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Variations in institutional review board processes and consent requirements for trauma research: an EAST multicenter survey

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ABSTRACT

Oversight of human subject research has evolved considerably since its inception. However, previous studies identified a lack of consistency of institutional review board (IRB) determination for the type of review required and whether informed consent is necessary, especially for prospective observational studies, which pose minimal risk of harm. We hypothesized that there is significant inter-institution variation in IRB requirements for the type of review and necessity of informed consent, especially for prospective observational trials without blood/tissue utilization. We also sought to describe investigators' and IRB members' attitudes toward the type of review and need for consent. Eastern Association for the Surgery of Trauma (EAST) and IRB members were sent an electronic survey on IRB review and informed consent requirement. We performed descriptive analyses as well as Fisher's exact test to determine differences between EAST and IRB members' responses. The response rate for EAST members from 113 institutions was 13.5%, whereas a convenience sample of IRB members from 14 institutions had a response rate of 64.4%. Requirement for full IRB review for retrospective studies using patient identifiers was reported by zero IRB member compared with 13.1% of EAST members (p=0.05). Regarding prospective observational trials without blood/tissue collection, 48.1% of EAST members reported their institutions required a full IRB review compared with 9.5% of IRB members (p=0.01). For prospective observational trials with blood/tissue collection, 80% of EAST members indicated requirement to submit a full IRB review compared with only 13.6% of IRB members (p<0.001). Most EAST members (78.6%) stated that informed consent is not ethically necessary in prospective observational trials without blood/tissue collection, whereas most IRB members thought that informed consent was ethically necessary (63.6%, p<0.001). There is significant variation in perception and practice regarding the level of review for prospective observational studies and whether informed consent is necessary. We recommend future interdisciplinary efforts between researchers and IRBs should occur to better standardize local IRB efforts.

Level of evidence IV.

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INTRODUCTION

In the USA, research is supervised by local institutional review boards (IRBs). Previously identified major obstacles to research that result from this regulatory structure include (1) a lack of consistent interpretation between IRBs of the types of risk in data collection; and (2) a lack of data to determine if consistency of process is being achieved at each site (ie, consistent need for full IRB review and/or need for consent).[1-4] Although the benefits of intense review might justify the barriers generated by local processes, it is less clear whether this is true for studies posing minimal risk to subjects.

Unfortunately, there is a paucity of literature on this topic. However, based on feedback received from primary investigators leading Eastern Association for the Surgery of Trauma (EAST) multicenter trials, as well as discussions of varying practices among committee members, we hypothesized that there is significant variation in perceptions of EAST members compared with IRB members regarding IRB requirements for review of observational trials, especially prospective observational trials without need for blood/tissue collection. Second, we hypothesized that there is significant variation in perceptions of need for informed consent between EAST members and IRB members. Third, we hypothesized that there would be significant variation within subgroups of EAST members based on research experience of the investigator (ie, >2 previous IRB submissions vs. ≤2 IRB submissions) or institution (ie, level I American College of Surgeons (ACS) or state-verified center vs. non-level I ACS or state-verified center). Additionally, we sought to describe primary investigators' and IRB members' attitudes toward the need for review and consent in these types of studies.

METHODS

The EAST Multicenter Trials (MCT) Committee conducted a study to evaluate the experiences of trauma researchers with their local IRB processes for studies posing minimal risk. At these same institutions, IRB members were asked to share their practices and their perceptions of the process. After obtaining IRB exemption at the University of California, Irvine, the EAST MCT Committee distributed an electronic survey to all currently active (licensed, board-certified surgeons, under the age of 50) and associate (physicians in non-surgical specialties and non-physicians) EAST members. The EAST MCT Committee members were also

asked to provide a convenience sample of colleagues from their 14 affiliated institutions who were IRB members. This decision to use a convenience sample was due to the fact that there was no national organization or entity that could provide a list of similar institutions' IRB members. All IRB members came from an institution with at least one EAST member involved in the survey. The survey was distributed from June to October 2017 using a link to an anonymous REDCap survey.[5] Responses from EAST members who self-indicated that they had not been a primary investigator of an IRB-requiring project and from IRB members who self-indicated they were not currently part of an IRB were excluded from analysis. There were minor differences in the surveys administered to EAST versus IRB members (see online supplementary appendix).

Descriptive statistics were performed for all data. Analyses were conducted comparing the responses from different groups of EAST members and also comparing those of EAST members with those of IRB personnel using the Fisher's exact test. All statistical analyses were performed with Stata V.14.2.

RESULTS

From 1181 EAST members, 219 from the USA and Canada responded (18.5% overall response rate) to our online survey, with 160 meeting the inclusion criteria (13.5% response rate for those meeting the inclusion criteria) as a primary investigator of a current or previous project requiring IRB submission. These respondents declared their affiliation to be from 36 states. EAST members participated from 113 unique institutions, whereas IRB members participated from 14 institutions. From 14 different institutions, 45 potential IRB members were queried, and 29 responded (64.4% response rate), with 23 indicating they were currently an active IRB member. All IRB members who responded had corresponding EAST members from their home institution who also replied. EAST and IRB member demographic information is shown in table 1.

Table 1 Group demographics of EAST and IRB members

	EAST	IRB
Survey	Frequency (%)	Frequency (%)
IRB submissions in the past year	(n=158)	–
1	18 (11.4)	–
2	27 (17.1)	–
3	41 (25.9)	–
4	18 (11.4)	–
5 or more	54 (34.2)	–
Turnaround time (weeks) for IRB submissions	(n=155)	(n=22)
<1 week	5 (3.2)	3 (13.6)
2–4 weeks	70 (45.2)	12 (54.5)
4–8 weeks	59 (38.1)	6 (27.3)
>8 weeks	21 (13.5)	1 (4.5)
Institution setting	(n=159)	(n=21)
University	121 (76.1)	20 (95.2)
Private academic	32 (20.1)	1 (4.8)
Private non-academic	6 (3.8)	0 (0)
Trauma center verification (ACS or state)	(n=160)	–
Level I	142 (88.8)	–
Level II	15 (9.4)	–
Level III	2 (1.3)	–
Not verified	1 (0.6)	–

ACS, American College of Surgeons; EAST, Eastern Association for the Surgery of Trauma; IRB, institutional review board.

Retrospective observational studies

A full IRB review for retrospective studies using patient identifiers was reported to be required by 13.1% of EAST members, whereas 11.9% reported being assigned exemption from IRB review. In contrast, zero IRB member reported ever requiring a full IRB review or an exemption. Rather, the overwhelming majority reported a need for an expedited review (95.5%) (p=0.05) (table 2).

Prospective observational studies

Regarding prospective observational trials without blood/tissue collection, 48.1% of EAST members reported that their institutions required full IRB review and 36.5% required informed consent. The majority of IRB members (57.1%, p=0.01) reported their institutions allowed expedited review in these cases, with informed consent determined on a case-by-case basis (86.4%, p<0.001). For prospective observational trials with blood/tissue collection, 80.0% of EAST members indicated a requirement to submit a full IRB review as compared with only 13.6% of IRB members (p<0.001).

Informed consent, multicenter studies, and application fees

EAST and IRB members were queried on their opinions about the balance between subject protection and investigator research burden (table 3). Most EAST members (78.6%) stated that informed consent is not ethically necessary and thought that it was an unreasonable burden to research in prospective observational trials without blood/tissue collection. In contrast, most IRB members thought that informed consent was ethically necessary (63.6%, p<0.001).

With regard to multicenter trials, 62.7% of EAST members reported that their home institution does not allow IRB approval from an outside centralized institution coordinating site to participate in multicenter studies/trials. In contrast all IRB members indicated their home institutions allow this (p<0.001).

A fee for non-industry retrospective study applications was required in 13.2% of EAST members' responses (fee ranged from $95 to $3500), but in none of the IRB members' responses (see online supplementary appendix table 1).

Subgroup analyses

On subgroup analysis comparing the responses of EAST members from a level I state or ACS-verified trauma center with those of a non-level I center, there were no significant differences in any of the questions (see online supplementary appendix tables 2–4).

We then compared EAST members involved in ≤2 IRB-required projects with those who had completed ≥3 IRB-required projects. More EAST members with less than two IRB-required projects reported the requirement of a full IRB review for retrospective studies compared with those EAST members involved with three or more IRB-required projects (26.7% vs. 7.1%, p=0.01). Conversely, EAST members with ≤2 IRB-required projects reported a lower rate for waiver of informed consent (66.7% vs. 79.7%, p=0.03) (table 4). There were no significant differences for the other questions (see online supplementary appendix tables 5–6).

Finally, we compared EAST members from private institutions with those from a university setting. There were no significant

Table 2 IRB review and informed consent for EAST and IRB members

Survey	EAST Frequency (%)	IRB Frequency (%)	P values
Level of IRB review required for retrospective observational trials using patient identifiers	(n=160)	(n=22)	0.05
Exempt	19 (11.9)	0 (0)	
Expedited review	110 (68.8)	21 (95.5)	
Full IRB review	21 (13.1)	0 (0)	
Case-by-case basis	10 (6.3)	1 (4.5)	
Level of informed consent required when using patient identifiers for retrospective studies	(n=160)	(n=22)	0.46
Waiver of informed consent	121 (75.6)	19 (86.4)	
Require informed consent	13 (8.1)	0 (0)	
Case-by-case basis	26 (16.3)	3 (13.6)	
Level of IRB review required for prospective observational trials WITHOUT blood/tissue collection	(n=160)	(n=21)	0.01
Exempt	4 (2.5)	1 (4.8)	
Expedited review	60 (37.5)	12 (57.1)	
Full IRB review	77 (48.1)	2 (9.5)	
Case-by-case basis	19 (11.9)	6 (28.6)	
Level of informed consent required for prospective observational trials WITHOUT blood/tissue collection	(n=159)	(n=22)	<0.001
Waiver of informed consent	49 (30.8)	1 (4.5)	
Require informed consent	58 (36.5)	2 (9.1)	
Case-by-case basis	52 (32.7)	19 (86.4)	
Level of IRB review required for prospective observational trials WITH blood/tissue collection	(n=155)	(n=22)	<0.001
Exempt	1 (0.6)	0 (0)	
Expedited review	6 (3.9)	10 (45.5)	
Full IRB review	124 (80.0)	3 (13.6)	
Case-by-case basis	24 (15.5)	9 (40.9)	
Level of informed consent required for prospective observational trials WITH blood/tissue collection	(n=156)	(n=22)	0.34
Waiver of informed consent	3 (1.9)	0 (0)	
Require informed consent	118 (75.6)	14 (63.6)	
Case-by-case basis	35 (21.9)	8 (36.4)	
Accepted policy/precedence available for prospective observational trials requiring informed consent	(n=150)	(n=21)	0.81
No	65 (43.3)	10 (47.6)	
Yes	85 (56.7)	11 (52.4)	

EAST, Eastern Association for the Surgery of Trauma; IRB, institutional review board.

Table 3 Informed consent and coordinating site for EAST and IRB members

Survey	EAST Frequency (%)	IRB Frequency (%)	P values
Do you feel informed consent for prospective observational trials WITHOUT blood/tissue collection is ethically necessary and a reasonable burden to research?	(n=159)	(n=22)	<0.001
No	125 (78.6)	8 (36.4)	
Yes	34 (21.3)	14 (63.6)	
Do you feel informed consent for prospective observational trials WITH blood/tissue collection is ethically necessary and a reasonable burden to research?	(n=158)	(n=22)	0.07
No	19 (12.0)	0 (0)	
Yes	139 (88.0)	22 (100)	
Does your IRB currently accept IRB approval from an outside centralized institutional coordinating site to participate in multicenter studies/trials?	(n=157)	(n=22)	<0.001
No	99 (62.7)	0 (0)	
Yes	59 (37.3)	22 (100)	
Does your IRB currently allow your institution to serve as a coordinating site IRB holder for multicenter studies/trials?	(n=157)	(n=22)	0.41
No	36 (22.9)	3 (13.6)	
Yes	121 (77.1)	19 (86.4)	

EAST, Eastern Association for the Surgery of Trauma; IRB, institutional review board.

differences (see online supplementary appendix tables 7–8), except that a lower rate of EAST members from a university setting thought that informed consent for prospective studies with blood/tissue collection is ethically necessary and a reasonable burden to research (84.9% vs. 97.4%, p=0.03) (table 5).

DISCUSSION

Our study demonstrates significant discrepancies between EAST and IRB members' perceptions of local review and consent practices. Over 95% of the IRB members reported that retrospective studies met the criteria for expedited review, whereas only about two-thirds of EAST members understood this to be the case at their institution. Over 13% of EAST members stated these studies required full IRB review, whereas no IRB member reported a retrospective study with patient identifiers required full IRB review. Until recently, the Office for Human Research Protections' expedited review was intended for research activities that present no more than minimal risk to human subjects and meet one of nine categories of research.[6] However, beginning January 2018 the Common Rule included new categories of exemption, including secondary research involving identifiable private information if the research is regulated by and participants protected under the Health Insurance Portability and Accountability Act rules.[7] Clearly, greater investigator education is needed focusing on which studies qualify for expedited review.

Perceptions of review and consent requirements for prospective observational research studies without blood/tissue sampling demonstrated significant variation between IRB and EAST members but also among the members of each group. Both EAST and IRB members had answers ranging from IRB exemption to full IRB review, with neither group having a single answer that achieved 50% majority. Furthermore, over 86% of IRB members' responses indicated that requirement of informed consent for study participants in prospective observational research without blood/tissue sampling was decided on a case-by-case basis. Polito *et al*[8] highlighted this issue in a survey of 36 primary investigators at four centers, citing IRB concerns about waiver of consent as a major barrier to approval of a multicenter observational critical care study.

Table 4 IRB review and informed consent for EAST members with ≤2 IRBs compared with those with >2

Survey	≤2 IRBs Frequency (%)	>2 IRBs Frequency (%)	P values
Level of IRB review required for retrospective observational trials using patient identifiers	(n=45)	(n=112)	0.01
Exempt	3 (6.7)	16 (14.2)	
Expedited review	26 (57.8)	83 (73.5)	
Full IRB review	12 (26.7)	8 (7.1)	
Case-by-case basis	4 (8.9)	6 (5.3)	
Level of informed consent required when using patient identifiers	(n=45)	(n=113)	0.03
Waiver of informed consent	30 (66.7)	90 (79.7)	
Require informed consent	8 (17.8)	5 (4.4)	
Case-by-case basis	7 (15.6)	18 (15.9)	
Level of IRB review required for prospective observational trials WITHOUT blood/tissue collection	(n=45)	(n=113)	0.80
Exempt	1 (2.2)	3 (2.7)	
Expedited review	15 (33.3)	45 (39.8)	
Full IRB review	22 (48.9)	53 (46.9)	
Case-by-case basis	7 (15.6)	12 (10.6)	
Level of informed consent required for prospective observational trials WITHOUT blood/tissue collection	(n=44)	(n=113)	0.57
Waiver of informed consent	11 (25.0)	38 (33.6)	
Require informed consent	18 (40.9)	39 (34.5)	
Case-by-case basis	15 (34.1)	36 (31.9)	
Level of IRB review required for prospective observational trials WITH blood/tissue collection	(n=44)	(n=109)	0.08
Exempt	0 (0.0)	1 (0.9)	
Expedited review	0 (0.0)	6 (5.5)	
Full IRB review	33 (75.0)	89 (81.7)	
Case-by-case basis	11 (25.0)	13 (11.9)	
Level of informed consent required for prospective observational trials WITH blood/tissue collection	(n=44)	(n=110)	0.93
Waiver of informed consent	1 (2.3)	2 (1.8)	
Require informed consent	34 (77.3)	83 (75.5)	
Case-by-case basis	9 (20.5)	25 (22.7)	
Accepted policy/precedence available for prospective observational trials requiring informed consent	(n=43)	(n=105)	0.08
No	23 (53.5)	41 (39.0)	
Yes	20 (46.5)	64 (61.0)	

EAST, Eastern Association for the Surgery of Trauma; IRB, institutional review board.

Table 5 Informed consent and coordinating site for EAST members from private compared with university setting

Survey	Private Frequency (%)	University Frequency (%)	P values
Do you feel informed consent for prospective observational trials WITHOUT blood/tissue collection is ethically necessary and a reasonable burden to research?	(n=38)	(n=120)	0.57
No	30 (79.0)	94 (78.3)	
Yes	8 (21.0)	26 (21.7)	
Do you feel informed consent for prospective observational trials WITH blood/tissue collection is ethically necessary and a reasonable burden to research?	(n=38)	(n=119)	0.03
No	1 (2.6)	18 (15.1)	
Yes	37 (97.4)	101 (84.9)	
Does your IRB currently accept IRB approval from an outside centralized institutional coordinating site to participate in multicenter studies/trials?	(n=37)	(n=120)	0.44
No	21 (56.8)	77 (64.2)	
Yes	16 (43.2)	43 (35.8)	
Does your IRB currently allow your institution to serve as a coordinating site IRB holder for multicenter studies/trials?	(n=37)	(n=119)	0.02
No	14 (37.8)	22 (18.5)	
Yes	23 (62.2)	97 (81.5)	

EAST, Eastern Association for the Surgery of Trauma; IRB, institutional review board.

Multiple publications have similarly concluded that there is significant variation to the IRB process and approval in multicenter observational studies that pose minimal risk of harm.[9 10] A proposed solution to this issue is the use of a single centralized IRB. Although 100% of IRB members in our study reported allowing the use of outside central IRBs, this approach has notable disadvantages, including the lack of a local brick-and-mortar structure and IRB relationship with the communities it serves.[11] The role of centralized IRBs will increase with the implementation of the new Common Rule in January 2018. Under this revised rule, single-IRB review for multi-institutional studies will become the default; however, due to some concerns, the rule provides provisions allowing any federal agency supporting or conducting research to be permitted to determine if a single IRB is not appropriate for a particular context and therefore review should be done at each center's IRB.[7 11 12] Despite these efforts, there is no doubt that for single-center studies, efforts must be made to increase consistency of which prospective observational studies require or do not require informed consent. This is especially pertinent for trauma research, where the burden of consent of many subjects coupled with the emergent nature of injuries may inhibit investigation regarding emergent conditions.

For prospective observational studies, 56.7% of EAST members and 52.4% of IRB members replied there is a precedent or policy for consent determination. Additionally, our study demonstrated that 21.3% of EAST members thought it a reasonable research burden or ethically necessary or both to require informed consent as compared with almost two-thirds of IRB members. A previous study at a level I trauma center reported that 43% of trauma patients appeared incapable of consent, with 20% being 'unconsentable' even with use of a legally authorized representative.[13] Our survey included a space for free-text responses. A common theme reported was that investigators appeared to avoid prospective observational studies if they were from centers that required informed consent to conduct such studies. Fox *et al*[14] studied the waiver of consent in non-interventional research based on the Prospective Observational Multicenter Major Trauma Transfusion study. They found that if one of the sites' IRB had required withdrawal of patients unable to consent, this would have introduced significant bias to their

data. They recommended that more observational studies should publish details about consent to gain more information about refusal rates and how these might affect non-interventional study results and quality.

Our study is small and based on survey opinions and as such has many limitations. The data collected from a small cohort of EAST and IRB members represent perceptions, not necessarily norms, regulations or even actual occurrences within each respondent's institution. Also, 90% of centers with respondents had only one or two respondents, making any intrainstitutional analysis unfeasible. Responder bias is also a significant limitation given the 13.5% EAST member response rate. Although we cannot completely assuage concerns about selection bias, we think the results are generalizable especially given the variation in answers between IRB members, who should in a manner act as a control for the knowledge of actual procedures within an institution. Of note, all of these IRB members resided at an institution where there were concurrent EAST members. That said, there is a clear limitation to the use of a small (14 centers) convenience sample size of IRB members. Unfortunately, there is no national registry or database of IRB members to query, and it was thought that an unsolicited email survey regarding an institution's IRB processes would achieve an unacceptably low response rate.

Despite these limitations, the authors involved in this study think the study clearly demonstrates that there is significant variation regarding the need for informed consent. Although any final decision regarding this topic would require a multidisciplinary consensus statement involving researchers, ethicists, national research organizations and members from IRBs, we do think that prospective observational research that does not require blood/tissue utilization clearly falls within a category of minimal risk/harm and should not require informed consent. We aspire that this article will serve as an impetus to create a national multidisciplinary coalition that can attempt to solve this issue that affects multicenter research throughout the nation.

CONCLUSION

There appears to be significant variation in perception and practice regarding prospective observational studies for IRB review process and whether informed consent is necessary. Review requirements for these observational studies ranged from exempt to full IRB review as described by both EAST and IRB members. Over two-thirds of IRB and EAST members reported that the need for consent for prospective observational studies was determined either on a case-by-case basis or required full review. Future discussion and research with respect to trauma investigations using an observational approach are needed to better determine the benefits of consent balanced with potential bias of study results. Additionally, there was significant variation between EAST and IRB members regarding IRB exemption criteria. We recommend that future interdisciplinary efforts between researchers and IRBs occur to better standardize local IRB efforts across the country.

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REFERENCES

1 Grady C. Institutional review boards: Purpose and challenges. *CHEST Journal* 2015;148:1148–55.
2 Coleman CH, Bouësseau MC. How do we know that research ethics committees are really working? The neglected role of outcomes assessment in research ethics review. *BMC Med Ethics* 2008;9:6.
3 Abbott L, Grady C. A systematic review of the empirical literature evaluating IRBs: what we know and what we still need to learn. *J Empir Res Hum Res Ethics* 2011;6:3–19.
4 Emanuel EJ, Menikoff J. Reforming the regulations governing research with human subjects. *N Engl J Med* 2011;365:1145–50.
5 Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
6 Pew Research Center. http://www.pewresearch.org/fact-tank/2015/04/16/car-bike-or-motorcycle-depends-on-where-you-live/ (accessed 13 Dec 2017.).
7 The US Department of Health and Human Services. Final rule enhances protections for research participants, modernizes oversight system. https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html (accessed 5 Dec 2017).
8 Polito CC, Cribbs SK, Martin GS, O'Keeffe T, Herr D, Rice TW, Sevransky JE. Navigating the institutional review board approval process in a multicenter observational critical care study. *Crit Care Med* 2014;42:1105–9.
9 Green LA, Lowery JC, Kowalski CP, Wyszewianski L. Impact of institutional review board practice variation on observational health services research. *Health Serv Res* 2006;41:214–30.

10 Petersen LA, Simpson K, Sorelle R, Urech T, Chitwood SS. How variability in the institutional review board review process affects minimal-risk multisite health services research. *Ann Intern Med* 2012;156:728–35.
11 Klitzman R. How local IRBs view central IRBs in the US. *BMC Med Ethics* 2011;12:13.
12 Menikoff J, Kaneshiro J, Pritchard I. The common rule, updated. *N Engl J Med* 2017;376:613–5.
13 Dutton RP, Stansbury LG, Hemlock B, Hess JR, Scalea TM. Impediments to obtaining informed consent for clinical research in trauma patients. *J Trauma* 2008;64:1106–12.
14 Fox EE, Bulger EM, Dickerson AS, del Junco DJ, Klotz P, Podbielski J, Matijevic N, Brasel KJ, Holcomb JB, Schreiber MA, *et al*. Waiver of consent in noninterventional, observational emergency research: the PROMMTT experience. *J Trauma Acute Care Surg* 2013;75:S3–S8.