutral educator spending more time with the patient proved to be useful as well[39].

However, according to the GPC[1-4] all of these ICFs have been previously reviewed and approved by the IRB. Our study found that unreadability is the main cause for the IRB non-approval, but modifications required by them for approval in terms of the readability *were apparently insufficient.* In this regard, Paasche-Orlow et al.[40], analysed sample texts of informed forms provided by the IRBs of the U.S. medical schools. They observed that they generally fail to meet their own standards for readability regardless the level of research or the level of literacy. Readability standards ranged from 5th grade reading level (10-11 age range) to a 10th grade reading level (15-16 age range). Their study suggests that 4th to 6th grade reading level (9-10 and 11-12 age range) would be a suitable target to be clear for candidates to participate.

The second and third most frequent reason for objection was inadequate explanation in the ICFs of the rights, according to our country regulations, that patients have regarding who is allowed to access their personal data, rights of rectification or cancellation of their files, and the right to be opposed to having their personal data used for purposes that are not related to the study (ARCO rights) and biomedical materials management. In accordance with the Spanish law on the protection of personal data[20] and biomedical research law[22], informed consent forms have to mention the ARCO rights. In this regard, the lack of consensus and allowance for the different laws in different countries, which can explain this high prevalence of objections, often cause problems to the investigators in the informed consent process when conducting international researches[41].

Apart from legislative issues, we also detected that the excessive length of the text was also a frequent reason for the IRB´s objections and non-approvals. Beardsley et al.[42] observed that the page count for ICFs submitted for ethics approval increased dramatically in 6 years, from 3-9 pages in 2000 to 7- 21 in 2005. It should be also taken into account that longer text length means more complexity, and both aspects contribute to less understanding[9].

In our study we divided analysed aspects required in the ICFs into two categories according to the type of objections: items omitted and items that were included but

needed to be modified before approval by the IRB. Objections due to omissions were related mainly with our country regulations about ARCO rights[21], and purpose and storage of tissue or biological samples[22]. In addition, we found a high proportion of objections concerning omitted information about available alternatives as standard treatment. In this regard, Resnik et al.[43] found that only 17.4% of consent forms for oncology randomized controlled trials stated that patients could receive the treatments being investigated without participating in the study. In a more recent study[41] researchers observed that 57.7% of ICFs of oncology clinical trials described alternatives but did not provide adequate information that could be useful to the decision making process.

Regarding modifications to the text required by the IRB, they were mainly associated with the language used in consent forms for mature-minors, confidentiality and explanations of benefits. Like other authors[44-47], we observed that modifications requested about benefits gave unrealistically high expectations for therapeutic benefit from participation.

Our results draw attention that often the information given on the expected benefits needed to be modified because it created false expectations for potential participants. We also detected that alternative therapies were frequently omitted. This combination might mislead the patient towards the enrolment in a clinical study with persuasive rebasing methods.

The proportion of objections to ICFs was lower in medical specialties that are usually involved in clinical research. In fact, more than 80% of the objections concerning ICFs corresponded to medical specialties different from the top ten that lead the clinical investigation in our hospital.

Study limitations

First, there were limitations derived from the study design itself as it is an observational, retrospective, and single centre study.

On the other hand, even though the decisions recorded in minutes are the result of a consensus agreement among members of the IRB, the assessment of informed consent may be subjective in some respects. We must also take into account that the composition of the IRB has changed over the four years during which the data have been collected.

Conclusions

Information documents that investigators delivered to patients for participation in a study have been previously reviewed and approved by the IRB. According to our work, the documentation's deficiencies are the main reason for non-approval by the IRB while evaluating research protocols.

There are three fundamental weaknesses in these documents on which the intervention of the IRB is the key in its role of bridging patients and researchers. First, improving wording in order to be easier to understand by patients; second, adapting them to the state regulations mainly concerning personal data protection and biological materials management, and last but not least, avoiding misleading towards the enrolment since there is a tendency to exaggerate the benefits expected from taking part in the study and, at the same time, to omit available alternative treatments.

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Prevladavanje jaza između istraživača i pacijenata: uloga institucijskih odbora za procjenu u procesu informiranog pristanka

SAŽETAK

Pozadina: Institucijski odbor za procjenu (Etičko povjerenstvo) često daje nepovoljno mišljenje za istraživanja čiji se uzrok tumači nedostatkom obrazaca informiranog pristanka. Spomenuto odgađa etičko odobravanje istraživanja, povećavajući gubitak u istraživanju. Cilj: Analizirati u kojoj mjeri Odbor za procjenu u našem centru daje nepovoljna mišljenja zbog nedostataka dokumenata i procijeniti vrste prigovora. Materijal i metode: Retrospektivno opservacijsko proučavanje odluka pri prvom pregledu Odbora u našem centru (2012. – 2015.). Provodili smo sustavni pregled zapisnika o tome kada se prikupljaju odluke o odobravanju istraživanja. Ako ne odobrenje, analizirali smo žalbene primjedbe. Rezultati: Odbor je procijenio 1858 kliničkih ispitivanja. Informirani pristanak za sudjelovanje zahtijevalo je 1558 (83,9 %, CI 95 %: 82,1 – 85,5), 987 nije odobreno pri prvom pregledu zbog nedostataka u ICF-u (63,3 %, CI 95 %: 60,9 – 65,7). Glavni uzroci prigovora neodobrenja bili su nečitljivost (11,7 %, CI 95 %: 10,6 – 12,9), neadekvatne informacije o pravima na pristup informacijama o osobnim podatcima (9,2 %, CI 95 %: 8,1 – 10,2), upravljanje biološkim uzorcima (7,8 %, IC 95 %: 6,9 – 8,8) i očekivana korist (7,6 %, IC 95 %: 6,7 – 8,6). Zaključak: Nedostatci u obrascima informiranog pristanka važan su razlog zbog kojeg Odbor ne odobrava protokol. Postoje tri osnovne slabosti u kojima Odbor ima ključnu ulogu: 1) poboljšanje čitljivosti; 2) usklađivanje s propisima koji se odnose na zaštitu podataka i upravljanje biološkim materijalima; 3) izbjegavanje obmanjujućih informacija prilikom upisivanja.

Ključne riječi: obrasci informiranog pristanka, institucijski odbori za procjenu, prigovor, odobrenje.