Table1. Fees for EAST and IRB members

|  |  |  |  |
| --- | --- | --- | --- |
|  | **EAST** | **IRB** |  |
| **Survey** | **Frequency, percentage** | **Frequency, percentage** | **p-value** |
| Does your IRB charge a fee to review non-industry applications for retrospective observational studies conducted soley at your institution?  | (n=152) | (n=21) | 0.13 |
|  No | 132 (86.8%) | 21 (100%) |  |
|  Yes | 20 (13.2%) | 0 (0%) |  |
|  $0-199 | 4 (20%) | - |  |
|  $200-599 | 7 (35%) | - |  |
|  >$600 | 3 (15%) | - |  |
|  Unknown | 6 (30%) | - |  |
| Does your IRB charge a fee to review non-industry applications for prospective observational studies conducted soley at your institution?  | (n=152) | (n=21) | 0.47 |
|  No | 132 (86.6%) | 20 (90.9%) |  |
|  Yes | 20 (13.2%) | 1 (4.8%) |  |
|  $0-199 | 3 (15%) | - |  |
|  $200-599 | 2 (10%) | - |  |
|  >$600 | 5 (25%) | - |  |
|  Unknown | 10 (50%) | 1 (100%) |  |

Table 2. IRB Review and Informed Consent for EAST members from Level-1 state or ACS verified trauma-center compared to non-level-1

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Non-Level-1** | **Level-1** |  |
| **Survey** | **Frequency, percentage** | **Frequency, percentage** | **p-value** |
| Level of IRB-review required for retrospective observational trials utilizing patient identifiers  | *(n=19)* | *(n=142)* | *0.16* |
|  *Exempt* | 1 (5.3%) | 18 (12.7%) |  |
|  *Expedited review* | 11 (57.9%) | 100 (70.4%) |  |
|  *Full IRB review* | 5 (26.3%) | 16 (11.3%) |  |
|  *Case-by-case basis* | 2 (10.5%) | 8 (5.6%) |  |
| Level of informed consent required when utilizing patient identifiers  | *(n=19)* | *(n=142)* | *0.52* |
|  *Waiver of informed consent* | 13 (68.4%) | 109 (76.8%) |  |
|  *Require informed consent* | 1 (5.3%) | 12 (8.5%) |  |
|  *Case-by-case basis* | 5 (26.3%) | 21 (14.8%) |  |
| Level of IRB-review required for prospective observational trials WITHOUT blood/tissue collection  | *(n=19)* | *(n=142)* | *0.97* |
|  *Exempt* | 0 (0.0%) | 4 (2.8%) |  |
|  *Expedited review* | 8 (42.1%) | 53 (37.3%) |  |
|  *Full IRB review* | 9 (47.4%) | 68 (47.9%) |  |
|  *Case-by-case basis* | 2 (10.5%) | 17 (12.0%) |  |
| Level of informed consent required for prospective observational trials WITHOUT blood/tissue collection  | *(n=19)* | *(n=141)* | *0.71* |
|  *Waiver of informed consent* | 5 (26.3%) | 44 (31.2%) |  |
|  *Require informed consent* | 6 (31.6%) | 52 (36.9%) |  |
|  *Case-by-case basis* | 8 (42.1%) | 45 (31.9%) |  |
| Level of IRB-review required for prospective observational trials WITH blood/tissue collection  | *(n=19)* | *(n=137)* | *0.72* |
|  *Exempt* | 0 (0.0%) | 1 (0.7%) |  |
|  *Expedited review* | 0 (0.0%) | 6 (4.4%) |  |
|  *Full IRB review* | 15 (79.0%) | 124 (79.5%) |  |
|  *Case-by-case basis* | 4 (21.0%) | 21 (15.3%) |  |
| Level of informed consent required for prospective observational trials WITH blood/tissue collection  | *(n=19)* | *(n=138)* | *0.85* |
|  *Waiver of informed consent* | 0 (0.0%) | 3 (2.2%) |  |
|  *Require informed consent* | 14 (73.7%) | 104 (75.4%) |  |
|  *Case-by-case basis* | 5 (26.3%) | 31 (22.5%) |  |
| Accepted policy/precedence available for prospective observational trials requiring informed consent  | *(n=19)* | *(n=132)* | *0.22* |
|  *No* | 11 (57.9%) | 54 (40.9%) |  |
|  *Yes* | 8 (42.1%) | 78 (59.1%) |  |

Table 3. Informed consent and coordinating site for EAST members from Level-1 state or ACS verified trauma-center compared to non-level-1

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Non-Level-1** | **Level-1** |  |
| **Survey** | **Frequency, percentage** | **Frequency, percentage** | **p-value** |
| Do you feel informed consent for prospective observational trials WITHOUT blood/tissue collection is ethically necessary and a reasonable burden to research?  | *(n=19)* | *(n=141)* | *0.14* |
|  *No* | 12 (63.2%) | 113 (80.1%) |  |
|  *Yes* | 7 (36.8%) | 28 (19.9%) |  |
| Do you feel informed consent for prospective observational trials WITH blood/tissue collection is ethically necessary and a reasonable burden to research?  | *(n=19)* | *(n=140)* | *0.13* |
|  *No* | 0 (0.0%) | 19 (13.6%) |  |
|  *Yes* | 19 (100.0%) | 121 (86.4%) |  |
| Does your IRB currently accept IRB approval from an outside centralized institutional coordinating site to participate in multi-center studies/trials?  | *(n=19)* | *(n=140)* | *0.08* |
|  *No* | 8 (42.1%) | 91 (65.0%) |  |
|  *Yes* | 11 (57.9%) | 49 (35.0%) |  |
| Does your IRB currently allow your institution to serve as a coordinating site IRB holder for multi-center studies/trials? | *(n=19)* | *(n=139)* | *0.38* |
|  *No* | 6 (31.6%) | 30 (21.6%) |  |
|  *Yes* | 13 (68.4%) | 109 (78.4%) |  |

Table 4. Fees for EAST members from Level-1 state or ACS verified trauma-center compared to non-level-1

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Non-Level-1** | **Level-1** |  |
| **Survey** | **Frequency, percentage** | **Frequency, percentage** | **p-value** |
| Does your IRB charge a fee to review non-industry applications for retrospective observational studies conducted soley at your institution?  | (n=18) | (n=135) | 0.13 |
|  No | 18 (100%) | 115(85.2%) |  |
|  Yes | 0 (0.0%) | 20 (14.8%) |  |
| Does your IRB charge a fee to review non-industry applications for prospective observational studies conducted soley at your institution?  | (n=19) | (n=134) | 0.47 |
|  No | 18 (94.7%) | 115 (85.8%) |  |
|  Yes | 1 (5.3%) | 19 (14.2%) |  |

Table 5. Informed consent and coordinating site for EAST members with < 2 IRBs compared to those with >2

|  |  |  |  |
| --- | --- | --- | --- |
|  | **< 2 IRBs** | **>2 IRBs** |  |
| **Survey** | **Frequency, percentage** | **Frequency, percentage** | **p-value** |
| Do you feel informed consent for prospective observational trials WITHOUT blood/tissue collection is ethically necessary and a reasonable burden to research?  | *(n=44)* | *(n=113)* | *0.33* |
|  *No* | 33 (75.0%) |  90 (79.7%) |  |
|  *Yes* | 11 (25.0%) | 23 (20.3%) |  |
| Do you feel informed consent for prospective observational trials WITH blood/tissue collection is ethically necessary and a reasonable burden to research?  | *(n=44)* | *(n=112)* | *0.33* |
|  *No* | 4 (9.1%) | 15 (13.4%) |  |
|  *Yes* | 40 (90.9%) | 97 (86.6%) |  |
| Does your IRB currently accept IRB approval from an outside centralized institutional coordinating site to participate in multi-center studies/trials?  | *(n=43)* | *(n=113)* | *0.43* |
|  *No* | 28 (65.1%) | 70 (62.0%) |  |
|  *Yes* | 15 (34.9%) | 43 (38.0%) |  |
| Does your IRB currently allow your institution to serve as a coordinating site IRB holder for multi-center studies/trials? | *(n=42)* | *(n=113)* | *0.09* |
|  *No* | 14 (33.3%) | 22 (19.5%) |  |
|  *Yes* | 28 (66.7%) | 91 (80.5%) |  |

Table 6. Fees for EAST members with < 2 IRBs compared to those with >2

|  |  |  |  |
| --- | --- | --- | --- |
|  | **< 2 IRBs** | **>2 IRBs** |  |
| **Survey** | **Frequency, percentage** | **Frequency, percentage** | **p-value** |
| Does your IRB charge a fee to review non-industry applications for retrospective observational studies conducted soley at your institution?  | (n=41) | (n=109) | 0.79 |
|  No | 35 (85.4%) | 95 (87.2%) |  |
|  Yes | 6 (14.6%) | 14 (12.8%) |  |
| Does your IRB charge a fee to review non-industry applications for prospective observational studies conducted soley at your institution?  | (n=41) | (n=109) | 0.79 |
|  No | 35 (85.4%) | 95 (87.2%) |  |
|  Yes | 6 (14.6%) | 14 (12.8%) |  |

Table 7. IRB Review and Informed Consent for EAST members from private compared to university setting

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Private** | **University** |  |
| **Survey** | **Frequency, percentage** | **Frequency, percentage** | **p-value** |
| Level of IRB-review required for retrospective observational trials utilizing patient identifiers  | *(n=38)* | *(n=121)* | *0.65* |
|  *Exempt* | 3 (7.9%) | 16 (13.2%) |  |
|  *Expedited review* | 26 (68.4%) | 83 (68.6%) |  |
|  *Full IRB review* | 7 (18.4%) | 14 (11.6%) |  |
|  *Case-by-case basis* | 2 (5.3%) | 8 (6.6%) |  |
| Level of informed consent required when utilizing patient identifiers  | *(n=38)* | *(n=121)* | *0.95* |
|  *Waiver of informed consent* | 28 (73.7%) | 92 (76.0%) |  |
|  *Require informed consent* | 3 (7.9%) | 10 (8.3%) |  |
|  *Case-by-case basis* | 7 (18.3%) | 19 (15.7%) |  |
| Level of IRB-review required for prospective observational trials WITHOUT blood/tissue collection  | *(n=38)* | *(n=121)* | *0.15* |
|  *Exempt* | 0 (0.0%) | 4 (3.3%) |  |
|  *Expedited review* | 12 (31.6%) | 48 (39.7%) |  |
|  *Full IRB review* | 24 (63.2%) | 52 (43.0%) |  |
|  *Case-by-case basis* | 2 (5.3%) | 17 (14.1%) |  |
| Level of informed consent required for prospective observational trials WITHOUT blood/tissue collection  | *(n=38)* | *(n=120)* | *0.97* |
|  *Waiver of informed consent* | 11 (29.0%) | 38 (31.7%) |  |
|  *Require informed consent* | 14 (36.8%) | 44 (36.7%) |  |
|  *Case-by-case basis* |  13 (34.2%) | 38 (31.7%) |  |
| Level of IRB-review required for prospective observational trials WITH blood/tissue collection  | *(n=38)* | *(n=116)* | *0.40* |
|  *Exempt* | 0 (0.0%) | 1 (0.9%) |  |
|  *Expedited review* | 2 (5.3%) | 4 (3.5%) |  |
|  *Full IRB review* | 33 (86.8%) | 90 (77.6%) |  |
|  *Case-by-case basis* | 3 (7.9%) | 21 (18.1%) |  |
| Level of informed consent required for prospective observational trials WITH blood/tissue collection  | *(n=38)* | *(n=117)* | *0.52* |
|  *Waiver of informed consent* | 0 (0.0%) | 3 (2.6%) |  |
|  *Require informed consent* | 31 (81.6%) |  86 (73.5%) |  |
|  *Case-by-case basis* | 7 (18.4%) | 28 (23.9%) |  |
| Accepted policy/precedence available for prospective observational trials requiring informed consent  | *(n=38)* | *(n=111)* | *0.01* |
|  *No* | 24 (63.2%) |  40 (36.0%) |  |
|  *Yes* | 14 (36.8%) | 71 (64.0%) |  |

Table 8. Fees for EAST members from private compared to university setting

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Private** | **University** |  |
| **Survey** | **Frequency, percentage** | **Frequency, percentage** | **p-value** |
| Does your IRB charge a fee to review non-industry applications for retrospective observational studies conducted soley at your institution?  | (n=36) | (n=115) | 0.41 |
|  No | 33 (91.7%) | 98 (85.2%) |  |
|  Yes | 3 (8.3%) | 17 (14.8%) |  |
| Does your IRB charge a fee to review non-industry applications for prospective observational studies conducted soley at your institution?  | (n=36) | (n=115) | 0.79 |
|  No | 32 (88.9%) | 99 (86.1%) |  |
|  Yes | 4 (11.1%) | 16 (13.9%) |  |