SINGLE IRB SURVEY SUMMARY RESULTS

April 17, 2018
General Information

- **Survey Duration:** 01/26/2018 – 02/28/2018
- **Survey Platform:** REDCap
- **Total Number of Participants:** 122
  - 108 completed survey records
  - 14 not completed survey records
Participating Institutions

- Total of 105 Unique institutions participated in the survey
  - 15 Institutions are not affiliated with the CTSA
  - 59 CTSA Affiliated Institutions
  - 31 Not sure responses
Participating CTSA Institutions

- Albert Einstein (2)
- Boston University (1)
- Case Western Reserve University (1)
- Columbia University (1)
- Georgetown University (1)
- Harvard University (1)
- Indiana University Purdue University (1)
- Johns Hopkins University (1)
- Mayo Clinic (2)
- Ohio State University (6)
- Oregon Health & Science University (2)
- Rockefeller University (1)
- Stanford University (1)
- University of California Davis (2)
- University of California Irvine (1)
- University of California Los Angeles (3)
- University of California San Diego (1)
- University of California San Francisco (2)
- University of Chicago (1)
- University of Colorado (1)
- University of Florida (2)
- University of Illinois (3)
- University of Massachusetts (1)
- University of Miami (1)
- University of Michigan (1)
- University of North Carolina (1)
- University of Rochester (1)
- University of Southern California (1)
- University of Texas Dallas (1)
- University of Texas Houston (2)
- University of Texas San Antonio (3)
- University of Utah (3)
- University of Washington (3)
- Vanderbilt University (1)
- Virginia Commonwealth University (2)
- Wake Forest University (1)

(number of participants per institutions)
Section I. Administrative Information

Does your institution have a Federal Wide Assurance?

- Yes, 105
- Not sure, 3

Is your institution accredited by AAHRPP?

- Yes, 98
- No, 8
- Not sure, 2
Section I. Administrative Information

Does your institute have an executed agreement with SMART IRB?

- Yes, 101
- No, 2
- Pending, 5

Does your IRB also act as the institutional privacy board?

- Yes, 104
- No, 2
- Not sure, 2
Section I. Administrative Information

Does your institution use an electronic IRB system (eIRB)?

- Yes, 94
- No, 3
- Not sure, 11

If yes, which eIRB Platform?
- Click/Huron (10)
- iMedRIS (16)
- InfoEd (12)
- IRBManager (4)
- IRBnet (35)
- Key Solutions (8)
- Other (9)
  - Developed at UCI (1)
  - eProtocol (1)
  - home grown system (2)
  - home made 'BuckIRB' (1)
  - HS FOX Database (1)
  - Kuali Coeus IRB (1)
  - Rascal (home-grown) (1)
  - homegrown IRB IS system (1)

**All No or Not Sure responders indicated that they are willing to use an eIRB**

(number of participant responses)
Section I. Administrative Information

For institutions using an eIRB platform: Has your eIRB been customized to the specific needs of your institution?

- Yes, 92
- No, 1
- Not sure, 1

describe how extensively your electronic IRB system ('eIRB') can be modified:

- Very simple modifications: logo, pick lists
- Complex modifications: we can add whole new submission forms, whole additional pages, integrate with our single sign-on system, etc.
- Basic modifications: custom question fields, new question fields, etc.

Other

- Other: 1

Basic modifications: 42
Complex modifications: 42
Very simple modifications: 7
Section I. Administrative Information

Can your eIRB work with external systems (i.e. get live feed of your staff lists from an HR system, receive updated training statuses from CITI, feed IRB approval status out to EPIC, etc.)?

- Yes, 82
- No, 5
- Not sure, 6

Would you be interested using a public API that allowed your eIRB to work with other eIRBs to manage an NIH single IRB/multi-site trial?

- Yes, 72
- No, 2
- Not sure, 8
Section I. Administrative Information

Has your institution ever acted as an sIRB in the past, or currently

- Yes, 87
- No, 4
- Not sure, 17

If yes, how many times has your institution acted as sIRB in past 5 years?

- 1-5 times: 34
- 6-10 times: 16
- 11-15 times: 7
- 16-20 times: 13
- 21+ times: 15
- Not sure: 2

If yes, what was the largest number of participating sites in the past 5 years?

- 1-5 participating sites: 14
- 6-10 participating sites: 9
- 11-15 participating sites: 1
- 16-20 participating sites: 10
- 21+ participating sites: 48
- Not sure: 5
Section II. IRB Review Volume

Does your institution receive IRB applications sponsored by the NIH?

- Yes, 93
- No, 15
The goal of the following survey questions was to determine the amount of flexibility requested/required for IRB study documents leading to the development of best practices/standards for sIRB operations and efficient study startup.

Responses are:

- **Full sIRB Standardization** - your site will accept sIRB standardized language/forms/processes with no local IRB review (your local IRB will not review these instruments in order to adapt these instruments to the local environment).

- **Hybrid Approach** - your site will be able to accept some sIRB standardized language/forms/processes after local IRB review. (your local IRB will review these instruments and may choose to modify some of these instruments for the local environment)

- **Significant Local Modifications** - your site requires review of all language/forms/processes and would rarely approve a standardized (unmodified) study-wide instrument.
### SECTION III.A. Informed Consent Language

<table>
<thead>
<tr>
<th>Item</th>
<th>Full sIRB Standardization</th>
<th>Hybrid Approach</th>
<th>Significant Local Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidentiality of records</td>
<td>93%</td>
<td>7%</td>
<td></td>
</tr>
<tr>
<td>Experimental procedures</td>
<td>92%</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td>Subject Remuneration (Subject Compensation)</td>
<td>82%</td>
<td>18%</td>
<td></td>
</tr>
<tr>
<td>Risks related to genetics research</td>
<td>79%</td>
<td>21%</td>
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<tr>
<td>Research statement</td>
<td>73%</td>
<td>26%</td>
<td>1%</td>
</tr>
<tr>
<td>NIH Certificate of Confidentiality Statement</td>
<td>72%</td>
<td>28%</td>
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</tr>
<tr>
<td>Benefits to the subject</td>
<td>70%</td>
<td>29%</td>
<td>1%</td>
</tr>
<tr>
<td>In case of injury explanation</td>
<td>66%</td>
<td>28%</td>
<td>6%</td>
</tr>
<tr>
<td>Privacy Protection (HIPAA Authorization)</td>
<td>66%</td>
<td>33%</td>
<td>1%</td>
</tr>
<tr>
<td>Purpose of research</td>
<td>65%</td>
<td>34%</td>
<td>1%</td>
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<tr>
<td>Alternate procedures and courses of treatment</td>
<td>58%</td>
<td>42%</td>
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<tr>
<td>Risks or discomforts to the subject</td>
<td>55%</td>
<td>35%</td>
<td>10%</td>
</tr>
<tr>
<td>Duration of participation</td>
<td>53%</td>
<td>44%</td>
<td>3%</td>
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</tbody>
</table>

*Percentages indicate the proportion of cases where each item is included.*
### SECTION III.A.1. Informed Consent Language

If “hybrid” or “local”, who is responsible for local review (multiple choices allowed):

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

<table>
<thead>
<tr>
<th>Topic</th>
<th>Reliance Coordinator</th>
<th>Legal Counsel</th>
<th>Conflict of Interest Committee</th>
<th>Compliance Officer</th>
<th>IRB Director</th>
</tr>
</thead>
<tbody>
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<td>NIH Certificate of Confidentiality Statement</td>
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<td>Duration of participation</td>
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<tr>
<td>Purpose of research</td>
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<td></td>
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<tr>
<td>Research statement</td>
<td></td>
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</tbody>
</table>
### SECTION III.A.2. Informed Consent Language

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

<table>
<thead>
<tr>
<th>Topic</th>
<th>1 - 7 days/s</th>
<th>8 - 14 days</th>
<th>15 - 21 days</th>
<th>22+ days</th>
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<td>32%</td>
<td>21%</td>
<td>42%</td>
<td>5%</td>
</tr>
<tr>
<td>Privacy Protection (HIPAA Authorization)</td>
<td>50%</td>
<td>22%</td>
<td>25%</td>
<td>3%</td>
</tr>
<tr>
<td>In case of injury explanation</td>
<td>40%</td>
<td>23%</td>
<td>31%</td>
<td>6%</td>
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<tr>
<td>Subject Remuneration (Subject Compensation)</td>
<td>24%</td>
<td>58%</td>
<td>12%</td>
<td>6%</td>
</tr>
<tr>
<td>Confidentiality of records</td>
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<td>25%</td>
<td>27%</td>
<td>20%</td>
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<td>Alternate procedures and courses of treatment</td>
<td>17%</td>
<td>28%</td>
<td>47%</td>
<td>8%</td>
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<tr>
<td>Benefits to the subject</td>
<td>16%</td>
<td>47%</td>
<td>34%</td>
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<tr>
<td>Risks related to genetics research</td>
<td>30%</td>
<td>23%</td>
<td>43%</td>
<td>3%</td>
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<tr>
<td>Risks or discomforts to the subject</td>
<td>23%</td>
<td>18%</td>
<td>55%</td>
<td>5%</td>
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<tr>
<td>Experimental procedures</td>
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<td>32%</td>
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<tr>
<td>Duration of participation</td>
<td>14%</td>
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<tr>
<td>Purpose of research</td>
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<td>56%</td>
<td>22%</td>
<td></td>
</tr>
<tr>
<td>Research statement</td>
<td>29%</td>
<td>57%</td>
<td>14%</td>
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</tbody>
</table>
SECTION III.B. Other IRB documents/definitions

- **Full sIRB Standardization**
- **Hybrid Approach**
- **Significant Local Modifications**

### Data Safety Monitoring Plan/Charter
- 79% Full sIRB Standardization
- 21% Hybrid Approach

### Review of Recruitment Materials
- 74% Full sIRB Standardization
- 26% Hybrid Approach

### Definition/Description of vulnerable populations
- 56% Full sIRB Standardization
- 44% Hybrid Approach

### Education, training and certifications (i.e. Human subjects training, good clinical practice, CITI modules)
- 49% Full sIRB Standardization
- 38% Hybrid Approach
- 13% Significant Local Modifications

### Review of Conflict of Interests (Financial Disclosures)
- 33% Full sIRB Standardization
- 54% Hybrid Approach
- 13% Significant Local Modifications
SECTION III.B.1. Other IRB documents/ definitions

If “hybrid” or “local”, who is responsible for local review (multiple choices allowed):

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

![Bar chart showing the responsibility of different roles for various tasks.]

- Review of Recruitment Materials
- Education, training and certifications (i.e. Human subjects training, good clinical practice, CITI modules)
- Review of Conflict of Interests (Financial Disclosures)
- Definition/Description of vulnerable populations
- Data Safety Monitoring Plan/ Charter

0  5  10  15  20  25  30  35  40  45  50  55  60  65  70
SECTION III.B.2. Other IRB documents/ definitions

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

<table>
<thead>
<tr>
<th>Document/Definition</th>
<th>1 - 7 day/s</th>
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<th>22+ days</th>
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<tr>
<td>Review of Recruitment Materials</td>
<td>33%</td>
<td>30%</td>
<td>22%</td>
<td>15%</td>
</tr>
<tr>
<td>Education, training and certifications (i.e. Human subjects training, good clinical practice, CITI modules)</td>
<td>32%</td>
<td>15%</td>
<td>40%</td>
<td>13%</td>
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<tr>
<td>Review of Conflict of Interests (Financial Disclosures)</td>
<td>13%</td>
<td>31%</td>
<td>44%</td>
<td>11%</td>
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<tr>
<td>Definition/Description of vulnerable populations</td>
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<td>11%</td>
<td>44%</td>
<td>31%</td>
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<tr>
<td>Data Safety Monitoring Plan/ Charter</td>
<td>9%</td>
<td>9%</td>
<td>64%</td>
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<tbody>
<tr>
<td>1 - 7 day/s</td>
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</table>
The goal of the following survey questions was to determine the amount of flexibility requested/required for IRB study documents leading to the development of best practices/standards for sIRB operations and efficient study startup.

Responses are:

- **Full sIRB Standardization** - your site will accept sIRB standardized language/forms/processes with no local IRB review (your local IRB *will not review* these instruments in order to adapt these instruments to the local environment).

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- **Significant Local Modifications** - your site *requires review* of all language/forms/processes and would rarely approve a standardized (unmodified) study-wide instrument.
SECTION IV. Reportable Events and Subject Complaints

- Full sIRB Standardization
- Hybrid Approach
- Significant Local Modifications

### Defining IRB Reportable events
- Full sIRB Standardization: 65%
- Hybrid Approach: 32%
- Significant Local Modifications: 3%

### Reporting Time Frame for Reportable events
- Full sIRB Standardization: 57%
- Hybrid Approach: 39%
- Significant Local Modifications: 4%

### Subject Complaint procedures
- Full sIRB Standardization: 33%
- Hybrid Approach: 63%
- Significant Local Modifications: 4%

### Reporting Time Frame for subject complaints
- Full sIRB Standardization: 33%
- Hybrid Approach: 63%
- Significant Local Modifications: 4%
SECTION IV.1. Reportable Events and Subject Complaints

If “hybrid” or “local”, who is responsible for local review
(*multiple choices allowed*):

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

### Reporting Time Frame for subject complaints

- Reliance Coordinator: 60
- Legal Counsel: 60
- Conflict of Interest Committee: 55
- Compliance Officer: 50
- IRB Director: 60

### Subject Complaint procedures

- Reliance Coordinator: 60
- Legal Counsel: 60
- Conflict of Interest Committee: 55
- Compliance Officer: 50
- IRB Director: 60

### Reporting Time Frame for Reportable events

- Reliance Coordinator: 25
- Legal Counsel: 30
- Conflict of Interest Committee: 35
- Compliance Officer: 40
- IRB Director: 50

### Defining IRB Reportable events

- Reliance Coordinator: 5
- Legal Counsel: 10
- Conflict of Interest Committee: 20
- Compliance Officer: 25
- IRB Director: 30
SECTION IV.2. Reportable Events and Subject Complaints

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

- Reporting Time Frame for subject complaints:
  - 1 - 7 days: 20%
  - 8 - 14 days: 26%
  - 15 - 21 days: 36%
  - 22+ days: 19%

- Subject Complaint procedures:
  - 1 - 7 days: 23%
  - 8 - 14 days: 29%
  - 15 - 21 days: 41%
  - 22+ days: 7%

- Reporting Time Frame for Reportable events:
  - 1 - 7 days: 16%
  - 8 - 14 days: 16%
  - 15 - 21 days: 49%
  - 22+ days: 20%

- Defining IRB Reportable events:
  - 1 - 7 days: 19%
  - 8 - 14 days: 27%
  - 15 - 21 days: 41%
  - 22+ days: 14%
SECTION V – Assess Processes for Evaluation of Protocol Documents by Ancillary Committees and Tolerance for Process Standardization for sIRB Participating Sites

The goal of the following survey questions was to determine the amount of flexibility requested/required for IRB study documents leading to the development of best practices/standards for sIRB operations and efficient study startup.

Responses are:

- **Full sIRB Standardization** - your site will accept sIRB standardized language/forms/processes with no local IRB review (your local IRB **will not review** these instruments in order to adapt these instruments to the local environment).

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- **Significant Local Modifications** - your site **requires review** of all language/forms/processes and would rarely approve a standardized (unmodified) study-wide instrument.
# SECTION V. Evaluation of Protocol Documents by Ancillary Committees

<table>
<thead>
<tr>
<th>Category</th>
<th>Full sIRB Standardization</th>
<th>Hybrid Approach</th>
<th>Significant Local Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defining ancillary reviews (i.e., confidentiality, risk mgmt., IBC, PRMC)</td>
<td>62%</td>
<td>26%</td>
<td>13%</td>
</tr>
<tr>
<td>Timing of ancillary reviews</td>
<td>57%</td>
<td>31%</td>
<td>13%</td>
</tr>
<tr>
<td>Outcomes of ancillary review(s) and process for re-review(s)</td>
<td>55%</td>
<td>33%</td>
<td>13%</td>
</tr>
</tbody>
</table>

- **Full sIRB Standardization**: Represents the percentage of cases where full sIRB standardization is applied.
- **Hybrid Approach**: Represents the percentage of cases where a hybrid approach is used.
- **Significant Local Modifications**: Represents the percentage of cases where significant local modifications are made.

<table>
<thead>
<tr>
<th>Percentage</th>
<th>0%</th>
<th>10%</th>
<th>20%</th>
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<td>80</td>
<td>90</td>
<td>100</td>
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</tbody>
</table>
SECTION V.1. Evaluation of Protocol Documents by Ancillary Committees

If “hybrid” or “local”, who is responsible for local review *(multiple choices allowed)*:

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

**Outcomes of ancillary review(s) and process for re-review(s)**

**Timing of ancillary reviews**

**Defining ancillary reviews (i.e., confidentiality, risk mgmt., IBC, PRMC)**

![Bar chart showing the distribution of responsibilities for ancillary committee reviews.](chart.png)
SECTION V.2. Evaluation of Protocol Documents by Ancillary Committees

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

- **Outcomes of ancillary review(s) and process for re-review(s)**
  - 1 - 7 days: 19%
  - 8 - 14 days: 21%
  - 15 - 21 days: 45%
  - 22+ days: 15%

- **Timing of ancillary reviews**
  - 1 - 7 days: 16%
  - 8 - 14 days: 27%
  - 15 - 21 days: 47%
  - 22+ days: 11%

- **Defining ancillary reviews (i.e., confidentiality, risk mgmt., IBC, PRMC)**
  - 1 - 7 days: 28%
  - 8 - 14 days: 23%
  - 15 - 21 days: 45%
  - 22+ days: 5%
SECTION VI. Acceptance of Reliance Agreement for sIRB Participating Sites

Would your institution be willing to engage in a Reliance agreement with a sIRB?

- Yes, 100
- No, 1
- Not sure, 5
The goal of the following survey questions was to determine the amount of flexibility requested/required for IRB study documents leading to the development of best practices/standards for sIRB operations and efficient study startup.

Responses are:

- **Full sIRB Standardization** - your site will accept sIRB standardized language/forms/processes with no local IRB review (your local IRB will not review these instruments in order to adapt these instruments to the local environment).

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SECTION VI. Acceptance of Reliance Agreement for sIRB Participating Sites

Distribution of responsibilities
*Verification of human subjects training, review and management of conflicts of interest, management of changes in study personnel.

Indemnification Statement
*Historically this has probably been the most difficult issue to address universally. In the past, issues where the Reviewing IRB has an indemnification agreement with language inconsistent with the participating site's institutional requirements.
SECTION VI.1. Acceptance of Reliance Agreement for sIRB Participating Sites

If “hybrid” or “local”, who is responsible for local review
(multiple choices allowed):

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

**Distribution of responsibilities**

*Verification of human subjects training, review and management of conflicts of interest, management of changes in study personnel.*

**Indemnification Statement**

*Historically this has probably been the most difficult issue to address universally. In the past, issues where the Reviewing IRB has an indemnification agreement with language inconsistent with the participating-site’s institutional requirements*
SECTION VI.2. Acceptance of Reliance Agreement for sIRB Participating Sites

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

- 1 - 7 day/s
- 8 - 14 days
- 15 - 21 days
- 22+ days

Distribution of responsibilities
*Verification of human subjects training, review and management of conflicts of interest, management of changes in study personnel.

Indemnification Statement
*Historically this has probably been the most difficult issue to address universally. In the past, issues where the Reviewing IRB has an indemnification agreement with language inconsistent with the participating site's institutional requirements
Survey for sIRB Primary Sites

- We recognize that each survey participant’s responses to the survey questions may vary depending on whether their institution is joining a multisite study as the Participating Site or acting as the sIRB Primary Site of record for a multisite study. Therefore, we asked survey participants to provide their responses to the same series of questions as the sIRB Primary site of record for a multisite study.

- Out of 108 survey participants who completed the survey
  - 73 survey participants opted not to respond
  - 17 survey participants did respond to the question (missing response)
  - 18 survey participants provided their responses as the sIRB Primary site
The goal of these survey questions is to determine the amount of flexibility requested/required for IRB study documents leading to the development of best practices/standards for sIRB operations and efficient study startup.

Responses are:

- **Full sIRB Standardization** – as a primary site you would prefer participating sites to accept all sIRB standardized language/forms/processes with no local IRB review (the participating site’s local IRB will not review these instruments in order to adapt these instruments to the local environment).

- **Hybrid Approach** – as a primary site you would accept local review of sIRB standardized language/forms/processes and would allow modifications to some of these instruments. (the participating site’s local IRB will review these instruments and may choose to modify some of these instruments for the local environment)

- **Significant Local Modifications** – as a primary site you would allow the participating site’s local IRB to review all language/forms/processes in order to adapt all instruments to the local environment.
### SECTION III (Primary Site).A. Informed Consent Language

<table>
<thead>
<tr>
<th>Topic</th>
<th>Full sIRB Standardization</th>
<th>Hybrid Approach</th>
<th>Significant Local Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risks or discomforts to the subject</td>
<td>7%</td>
<td>86%</td>
<td>7%</td>
</tr>
<tr>
<td>Purpose of research</td>
<td>7%</td>
<td>86%</td>
<td>7%</td>
</tr>
<tr>
<td>Research statement</td>
<td>7%</td>
<td>86%</td>
<td>7%</td>
</tr>
<tr>
<td>Benefits to the subject</td>
<td>79%</td>
<td>14%</td>
<td>7%</td>
</tr>
<tr>
<td>Risks related to genetics research</td>
<td>79%</td>
<td>14%</td>
<td>7%</td>
</tr>
<tr>
<td>Experimental procedures</td>
<td>79%</td>
<td>14%</td>
<td>7%</td>
</tr>
<tr>
<td>Duration of participation</td>
<td>79%</td>
<td>14%</td>
<td>7%</td>
</tr>
<tr>
<td>NIH Certificate of Confidentiality Statement</td>
<td>71%</td>
<td>21%</td>
<td>7%</td>
</tr>
<tr>
<td>Alternate procedures and courses of treatment</td>
<td>64%</td>
<td>29%</td>
<td>7%</td>
</tr>
<tr>
<td>Confidentiality of records</td>
<td>43%</td>
<td>43%</td>
<td>14%</td>
</tr>
<tr>
<td>Subject Remuneration (Subject Compensation)</td>
<td>36%</td>
<td>50%</td>
<td>14%</td>
</tr>
<tr>
<td>Privacy Protection (HIPAA Authorization)</td>
<td>14%</td>
<td>57%</td>
<td>29%</td>
</tr>
<tr>
<td>In case of injury explanation</td>
<td>7%</td>
<td>64%</td>
<td>29%</td>
</tr>
</tbody>
</table>

Risks or discomforts to the subject: 7% Full sIRB Standardization, 86% Hybrid Approach, 7% Significant Local Modifications

Purpose of research: 7% Full sIRB Standardization, 86% Hybrid Approach, 7% Significant Local Modifications

Research statement: 7% Full sIRB Standardization, 86% Hybrid Approach, 7% Significant Local Modifications

Benefits to the subject: 79% Full sIRB Standardization, 14% Hybrid Approach, 7% Significant Local Modifications

Risks related to genetics research: 79% Full sIRB Standardization, 14% Hybrid Approach, 7% Significant Local Modifications

Experimental procedures: 79% Full sIRB Standardization, 14% Hybrid Approach, 7% Significant Local Modifications

Duration of participation: 79% Full sIRB Standardization, 14% Hybrid Approach, 7% Significant Local Modifications

NIH Certificate of Confidentiality Statement: 71% Full sIRB Standardization, 21% Hybrid Approach, 7% Significant Local Modifications

Alternate procedures and courses of treatment: 64% Full sIRB Standardization, 29% Hybrid Approach, 7% Significant Local Modifications

Confidentiality of records: 43% Full sIRB Standardization, 43% Hybrid Approach, 14% Significant Local Modifications

Subject Remuneration (Subject Compensation): 36% Full sIRB Standardization, 50% Hybrid Approach, 14% Significant Local Modifications

Privacy Protection (HIPAA Authorization): 14% Full sIRB Standardization, 57% Hybrid Approach, 29% Significant Local Modifications

In case of injury explanation: 7% Full sIRB Standardization, 64% Hybrid Approach, 29% Significant Local Modifications
SECTION III (Primary Site). A.1. Informed Consent Language

If “hybrid” or “local”, who is responsible for local review (multiple choices allowed):

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

<table>
<thead>
<tr>
<th>Component</th>
<th>Reliance Coordinator</th>
<th>Legal Counsel</th>
<th>Conflict of Interest Committee</th>
<th>Compliance Officer</th>
<th>IRB Director</th>
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<tbody>
<tr>
<td>NIH Certificate of Confidentiality Statement</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Privacy Protection (HIPAA Authorization)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>In case of injury explanation</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Subject Remuneration (Subject Compensation)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Confidentiality of records</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Alternate procedures and courses of treatment</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Benefits to the subject</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Risks related to genetics research</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Risks or discomforts to the subject</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Experimental procedures</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Duration of participation</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Purpose of research</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Research statement</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
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</tbody>
</table>
### SECTION III (Primary Site).A.2. Informed Consent Language

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

<table>
<thead>
<tr>
<th>Event</th>
<th>1 - 7 days/s</th>
<th>8 - 14 days</th>
<th>15 - 21 days</th>
<th>22+ days</th>
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<td>Privacy Protection (HIPAA Authorization)</td>
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</tr>
<tr>
<td>In case of injury explanation</td>
<td>25%</td>
<td>42%</td>
<td>25%</td>
<td>8%</td>
</tr>
<tr>
<td>Subject Remuneration (Subject Compensation)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confidentiality of records</td>
<td>29%</td>
<td>29%</td>
<td>13%</td>
<td>38%</td>
</tr>
<tr>
<td>Alternate procedures and courses of treatment</td>
<td></td>
<td>20%</td>
<td>20%</td>
<td>60%</td>
</tr>
<tr>
<td>Benefits to the subject</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risks related to genetics research</td>
<td>33%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risks or discomforts to the subject</td>
<td></td>
<td>33%</td>
<td></td>
<td>67%</td>
</tr>
<tr>
<td>Experimental procedures</td>
<td></td>
<td></td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>Duration of participation</td>
<td>33%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purpose of research</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research statement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

0%  10%  20%  30%  40%  50%  60%  70%  80%  90%  100%
SECTION III (Primary Site). B. Other IRB documents/ definitions

- Full sIRB Standardization
- Hybrid Approach
- Significant Local Modifications

<table>
<thead>
<tr>
<th>Category</th>
<th>Full sIRB Standardization</th>
<th>Hybrid Approach</th>
<th>Significant Local Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Safety Monitoring Plan/ Charter</td>
<td>83%</td>
<td>8%</td>
<td>8%</td>
</tr>
<tr>
<td>Definition/Description of vulnerable populations</td>
<td>62%</td>
<td></td>
<td>38%</td>
</tr>
<tr>
<td>Review of Recruitment Materials</td>
<td>54%</td>
<td>38%</td>
<td>8%</td>
</tr>
<tr>
<td>Education, training and certifications (i.e. Human subjects training, good clinical practice, CITI modules)</td>
<td>31%</td>
<td>15%</td>
<td>54%</td>
</tr>
<tr>
<td>Review of Conflict of Interests (Financial Disclosures)</td>
<td>23%</td>
<td>38%</td>
<td>38%</td>
</tr>
</tbody>
</table>
SECTION III (Primary Site). B.1. Other IRB documents/ definitions

If “hybrid” or “local”, who is responsible for local review (multiple choices allowed):

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

Graphical representation of responsibilities:

- Review of Recruitment Materials
- Education, training and certifications (i.e. Human subjects training, good clinical practice, CITI modules)
- Review of Conflict of Interests (Financial Disclosures)
- Definition/Description of vulnerable populations
- Data Safety Monitoring Plan/ Charter
SECTION III (Primary Site). B.2. Other IRB documents/ definitions

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

<table>
<thead>
<tr>
<th>Document/Legal Requirement</th>
<th>1 - 7 day/s</th>
<th>8 - 14 days</th>
<th>15 - 21 days</th>
<th>22+ days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of Recruitment Materials</td>
<td>33%</td>
<td>17%</td>
<td>50%</td>
<td></td>
</tr>
<tr>
<td>Education, training and certifications (i.e. Human subjects training, good clinical practice, Citi modules)</td>
<td>20%</td>
<td>40%</td>
<td>30%</td>
<td>10%</td>
</tr>
<tr>
<td>Review of Conflict of Interests (Financial Disclosures)</td>
<td>60%</td>
<td>40%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Definition/Description of vulnerable populations</td>
<td>60%</td>
<td>40%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Data Safety Monitoring Plan/ Charter</td>
<td>100%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>
SECTION IV (Primary Site) – Assess Processes for Reportable Events and Subject Complaints, and Tolerance for Process Standardization for sIRB Primary Sites

The goal of these survey questions is to determine the amount of flexibility requested/required for IRB study documents leading to the development of best practices/standards for sIRB operations and efficient study startup.

Responses are:

- **Full sIRB Standardization** – as a primary site you would prefer participating sites to accept all sIRB standardized language/forms/processes with no local IRB review (the participating site’s local IRB will not review these instruments in order to adapt these instruments to the local environment).

- **Hybrid Approach** – as a primary site you would accept local review of sIRB standardized language/forms/processes and would allow modifications to some of these instruments. (the participating site’s local IRB will review these instruments and may choose to modify some of these instruments for the local environment)

- **Significant Local Modifications** – as a primary site you would allow the participating site’s local IRB to review all language/forms/processes in order to adapt all instruments to the local environment.
SECTION IV (Primary Site). Reportable Events and Subject Complaints

- **Full sIRB Standardization**
- **Hybrid Approach**
- **Significant Local Modifications**

### Graph Details:

- **Reporting Time Frame for Reportable events**
  - Full sIRB Standardization: 85%
  - Hybrid Approach: 15%

- **Defining IRB Reportable events**
  - Full sIRB Standardization: 85%
  - Hybrid Approach: 15%

- **Reporting Time Frame for subject complaints**
  - Full sIRB Standardization: 62%
  - Hybrid Approach: 38%

- **Subject Complaint procedures**
  - Full sIRB Standardization: 54%
  - Hybrid Approach: 46%
SECTION IV (Primary Site).1. Reportable Events and Subject Complaints

If “hybrid” or “local”, who is responsible for local review
(multiple choices allowed):

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

Reporting Time Frame for reportable events

Subject Complaint procedures

Reporting Time Frame for subject complaints

Defining IRB reportable events
SECTION IV (Primary Site).2. Reportable Events and Subject Complaints

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

<table>
<thead>
<tr>
<th>Reporting Time Frame for subject complaints</th>
<th>1 - 7 day/s</th>
<th>8 - 14 days</th>
<th>15 - 21 days</th>
<th>22+ days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting Time Frame for Reportable events</td>
<td>50%</td>
<td>50%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Defining IRB Reportable events</td>
<td>50%</td>
<td>50%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Subject Complaint procedures
- 1 - 7 day/s: 33%
- 8 - 14 days: 33%
- 15 - 21 days: 33%
- 22+ days: 33%

Defining IRB Reportable events
- 1 - 7 day/s: 50%
- 8 - 14 days: 50%
- 15 - 21 days: 0%
- 22+ days: 50%
The goal of these survey questions is to determine the amount of flexibility requested/required for IRB study documents leading to the development of best practices/standards for sIRB operations and efficient study startup.

Responses are:

- **Full sIRB Standardization** – as a primary site you would prefer participating sites to accept all sIRB standardized language/forms/processes with no local IRB review (the participating site’s local IRB **will not review** these instruments in order to adapt these instruments to the local environment).

- **Hybrid Approach** – as a primary site you would accept local review of sIRB standardized language/forms/processes and would allow modifications to some of these instruments. (the participating site’s local IRB **will review** these instruments and may choose to modify some of these instruments for the local environment)

- **Significant Local Modifications** – as a primary site you would allow the participating site’s local IRB to review all language/forms/processes in order to adapt all instruments to the local environment.
SECTION V (Primary Site). Evaluation of Protocol Documents by Ancillary Committees

- **Defining ancillary reviews (i.e., confidentiality, risk mgmt., IBC, PRMC)**
  - Outcomes of ancillary review(s) and process for re-review(s): 23% Full sIRB Standardization, 31% Hybrid Approach, 46% Significant Local Modifications
  - Timing of ancillary reviews: 23% Full sIRB Standardization, 23% Hybrid Approach, 54% Significant Local Modifications

- **Other ancillary reviews**
  - Outcomes of ancillary review(s) and process for re-review(s): 23% Full sIRB Standardization, 31% Hybrid Approach, 46% Significant Local Modifications
  - Timing of ancillary reviews: 23% Full sIRB Standardization, 23% Hybrid Approach, 54% Significant Local Modifications
SECTION V (Primary Site).1. Evaluation of Protocol Documents by Ancillary Committees

If “hybrid” or “local”, who is responsible for local review (multiple choices allowed):

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

- Reporting Time Frame for subject complaints
- Subject Complaint procedures
- Reporting Time Frame for Reportable events
- Defining IRB Reportable events
SECTION V (Primary Site).2. Evaluation of Protocol Documents by Ancillary Committees

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

- 1 - 7 day/s
- 8 - 14 days
- 15 - 21 days
- 22+ days

Outcomes of ancillary review(s) and process for re-review(s)

Timing of ancillary reviews

Defining ancillary reviews (i.e., confidentiality, risk mgmt., IBC, PRMC)
SECTION VI (Primary Site). Acceptance of Reliance Agreement for sIRB Primary Sites

Would your institution be willing to engage in a Reliance agreement with other participating sites?

- Yes, 15
- Not sure, 1
SECTION VI (Primary Site). Acceptance of Reliance Agreement for sIRB Primary Sites

The goal of these survey questions is to determine the amount of flexibility requested/required for IRB study documents leading to the development of best practices/standards for sIRB operations and efficient study startup.

Responses are:

- **Full sIRB Standardization** – as a primary site you would prefer participating sites to accept all sIRB standardized language/forms/processes with no local IRB review (the participating site’s local IRB will not review these instruments in order to adapt these instruments to the local environment).

- **Hybrid Approach** – as a primary site you would accept local review of sIRB standardized language/forms/processes and would allow modifications to some of these instruments. (the participating site’s local IRB will review these instruments and may choose to modify some of these instruments for the local environment)

- **Significant Local Modifications** – as a primary site you would allow the participating site’s local IRB to review all language/forms/processes in order to adapt all instruments to the local environment.
SECTION (Primary Site). Acceptance of Reliance Agreement for sIRB Primary Sites

**Full sIRB Standardization**
- 15%

**Hybrid Approach**
- 46%

**Significant Local Modifications**
- 38%

**Distribution of responsibilities**
*Verification of human subjects training, review and management of conflicts of interest, management of changes in study personnel.*

**Indemnification Statement**
*Historically this has probably been the most difficult issue to address universally. In the past, issues where the Reviewing IRB has an indemnification agreement with language inconsistent with the participating site's institutional requirements.*
SECTION VI (Primary Site). 1. Acceptance of Reliance Agreement for sIRB Primary Sites

If “hybrid” or “local”, who is responsible for local review
(multiple choices allowed):

- Reliance Coordinator
- Legal Counsel
- Conflict of Interest Committee
- Compliance Officer
- IRB Director

Distribution of responsibilities
*Verification of human subjects training, review and management of conflicts of interest, management of changes in study personnel.

Indemnification Statement
*Historically this has probably been the most difficult issue to address universally. In the past, issues where the Reviewing IRB has an indemnification agreement with language inconsistent with the participating site's institutional requirements.
SECTION VI (Primary Site).2. Acceptance of Reliance Agreement for sIRB Primary Sites

If “hybrid” or “local”, for any of the above, how many days are typically required for completion of institutional review/revision of study documents?

- **1 - 7 day/s**: 45%
- **8 - 14 days**: 27%
- **15 - 21 days**: 27%
- **22+ days**: 8%

**Indemnification Statement**

*Historically this has probably been the most difficult issue to address universally. In the past, issues where the Reviewing IRB has an indemnification agreement with language inconsistent with the participating site's institutional requirements.*

**Distribution of responsibilities**

*Verification of human subjects training, review and management of conflicts of interest, management of changes in study personnel.*