Research Article

Impact of the Revised Common Rule on Enhancing Human Research Subject Protections and Reducing Researcher Burdens

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Objectives: The Common Rule, the U.S. Basic Federal Policy for Protection of Human Research Subjects, was revised extensively in 2018 to modernize the regulations by enhancing protections for human research subjects and reducing unnecessary burden and ambiguity for researchers. It was implemented on January 21, 2019. The purpose of this study was to determine whether the revised Common Rule, in fact, enhanced human research subject protections and reduced burdens to researchers.

Methods: Analysis of data collected on the performance of human research protection programs from 107-109 Department of Veterans Affairs research facilities between 2016 and 2024 was carried out to evaluate the impact of the revised Common Rule at five and a half years after its implementation.

Results: At five and a half years after the implementation of the revised Common Rule, when 77% of all active human research protocols were under the revised Common Rule requirements, there was an increase of 259% in the number of exempt protocols and a reduction of 44% in the number of protocols requiring institutional review board (IRB) continuing reviews. However, analysis of human research subject protection performance metric data during the same period revealed that of the five human research subject protection performance metrics studied, two, i.e., unanticipated, serious, research-related adverse events, and research conducted without IRB approval, remained unchanged, while three, i.e., required informed consent and Health Insurance Portability and Accountability Act authorization not obtained, as well as continued research activities during a lapse in IRB continuing reviews, deteriorated.

Conclusions: The revised Common Rule achieved its objective of reducing the burden of low-risk studies to researchers. However, it impaired, instead of enhancing, human research subject protections.

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 doi.org/10.32388/TU6VRN

Introduction

The Common Rule, i.e., the U.S. Basic Federal Policy for Protection of Human Research Subjects (45 Code of Federal Regulations 46, Subpart A), which outlined provisions for the institutional review board (IRB), informed consent form, and assurance of compliance, was revised extensively in 2018[1]. From the initial issuance of the Advance Notice of Proposed Rule-Making in 2011 to its final completion in 2018, this revision took 7 years to complete[2]. According to the Office for Human Research Protections, the federal office responsible for the implementation and oversight of the Common Rule, the intended purpose for revising the Common Rule was to modernize the regulations by i) enhancing protections for human research subjects, and ii) reducing unnecessary burden and ambiguity for researchers. To accomplish these objectives, the revisions included, but were not limited to, improving informed consent so that potential participants would be better informed when making decisions whether to participate in particular research studies; reducing the burdens of low-risk studies to allow IRBs and researchers to focus on high-risk studies; and requiring the use of a single-IRB review for multi-site studies in the U.S., eliminating the time and effort associated with multiple IRB reviews and the need for reconciling different IRB determinations and requirements[1][3].

To achieve the objective of reducing unnecessary burden and ambiguity for researchers, the revised Common Rule expanded the exempt research categories from 6 to 8, reduced the number of protocols requiring IRB continuing reviews, and required the use of a single-IRB review for multi-site studies[1][3]. However, the revised Common Rule included no specific provisions that were designed to enhance human research subject protections. This was in part because there were no procedures or interventions that had been shown to improve human research subject protections, as prior to 2018, we didn't know how to measure human research subject protections[4]. The proposed new requirements for informed consent may improve the quality of informed consent, leading to potential participants being better informed when making decisions whether to participate in particular research studies[5]. However, whether this improvement will lead to improved human research subject protections is not clear.

The Department of Veterans Affairs (VA) health care system is the largest integrated health care system in the U.S., with 107-109 VA medical centers conducting research involving human subjects. In the current study, data collected on the performance of human research protection programs at these VA research facilities from 2016 through 2024 were analyzed to determine the impact of the revised Common Rule on enhancing human research subject protections and reducing researcher burdens at five and a half years after the implementation of the revised Common Rule.

Methods

Data collection

Collection of VA human research protection program performance data was carried out as described previously by Tsan and Puglisi[6]. Briefly, as part of a quality assurance program, the VA Office of Research Oversight has collected quality assurance data from all VA human research protection programs each year starting in 2010. The Office of Research Oversight required facility research compliance officers to conduct audits of all informed consent documents annually and regulatory audits of all human research protocols once every three years using auditing tools developed by the Office of Research Oversight (available at https://www.va.gov/ORO/orochecklists.asp). Approximately one third of all active human research protocols were audited each year. For protocols that had been active for more than three years, protocol regulatory audits were limited to the last three years of research. Using a web-based system, results of these audits conducted between June 1 and May 31 of each year were collected from all VA research facilities[6].

Data on the numbers of exempt protocols and protocols requiring IRB continuing reviews, as well as human research subject protection performance metrics collected from 2016 through 2024, were analyzed to evaluate the impact of the revised Common Rule. Human research subject protection performance metrics consisted of the following five performance metrics:

- Local adverse events (as opposed to external adverse events in a multi-site research protocol) that were determined by IRBs to be serious, unanticipated, and related or probably related to research;
- Required informed consent was not obtained from the subjects or subject's legally authorized representatives;
- Required Health Insurance Portability and Accountability Act (HIPAA) authorization was not obtained from subjects or subject's legally authorized representatives;
- Non-exempt research was conducted without IRB review and approval; and
- Research activities were continued during a lapse in IRB continuing reviews, except when the IRB determined that it was in the best interest of already enrolled subjects to continue participating in the research[6].

The revised Common Rule was implemented on January 21, 2019. Data from 3 years between 2016 and 2018 were collected prior to the implementation of the revised Common Rule, while data from 5 years between 2020 and 2024 were collected after its implementation. Twenty nineteen (2019) was a transitional year. It contained approximately 7 months (from June 1, 2018, to January 20, 2019) of pre-implementation data and approximately 5 months (from January 21, 2019, to May 31, 2019) of post-implementation data.

Protection of human research subjects Statement

This quality assurance project did not involve human subjects and did not collect individually identifiable information. Therefore, no IRB review and approval was required[7].

Data analysis

We used analysis of ordinal categorical data as described by Agresti[8] to determine the trend of change of these performance data from 2016 through 2024. This was carried out using JavaStat ordinal contingency table analysis available at www.statpages.info. A p value of < 0.05 was considered to be statistically significant. For those performance data with statistically significant changes, we also calculated percent changes from 2016 through 2024 using the following formula:

Percent change = [(rate in 2024 – rate in 2016) ÷ rate in 2016] x 100[9].

Results

Implementation of the revised Common Rule

The revised Common Rule requirements applied to human research protocols that were exempt or required to be approved by an IRB on or after January 21, 2019, and those that had been approved by an IRB prior to January 21, 2019, but were determined by an IRB to be transitioned to the revised Common Rule requirements. Protocols that were exempt or approved by an IRB prior to January 21, 2019, continued to be subjected to pre-revised Common Rule requirements, unless they were transitioned to the revised Common Rule requirements as described above[1].

Table 1 shows data from 2016 through 2024 on the numbers and rates of protocols subjected to the revised Common Rule requirements. As shown here, the rates of protocols subjected to the revised Common Rule requirements increased progressively from 28.7% in 2020 to 77.0% in 2024.

	2016	2017	2018	2019	2020	2021	2022	2023	2024
Total number of active protocols	**15,699**	**15,279**	**15,258**	**15,061**	**14,637**	**15,015**	**14,917**	**14,685**	**14,484**
Protocols Subjected to revised Common Rule requirements	0	0	0	—[1]	4,201 (28.7%)	7,207 (48.0%)	9,142 (61.3%)	10,465 (71.3%)	11,153 (77.0%)

Table 1. Implementation of the revised Common Rule

[1] *Data not collected*

Number of exempt protocols and IRB continuing reviews

The revised Common Rule expanded the exempt categories from 6 to 8, adding Category 7, storage of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required, and Category 8, secondary research using identifiable private information or identifiable biospecimens for which broad consent is required[1].

Prior to the revision, the Common Rule required IRBs to conduct continuing review of ongoing research at intervals appropriate to the degree of risk, but not less than annually. The revised Common Rule removed the annual IRB continuing review requirements for studies approved using expedited review procedures and for studies merely analyzing study data after completing all study interventions or involving only observational follow-up in conjunction with standard clinical care[1][3].

The above changes in the revised Common Rule requirements should markedly increase the number of exempt protocols and reduce the number of protocols requiring IRB continuing reviews. However, the extent of these changes is not clear.

Table 2 shows data collected from 2016 through 2024 on total numbers of active protocols each year, numbers and rates of exempt protocols, numbers of protocols audited, and numbers and rates of protocols requiring IRB continuing reviews.

As shown in Table 2, the number of exempt protocols increased from approximately 6% of the total number of active protocols in 2016-18 to 21.9% in 2024, an increase of 259%. In contrast, the number of protocols requiring IRB continuing reviews decreased from 83.2% in 2016 to 46.9% in 2024, a reduction of 44%.

	2016	2017	2018	2019	2020	2021	2022	2023	2024	*P* value[1]	Change (%)[2]
Total number of active protocols	**15,699**	**15,279**	**15,258**	**15,061**	**14,637**	**15,015**	**14,917**	**14,685**	**14,484**		
Exempt protocols	960 (6.1%)[3]	943 (6.2%)	946 (6.2%)	1,145 (7.7%)	1,878 (12.8%)	2,379 (15.8%)	2,738 (18.4%)	3,044 (20.7%)	3,170 (21.9%)	0.0000	+259%
Total number of protocols audited	3,801	3,573	3,564	3,569	3,348	3,540	3,349	3,441	3,201		
Protocols requiring IRB[4] continuing review	3,162 (83.2%)	3,094 (86.6%)	3,035 (85.2%)	2,861 (80.2%)	2,547 (76.1%)	2,205 (62.3%)	1,900 (56.7%)	1,606 (46.7%)	1,501 (46.9%)	0.0000	-44%

Table 2. Impact of revised Common Rule on Exempt protocols and IRB continuing reviews

[1] *Determined using analysis of ordered categories for the trend of changes from 2016 through 2024.*

[2] *Percent change from 2016 to 2024.*

[3] *The numbers in parentheses were the percentages of the total number of active protocols or protocols audited.*

[4] *Abbreviation used: IRB, institutional review board.*

Protecting human subjects participating in research

The human research subject protection performance metrics proposed by Tsan & Puglisi[6] were used to assess the impact of the revised Common Rule on enhancing human research subject protections.

Unanticipated, serious and research-related adverse events: Table 3 shows data from 2016 through 2024 on numbers and rates of local adverse events that were determined by IRBs to be serious, unanticipated, and related or probably related to research. The numbers of protocols audited each year ranged from 3,201 in 2024 to 3,801 in 2016.

The rates of local adverse events that were determined to be serious, unanticipated, and related or probably related to research were low, ranging from 0.36%, i.e., 0.36 events per 100 protocols, in 2017, to 1.09% in 2018.

There was no statistically significant trend of change from 2016 through 2024.

	2016	2017	2018	2019	2020	2021	2022	2023	2024	*P* value[1]	Change (%)[2]
Total number of active protocols	**15,699**	**15,279**	**15,258**	**15,061**	**14,637**	**15,015**	**14,917**	**14,685**	**14,484**		
Total number of protocols audited	3,801	3,573	3,564	3,569	3,348	3,540	3,349	3,441	3,201		
Local adverse events that are serious, unanticipated, and related to research	15 (0.39%)[3]	13 (0.36%)	39 (1.09%)	15 (0.42%)	18 (0.54%)	13 (0.37%)	19 (0.56%)	20 (0.58%)	25 (0.78%)	0.2763	N/A[4]

Table 3. Local adverse events determined to be serious, unanticipated, and related or probably related to research

[1] *Determined using analysis of ordered categories for the trend of changes from 2016 through 2024.*

[2] *Percent change from 2016 to 2024.*

[3] *The numbers in parentheses were the percentages of the total number of protocols audited.*

[4] *N/A denotes not applicable*

Informed consent and HIPAA authorization: Table 4 shows data from 2016 through 2024 on numbers of informed consent documents audited each year; numbers and rates of informed consent documents that were not obtained; numbers of HIPAA Authorization required; and numbers and rates of these authorizations that were not obtained.

The numbers of informed consent documents audited ranged from 35,323 in 2021 to 90,153 in 2017. The rates of informed consent documents not obtained, which included missing informed consent documents as well as informed consent documents not signed by the subjects or legally authorized representatives, were small, ranging from 0.03% in 2016 to 0.39% in 2021. There was a statistically significant trend of change, increasing from 0.03% in 2016 to 0.12% in 2024, an increase (or deterioration) of 300%.

The numbers of protocols requiring HIPAA authorizations audited ranged from 33,356 in 2021 to 87,045 in 2017. The rates of required HIPAA authorization not obtained were small, ranging from 0.56% in 2016 to 1.43% in 2021. There was a statistically significant trend of change, increasing from 0.56% in 2016 to 0.85% in 2024, an increase (or deterioration) of 52%.

	2016	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	***P* value[1]**	**Change (%)[2]**
Total number of active protocols	**15,699**	**15,279**	**15,258**	**15,061**	**14,637**	**15,015**	**14,917**	**14,685**	**14,484**		
Total number of protocols audited	15,629	15,264	15,233	1,892	13,985	12,066	11,584	10,850	11,272		
Total number of ICDs[3] audited	89,024	90,153	82,849	73,331	57,827	35,323	52,525	61,237	71,724		
Informed consent not obtained	29 (0.03%)[4]	34 (0.04%)	85 (0.11%)	74 (0.10%)	38 (0.07%)	138 (0.39%)	33 (0.06%)	64 (0.10%)	84 (0.12%)	0.0000	+300%
Total number of HIPAA authorization required	86,109	87,045	78,372	69,970	52,756	33,356	46,218	55,417	66,185		
HIPAA authorization not obtained	486 (0.56%)	572 (0.66%)	518 (0.66%)	529 (0.76%)	535 (1.01%)	477 (1.43%)	337 (0.73%)	527 (0.95%)	562 (0.85%)	0.0000	+52%

Table 4. Informed consent document and Health Insurance Portability and Accountability Act authorization

[1] *Determined using analysis of ordered categories for the trend of changes from 2016 through 2024.*

[2] *Percent change from 2016 to 2024.*

[3] *Abbreviations used: ICD, informed consent document; HIPAA, Health Insurance Portability and Accountability.*

[4] *The numbers in parentheses were the percentages of the total number of protocols audited or HIPAA authorization required.*

Institutional review board initial and continuing reviews: Table 5 shows data from 2016 through 2024 on numbers and rates of protocols conducted and completed without IRB review and approval; and numbers and rates of protocols for which investigators continued research activities during a lapse in required IRB continuing reviews.

The numbers of protocols audited each year ranged from 3,201 in 2024 to 3,801 in 2016. Only one protocol was conducted without IRB approval in 2023. There was no statistically significant trend of change from 2016 through 2024.

The number of protocols requiring IRB continuing reviews ranged from 1,501 in 2024 to 3,162 in 2016. The rates of protocols for which investigators continued research activities during a lapse in IRB continuing reviews were small, ranging from 0.00% to 0.19%. There was a statistically significant trend of change from 0.00% in 2016 to 0.13% in 2024.

	2016	2017	2018	2019	2020	2021	2022	2023	2024	*P* value[1]	Change (%)[2]
Total number of active protocols	**15,699**	**15,279**	**15,258**	**15,061**	**14,637**	**15,015**	**14,917**	**14,685**	**14,484**		
Total number of protocols audited	3,801	3,573	3,564	3,569	3,348	3,540	3,349	3,441	3,201		
Conducted without IRB[3] approval	0 (0.00%)[4]	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.03%)	0 (0.00%)	0.2316	N/A[5]
Total number of protocols requiring IRB continuing reviews	3,162	3,094	3,035	2,861	2,547	2,205	1,900	1,606	1,501		
Continued research activities during lapse	0 (0.00%)	0 (0.00%)	3 (0.10%)	0 (0.00%)	2 (0.08%)	0 (0.00%)	2 (0.11%)	3 (0.19%)	2 (0.13%)	0.0106	XX[6]

Table 5. Institutional review board Initial and continuing reviews

[1] *Determined using analysis of ordered categories for the trend of changes from 2016 through 2024.*

[2] *Percent change from 2016 to 2024.*

[3] *Abbreviations used: IRB, institutional review board.*

[4] *The numbers in parentheses were the percentages of the total number of protocols audited or requiring IRB*

continuing reviews.

[5] *N/A denotes not applicable.*

[6] *XX Unable to calculate, because the 2016 value was zero.*

Discussion

The results presented in this report demonstrated that at five and a half years after the implementation of the revised Common Rule on January 21, 2019, when 77% of all active human research protocols were under the revised Common Rule requirements, there had been an increase of 259% in the number of exempt protocols and a reduction of 44% in the number of protocols requiring IRB continuing reviews from 2016 to 2024. Thus, the revised Common Rule has achieved its objective of markedly reducing the burden of low-risk studies on researchers.

On the other hand, these results also revealed that there had been no enhancement in human research subject protections. Of the five human research subject protection performance metrics studied, two, i.e., unanticipated, serious, research-related adverse events, and research conducted without IRB approval, remained unchanged, while three, i.e., required informed consent and HIPAA authorization not obtained, as well as continued research activities during a lapse in IRB continuing reviews, deteriorated. These data suggested that instead of enhancing human research subject protections, the implementation of the revised Common Rule actually led to reduced human research subject protections.

Specifically, the revised Common Rule did not affect the rates of unanticipated physical and psychological harms experienced by research participants (the first performance metric). However, it caused a 300% increase and a 52% increase in dignitary harms to research participants due to violations of their autonomy and privacy rights, respectively (the second and third performance metrics). Finally, while there was no change in the rate of research conducted without IRB review and approval (the fourth performance metric), there was a statistically significant increase in the rate of investigators continuing research activities during a lapse in IRB continuing reviews (the fifth performance metric), which placed research subjects at an increased risk of harms in the absence of objective oversight.

The questions are how the implementation of the revised Common Rule, which was intended to enhance human research subject protections, led to increased dignitary harms to research participants, and how the implementation of the revised Common Rule, while markedly reducing the number of protocols requiring IRB continuing reviews, led to more investigators continuing research activities during a lapse in required IRB continuing reviews?

It was disappointing that five and a half years after the implementation of the revised Common Rule, we found that the revised Common Rule actually hindered human research subject protections, instead of enhancing it

as the Office for Human Research Protections claimed. However, considering the following observations, this may not be something that is unexpected.

- Despite one of the objectives for revising the Common Rule being to enhance human research subject protections, the revised Common Rule didn't include any provisions that were designed to improve human research subject protections. We knew this was the case because there were no procedures or interventions that had been shown to improve human research subject protections, as prior to 2018, we didn't know how to measure human research subject protections[4].
- The revised Common Rule contained provisions designed to improve informed consent so that potential participants would be better informed when making decisions whether to participate in particular research studies. These included giving prospective participants information a reasonable person would want to know to make a decision whether to participate in research, providing sufficient detail, reorganizing consent forms to facilitate understanding, and presenting concise and focused key information at the beginning[1][3]. However, the revised Common Rule didn't provide sufficient guidelines on how these requirements should be implemented, including what constitutes information a reasonable person would want to know to make a decision whether to participate in research and what constitutes concise and focused "key information."[10][11] As a result, there has been no study demonstrating whether these new requirements have achieved the goal of improving potential participants' understanding of the informed consent, thereby facilitating their decisions on whether to participate in the research.
- The revised Common Rule required the use of a single-IRB review for multi-site studies in the U.S., eliminating the time and effort associated with multiple IRB reviews and the need for reconciling different IRB determinations and requirements.[1][3] The potential benefits of a single-IRB review for multi-site studies had been previously well documented using the experience of the National Cancer Institute Central IRB.[12] However, the implementation of this revised Common Rule requirement for the use of a single-IRB review for all federally funded/supported multi-site studies is daunting.[13][14] In a National Institutes of Health-sponsored workshop in 2022 examining why single-IRB review remained problematic, the workshop participants identified several major barriers such as additional responsibilities for study teams, persistent duplicative review processes, the lack of harmonization of policies and processes across institutions, the absence of additional guidance from federal agencies, and the need for greater flexibility in policy requirements. The workshop recommended additional resources and training for research teams, the commitment of institutional leaders to harmonize practices, and policy makers to critically evaluate the requirements and provide flexibility in applicability.[14]

It is clear that the implementation of the revised Common Rule is complex. The difficulties and confusions in implementing these revised Common Rule requirements, together with the disruptions caused by the coronavirus disease 2019 (COVID-19) pandemic in the U.S. between 2020 and 2022, might have prevented institutions and investigators from focusing on research and human research subject protections, leading to unfortunate lapses in obtaining informed consent and HIPAA authorization as required and investigators continuing research activities during lapses in IRB continuing reviews, as demonstrated in this study.

In a preliminary analysis of 16 performance metrics related to IRB, Tsan and Van Hook[15] reported that two and a half years after the implementation of the revised Common Rule, when 48% of all active protocols were under the revised Common Rule requirement, 4 improved, 4 deteriorated, and 8 remained unchanged from 2016 through 2021. The 4 performance metrics that deteriorated were all related to informed consent documents and HIPAA authorization requirements. It was speculated at that time that the disruptions caused by the COVID-19 pandemic in the U.S. in 2020 and 2021 were largely responsible for the observed deteriorations.[15]

In view of the continued deterioration of the second and third human research subject protection performance metrics and the development of an increased rate of investigators continuing research activities during a lapse in IRB continuing reviews (the fifth performance metric), when the COVID-19 pandemic was under control in the U.S. after 2022, I would have to conclude that the implementation of the revised Common Rule was largely responsible for the observed deterioration of the second, third, and fifth human research subject protection performance metrics from 2016 through 2024.

As we overcome the difficulties in implementing the revised Common Rule in the coming years, we hope to see human research subject protection performance metrics return to the levels of the pre-implementation years, i.e., 2016-2018. However, as the revised Common Rule didn't include any specific provisions that would enhance human research subject protections, I don't expect any improvement in human research subject protections as a result of the revised Common Rule.

Conclusion

At five and a half years after the implementation of the revised Common Rule on January 21, 2019, when 77% of all active human research protocols were under the revised Common Rule requirements, there was an increase of 259% in the number of exempt protocols and a reduction of 44% in the number of protocols requiring IRB continuing reviews from 2016 to 2024. Thus, the revised Common Rule has achieved its objective of markedly reducing the burden of low-risk studies on researchers.

On the other hand, analysis of human research subject protection performance metric data during the same period revealed that there was no enhancement in human research subject protections. Of the five human

research subject protection performance metrics studied, two, i.e., unanticipated, serious, research-related adverse events, and research conducted without IRB approval, remained unchanged, while three, i.e., required informed consent and HIPAA authorization not obtained, as well as continued research activities during a lapse in IRB continuing reviews, deteriorated. Thus, instead of enhancing human research subject protections, the implementation of the revised Common Rule actually led to reduced human research subject protections.

Notes

Running title: Impact of the Revised Common Rule.

Statements and Declarations

Conflicts of Interest

The author has no financial or proprietary interest in the subject matter of this article.

Acknowledgements

The author thanks Yen B. Nguyen, Pharm.D., and all VA research compliance officers for their contributions in conducting the audits and collecting the data presented in this report.

References

1. a, b, c, d, e, f, g, h*U.S. Department of Health and Human Services. Federal policy for the protection of human subjects: 45 code of Federal Registration (CFR) 46. 2018. http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html*
2. ^*U.S. Department of Health and Human Services. Human subjects research protections: enhancing protections for research subjects and reducing burden, delay, and ambiguity for investigators. Federal Register 2011; 76 (143): 44512-44531.*
3. a, b, c, d, e*Menikoff J, Kaneshiro J, Pritchard I. The common rule, updated. New Engl J Med 2017; 376(7): 613-615. doi:10.1056/NEJMp1700736.*
4. a, b*Tsan MF. How well are we protecting human research subjects? 2024. Qeios. doi:10.32388/7RS57W.*
5. ^*Yu M, Fischhoff B, Krishnamurti T. Implementing a new Common Rule requirement for informed consent: A randomized trial on adult asthma patients. MDM Policy & Practice 2019; 4: 1-6. doi:10.1177/2381468319839315*
6. a, b, c, d*Tsan MF, Puglisi JT. Protecting human subjects participating in research. Am J Transl Res 2023; 15(9): 5707-5714. (www.ajtr.org/ISSN:1943-8141/AJTR0151875)*

7. ^Tsan MF, Puglisi JT. Health care operations activities that may constitute research – The Department of Veteran s Affairs' perspective. IRB 2014; 36(1): 9-11.
8. ^Agresti A. Analysis of Ordinal Categorical Data. New York, NY: John Wiley & Sons; 1984.
9. ^Tsan MF, Nguyen Y. Effectiveness of human research protection program performance measurements. J Emp Re s Human Res Ethics 2017; 12(4): 217-228. doi:10.1177/1556264617720387
10. ^Bazzano LA, Durant J, Brantley PR. A modern history of informed consent and the role of Key information. Ochs ner J. 2021; 21(1):81-85.
11. ^Gelinas L, Morrell W, Tse T, Glazier A, Zarin DA, Bierer BE. Characterization of key information sections in infor med consent forms posted on ClinicalTrials.gov. J Clin Transl Sci. 2023; 7(1): e185. doi:10.1017/cts.2023.605.
12. ^Wagner TH, Murray C, Goldberg J, Adler JM, Abrams J. Costs and Benefits of the National Cancer Institute Centra l Institutional Review Board. J Clin Oncol. 2010; 28(4):662–666. doi:10.1200/JCO.2009.23.2470
13. ^Hu A, Holl JL, Raval MV. Pediatric specific challenges of the single institutional review board mandate. Trials 20 22; 23:224. doi.org/10.1186/s13063-022-06141-y.
14. a, bGreen JM, Goodman P, Kirby A, Cobb N, Bierer BE. Implementation of single IRB review for multisite human s ubjects research: Persistent challenges and possible solutions. J Clin Transl Sci. 2023; 7: e99, 1–5. doi:10.1017/cts.2 023.517.
15. a, bTsan MF, Van Hook H. Assessing the quality and performance of institutional review boards: impact of the revi sed Common Rule. J Emp Res Human Res Ethics. 2022; 17(4): 525-532. doi:10.1177/15562646221094407.

Declarations

Funding: No specific funding was received for this work.

Potential competing interests: No potential competing interests to declare.