

Institutional Review Board Researcher Assessment Tool (IRB-RAT)

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A USER'S GUIDE

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INTRODUCTION

It is fully recognized that Institutional Reviews Boards carry out extremely important functions, often without sufficient resources. In many commentaries in the scientific literature, however, research investigators have criticized the inner-workings and decision-making processes of IRBs. Among the complaints are superficial and hasty reviews of protocols, favoring the protocols of selected colleagues, being lenient in anticipation of receiving the same consideration when their own proposals are on the table, harboring conflicts of interest, and being poorly trained for the tasks at hand, harassment of certain researchers, lack of accountability, biases, ineffective communication with investigators, lack of knowledge about research, inability to accurately assess research risks, lack of appeal mechanisms, inconsistency, wide variations in the interpretation of the federal regulations, and an exclusive focus on participants while neglecting scientific merit. Additional criticisms include excessive dwell time before deciding on protocols, arrogant and rude treatment of researchers, using the "local standards" loophole as a justification to make idiosyncratic decisions, and being overly conservative and protective of the institution.

No systematic work had previously described how investigators would structure an *ideal* IRB. A sample of 2,283 biomedical and social/behavioral science recipients of PHS funding and members of the American Psychological Society received a survey asking them to rate the importance of 45 items describing actions and functions of IRBs, to compare their ideal IRB to their actual IRB, and to provide information regarding gender, type of institution, research area, years of research experience, and IRB membership within the last 5 years. Eight-hundred and eight-six investigators offered usable data for a return rate of 38.8%.

The apriori themes were confirmed (confirmatory factor analysis through structural equation modeling). It was assumed that the "ideal" IRB would differ for, as examples, biomedical as compared to social/behavioral investigators, for those typically conducting exempt research compared to those whose research requires more extensive review, for those with more and less research experience, and for those who recently served on an IRB compared to those who never served. However, only a very few statistically significant differences were found among the factor or items scores (and these were small), suggesting that

researchers in any setting or specialty would desire a similar IRB. *That is, the characteristics of IRBs themselves appear to be far more salient than are differences among investigators.*

The findings allowed for the creation of the IRB-RAT, an instrument for IRBs interested in self-study, assessment of how institutional investigators perceive their IRBs, or further research.

We were particularly interested in how investigators viewed IRB characteristics dealing with fairness issues and how the decisions were made and implemented. It is of interest to point out here that issues dealing with perceived treatment of investigators on dimensions of procedural and interactional justice were among the most important to investigators. Organizational research has consistently found links between fair decision-making and good citizenship behavior and job satisfaction. Conversely, there is a strong link between unfair decision-making and resentment, low morale, and dishonest behavior. Thus, IRBs would do well to ascertain how they are perceived by researchers along fairness dimensions.

The IRB-RAT PACK

Included herein are:

- A presentation of the items (by factors) including the comparison data provided by the national sample of biomedical and social and behavioral science researchers
- An overview of the two versions of the IRB-Rat (and the advantages and disadvantages of each as well as other adaptation options and suggested demographics items.)
- The IRB-RAT-A (double pass)
- The IRB-RAT-B (single pass)

Detail about the development of the survey itself will be available soon, and the reference will be posted here as soon as it is available.

Important Note: For anyone needing to personalize the IRB-RAT (e.g., adding special directions, etc.), please request a version of this document in Word from pkspiegel@comcast.net We also request being informed when anyone uses the IRB-RAT and would appreciate receiving any feedback.

UPDATE: In the original version of the survey, “don’t know” or “no opinion” options were included because the norming group was composed entirely of senior, experienced investigators. Anyone adapting the IRB-RAT may want to consider adding one of these response categories as a bubble off to the right for this purpose.

IRB-RAT: Items, Factor Loadings, and National Sample Data

Our PHS and APS samples were asked to rate each of 45 characteristics as to its importance in their work on a 7 point scale (7= “absolutely essential to you as an investigator” to 1= “not important to you”). This listing divides the items according to the factor loadings. The items appeared randomly in the actual survey. (Only one item, presented at the end of the list, did not load on any predicted factor.) The number preceding each item indicates its rank in terms of the assigned importance by the norming group. For example, “An IRB that reviews protocols in a timely fashion” was ranked as the most important IRB function, whereas “An IRB that is composed of more than one public member” was ranked as the least important. Means (with the higher the number, the higher the importance, on a 7 point scale) and standard deviations of the norming group data for each item are presented in parentheses.

Factor #1: IRB INDICATIONS OF PROCEDURAL JUSTICE

1. An IRB that reviews protocols in a timely fashion (6.43, 0.80)
6. An IRB that conducts a conscientious and complete review of protocols (5.86, 1.24)
9. An IRB that gives a complete rationale for any required changes to or disapprovals of protocols (5.73, 1.21)
12. An IRB that includes a complete rationale when it denies or mandates changes in a protocol based on criteria that are more stringent than or different from federal research policy (i.e., application of “local standards”) (5.59, 1.35)
16. An IRB that is open to reversing its earlier decisions (i.e., willing to consider investigator appeals) (5.52, 1.34)
17. An IRB that invites investigators to present their position whenever a question or concern about a research protocol arises (5.51, 1.33)
27. An IRB that recognizes when it lacks sufficient expertise to evaluate a protocol and seeks outside experts (5.28, 1.41)

Factor #2: IRB INDICATIONS OF INTERPERSONAL JUSTICE (RESPECTFULNESS, COOPERATIVENESS)

8. An IRB that responds in a timely manner to investigators’ inquiries about its processes and decisions (5.80, 1.15)
10. An IRB that works with investigators to find mutually satisfying solutions whenever disagreements exist (5.71, 1.27)
20. An IRB that treats investigators with respect (5.45, 1.45)
25. An IRB that acknowledges full responsibility for its errors or delays in processing protocols and attempts to correct them as expeditiously as possible (5.33, 1.44)
35. An IRB that is open and pleasant in its interactions with investigators (4.72, 1.61)

Factor #3: IRB INDICATIONS OF IMPARTIALITY (LACK OF BIAS)

2. An IRB with members who do not allow personal biases to affect their evaluation of protocols (6.17, 1.10)
21. An IRB whose members hold no preconceived biases against particular research topics (5.45, 1.46)
22. An IRB that requires members to abstain from evaluating protocols whenever a real or apparent conflict-of-interest arises (5.44, 1.46)
23. An IRB whose members hold no preconceived biases against particular research techniques (5.43, 1.47)
28. An IRB that is open to innovative approaches to conducting research (5.28, 1.43)

Factor #4: IRB INDICATIONS OF PRO-SCIENCE SENSITIVITY

3. An IRB that does a good job of upholding participants’ rights while, at the same time, facilitating the conduct of research (6.10, 1.11)
4. An IRB that does not use its power to suppress research that is otherwise methodologically sound and in compliance with federal policy whenever it perceives potential criticism from outside the scientific community (6.08, 1.19)
13. An IRB that views itself as an investigator’s ally rather than as a hurdle to clear (5.57, 1.44)

- 33. An IRB that shows considerable evidence that the advancement of science is part of its mission (4.82, 1.79)
- 37. An IRB that shows empathy with the difficulties that can present themselves during the design and conduct of research (4.66, 1.60)

Factor #5: IRB INDICATIONS OF COMPETENCE

- 5. An IRB with members who are very knowledgeable about IRB procedures and federal policy (6.01, 1.16)
- 14. An IRB that conducts a conscientious analysis of potential benefits weighed against potential risks before making decisions (5.54, 1.29)
- 19. An IRB that can competently distinguish exempt from nonexempt research (5.48, 1.44)
- 31. An IRB that ensures that at least one member is knowledgeable about the content domain of submitted protocols (5.13, 1.55)
- 32. An IRB whose members arrive at meetings well-prepared (5.07, 1.52)
- 36. An IRB with a Research Compliance Officer (or staff member in charge of IRB functions) who has a research background (4.68, 1.66)
- 38. An IRB that is composed primarily of members regarded as highly competent investigators (4.46, 1.70)
- 40. An IRB that provides a comprehensive training program for its new members (4.34, 1.64)

Factor #6: OUTREACH BY THE IRB

- 26. An IRB that offers information to improve the chances of gaining IRB approval (5.31, 1.45)
- 41. An IRB that offers consultation during the development of research protocols and grant applications (4.30, 1.76)
- 43. An IRB that offers investigators opportunities to be educated about federal research policy (4.03, 1.68)
- 44. An IRB that offers editorial suggestions regarding consent documents and protocols (typos, grammar, clarity, etc.) (3.20, 1.82)

Factor #7: FORMAL FUNCTIONING, STRUCTURE, AND COMPOSITION OF IRBs

- 11. An IRB whose members fully understand and act within the scope of their function (5.67, 1.27)
- 18. An IRB that maintains accurate records (5.50, 1.50)
- 24. An IRB that is allocated sufficient resources to carry out its functions (5.38, 1.44)
- 34. An IRB that requires that its Chair be an experienced investigator (4.75, 1.76)
- 39. An IRB that monitors the progress of each approved research project in line with federal policy (4.39, 2.16)
- 42. An IRB that has a diverse membership (i.e., includes women, minorities and junior and senior members of the institution) (4.07, 1.93)
- 45. An IRB that is composed of more than one public member (2.68, 1.69)

Factor #8: IRB INDICATIONS THAT THE RIGHTS OF HUMAN PARTICIPANTS ARE BEING UPHELD

- 7. An IRB that views protection of human participants as its primary function (5.80, 2.83)
- 15. An IRB that takes timely and appropriate action whenever scientific misconduct is alleged (5.52, 1.42)
- 30. An IRB that takes timely action when an investigator has violated its decisions (5.22, 1.51)

(The item that did not load on any factor)

- 29. An IRB that applies appropriately flexible standards regarding voluntary and informed consent requirements (e.g., required wording is not as demanding for minimal risk research as it is for more risky research) (5.23, 1.52)

OVERVIEW of Both IRB-RAT Versions (and other variations)



IRB-Researchers' Assessment Tool: Version A (IRB-RAT-A)

This “two pass” version of the IRB-RAT allows the best direct comparison between the large sample of PHS and APS investigators and those from a local institution. The first part contains the questions (in the same order) exactly as responded to by the PHS/APS investigators. The second part contains the same items, again in the same order. But, this time the institution’s investigators rate their own IRB on a 7 point scale from “describes our IRB exceptionally well” to “definitely does not describe our IRB.” For practical usage, the difference between the “ideal” IRB and one’s own institution for each description can be tallied by looking at the mean differences and the degree of variation. Items with a large mean difference and small variances (standard deviations) would be of particular interest for an institution to further explore.

Advantages: Version A provides the most valid way to compare what is important to local investigators with the findings of the large comparison sample. If one is conducting research using this instrument (as opposed to, e.g., an IRB self-study), this feature is especially important.

Disadvantages: This version is long, requiring the respondent to answer 90 items (45 rating the “ideal” and the 45 repeated to rate one’s own IRB) plus any demographic questions. The return rate might be lowered as a result. Stressing that the results will be seriously considered and put to practical use may enhance investigators’ willingness to participate. This version is also more difficult to sort into the 8 factors, if there is any interest in doing so.

IRB-Researchers' Assessment Tool: Version B (IRB-RAT-B)



The “single pass” version of the IRB-RAT contains only the 45 items, but the task requires two responses to each item. Also, in this version, the items are ordered differently than in Version A. Here items are grouped by factor clusters.

Advantages: This variation will seem shorter to respondents. It is also easier to see (and compute) difference scores and identify theme trends without having to reshuffle the items back into their factor headings.

Disadvantages: The large, comparison sample results may still have practical value when assessing the importance of certain items. However, it is important to note that even though the content of the item stems are the same as those responded to by the national sample, the item chronology (randomized in the comparison sample) and response formats differ. The impact of these differences on making comparisons between the national sample and another sample is unknown.

For possible data analysis purposes, the items on Version B (only) are clustered as follows:

- Items 1-7 Procedural justice (how the decisions are made)
- Items 8- 11 IRB outreach (offerings to assist researchers)
- Items 12-16 Interpersonal Justice (treating investigators respectfully, lack of arrogance))
- Items 17- 23 IRB Formal Functioning, Structure, and Composition
- Items 24- 29 Pro-Science Sensitivity (Item 29 did not load on this or any a priori factor, but remains in the survey)
- Items 30- 33 Bias
- Items 34- 41 Competence
- Items 42- 45 Upholding the Rights of Human Participants

More Variations

1. Respondents can be asked (in either version) to circle the item number of the THREE IRB descriptions that are the MOST important to them.

Advantage: Because so many items will be rated by respondents as at least somewhat important, this task may help discover which IRB activities and characteristics emerge as the most imperative.

Disadvantage: Not every respondent will complete this additional task.

2. A “quick” 45 item survey can be created by using only Part 2 of Version A. This gives an overview of how investigators see their institution’s IRB.

Advantage: The task is shorter, which will likely enhance the return rate.

Disadvantage: There is no way to know what value investigators’ place on any single item, that is, how important it is to them. For example, investigators may indicate that an item does not at all describe the institution’s IRB, but it may also be that they don’t really care about it either. This problem can be somewhat mitigated by consulting our national sample results for comparison as to what has been rated as more or less important.

3. Another “quick” 45 item survey can be created using only Part 1 of Version A. This requests investigators to rate *only* their “ideal” IRB by noting which IRB activities are the most important to them.

Advantages: This variation has the advantage of being the least sensitive (i.e., it is unlikely to cause controversy or suspicion) for respondents or the local IRB. The composite results could be useful to IRBs for self-study. That is, IRBs could ascertain what their investigators find most essential and then try to determine how well their IRB operation is meeting those most critical needs.

Disadvantage: There is no information about how researchers at the institution view their own IRB. That is, the results would indicate what investigators find as the most important, but not whether researchers perceive their local IRB as meeting these needs. To mitigate this drawback to some degree, an added item might be considered to add at the end of the survey: **“How does our IRB compare to your concept of an ideal IRB?”** 6=Very much similar to an ideal IRB; 5= Generally similar to an ideal IRB; 4= Somewhat similar to an ideal IRB; 3= Somewhat unlike an ideal IRB; 2= Generally unlike an ideal IRB; 1= Very unlike an ideal IRB.

Possible Demographic Questions to add (and appreciation note extended to participants)

Please provide the following information for data analysis purposes:

Number of post-degree years actively engaged in research 1-3___ 4-6 ___ 7-10___ 11 plus___

Research area: Biomedical___ Social/Behavioral___ Educational___ Humanities___

Other (please specify)_____

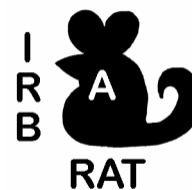
Approximate percentage of your work that would fall into the EXEMPT category: ___%

Number of years served on an IRB in past 5 years: _____

Thank you for your participation. Additional comments are welcome, including any additional attributes of IRBs that you think are particularly important or concerns about the IRB.

Version A: IRB Researchers' Assessment Tool

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Characteristics and activities of IRBs are reflected in the 45 items. This survey is divided into two parts and involves rating what you see as an ideal IRB and then rating your IRB on the same items. This exercise will assist in identifying how researchers see the strengths and weaknesses of our IRB and point to areas where improvements may be made.

PART ONE: As an investigator, how important is each one to you in your work? Rate how important the item would be to achieve your vision of an *ideal IRB*. Most of the items may represent characteristics or activities that are important to you in your work, but try reserve your highest ratings for those that are the most essential.

Please indicate your rating of the *IDEAL IRB* by circling the number corresponding to the following scale:

- 7= Absolutely *essential* to you as an investigator
- 6= Very important to you
- 5= Generally important to you
- 4= Moderately important to you
- 3= Somewhat important to you
- 2= Of *minor* importance to you
- 1= Not important to you

(1) An IRB that is open to reversing its earlier decisions (i.e., willing to carefully listen to investigators' appeals)

IDEAL IRB: 7 6 5 4 3 2 1

(2) An IRB with members who are very knowledgeable about IRB procedures and federal policy

IDEAL IRB: 7 6 5 4 3 2 1

(3) An IRB that reviews protocols in a timely fashion

IDEAL IRB: 7 6 5 4 3 2 1

(4) An IRB whose members do not allow personal biases to affect their evaluation of protocols

IDEAL IRB: 7 6 5 4 3 2 1

(5) An IRB that applies appropriately flexible standards regarding voluntary and informed consent requirements (e.g., required wording is less demanding for minimal risk research using competent adult participants)

IDEAL IRB: 7 6 5 4 3 2 1

(6) An IRB that recognizes when it lacks sufficient expertise to evaluate a protocol and seeks an outside evaluator

IDEAL IRB: 7 6 5 4 3 2 1

(7) An IRB that shows considerable evidence that the advancement of science is part of its mission

IDEAL IRB: 7 6 5 4 3 2 1

(8) An IRB that is willing to work with investigators to find mutually satisfying solutions whenever disagreements exist

IDEAL IRB: 7 6 5 4 3 2 1

(9) An IRB that offers editorial suggestions regarding consent documents and protocols (e.g., typos, grammar, clarity)

IDEAL IRB: 7 6 5 4 3 2 1

(10) An IRB that provides a comprehensive training program for its new members

IDEAL IRB: 7 6 5 4 3 2 1

(11) An IRB that treats investigators with respect

IDEAL IRB: 7 6 5 4 3 2 1

- (12) **An IRB that conducts a conscientious and complete review of protocols**
IDEAL IRB: 7 6 5 4 3 2 1
- (13) **An IRB that maintains complete and accurate records**
IDEAL IRB: 7 6 5 4 3 2 1
- (14) **An IRB that is open to innovative approaches to conducting research**
IDEAL IRB: 7 6 5 4 3 2 1
- (15) **An IRB that takes timely action when an investigator has violated the specifications of its rulings**
IDEAL IRB: 7 6 5 4 3 2 1
- (16) **An IRB that is composed primarily of highly competent investigators**
IDEAL IRB: 7 6 5 4 3 2 1
- (17) **An IRB that ensures that at least one member is knowledgeable about the content domain and discipline of submitted protocols**
IDEAL IRB: 7 6 5 4 3 2 1
- (18) **An IRB that takes timely and appropriate action whenever scientific misconduct is alleged**
IDEAL IRB: 7 6 5 4 3 2 1
- (19) **An IRB that views protection of human participants as its primary function**
IDEAL IRB: 7 6 5 4 3 2 1
- (20) **An IRB that includes a complete rationale when it denies or mandates changes in a protocol based on criteria that are more stringent than or different from federal research policy (i.e., application of “local standards”)**
IDEAL IRB: 7 6 5 4 3 2 1
- (21) **An IRB that requires members to abstain from evaluating protocols whenever a real or apparent conflict-of-interest arises**
IDEAL IRB: 7 6 5 4 3 2 1
- (22) **An IRB that is allocated sufficient resources to carry out functions efficiently and thoroughly**
IDEAL IRB: 7 6 5 4 3 2 1
- (23) **An IRB that conducts a conscientious, informed analysis of potential benefits weighed against potential risks before making decisions**
IDEAL IRB: 7 6 5 4 3 2 1
- (24) **An IRB that holds no preconceived biases against particular research techniques**
IDEAL IRB: 7 6 5 4 3 2 1
- (25) **An IRB that offers investigators information to improve the chances of gaining IRB approval**
IDEAL IRB: 7 6 5 4 3 2 1
- (26) **An IRB that does not use its power to suppress research that is otherwise methodologically sound and in compliance with federal policy whenever it perceives potential criticism from outside the scientific community**
IDEAL IRB: 7 6 5 4 3 2 1
- (27) **An IRB that gives a complete explanation for any required changes to or disapprovals of protocols**
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- (28) **An IRB that invites investigators to present their position whenever a question or concern about a research protocol arises**
IDEAL IRB: 7 6 5 4 3 2 1
- (29) **An IRB that offers consultation during the development of research protocols or grant applications**
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- (31) **An IRB that responds in a timely manner to investigators’ inquiries about its processes and decisions**
IDEAL IRB: 7 6 5 4 3 2 1
- (32) **IRB that acknowledges full responsibility for its errors or delays in processing protocols and attempts to correct them as expeditiously as possible**
IDEAL IRB: 7 6 5 4 3 2 1
- (33) **An IRB that is open and pleasant in its interactions with investigators**

IDEAL IRB: 7 6 5 4 3 2 1

(34) An IRB whose Research Compliance Officer (or staff member in charge of IRB functions) has a background in conducting research

IDEAL IRB: 7 6 5 4 3 2 1

(35) An IRB that monitors the progress of each approved research project in line with federal policy

IDEAL IRB: 7 6 5 4 3 2 1

(36) An IRB that requires that its Chair be an experienced investigator

IDEAL IRB: 7 6 5 4 3 2 1

(37) An IRB that has a diverse membership (i.e., includes women, minorities and both junior and senior members of the institution)

IDEAL IRB: 7 6 5 4 3 2 1

(38) And IRB whose members fully understand and act within the scope of their function

IDEAL IRB: 7 6 5 4 3 2 1

(39) An IRB that is composed of more than one public member

IDEAL IRB: 7 6 5 4 3 2 1

(40) An IRB that views its role as being an investigator's ally rather than as being a hurdle to clear

IDEAL IRB: 7 6 5 4 3 2 1

(41) An IRB that does a good job of upholding participants' rights while, at the same time, facilitating the conduct of research

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(42) An IRB that is empathetic with the difficulties that can present themselves during the design or conduct of research

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(43) An IRB that holds no preconceived biases against particular research topics

IDEAL IRB: 7 6 5 4 3 2 1

(44) An IRB that can competently distinguish exempt from nonexempt research

IDEAL IRB: 7 6 5 4 3 2 1

(45) An IRB composed of members who arrive at meetings well-prepared.

IDEAL IRB: 7 6 5 4 3 2 1

PART TWO: The same IRB functions and activities are presented again. For this round, you are asked to rate your own IRB in terms of how well it corresponds to each statement.

Please rate *YOUR* IRB on each item by circling the number corresponding to the following scale:

7= Describes our IRB exceptionally well

6= Describes our IRB very well

5= Describes our IRB well

4= Describes our IRB somewhat

3= Only slightly describes our IRB

2= Does not describe our IRB

1= Definitely does not describe our IRB

(1) Our IRB is open to reversing its earlier decisions (i.e., willing to carefully listen to investigators' appeals)

Our IRB: 7 6 5 4 3 2 1

(2) Our IRB has members who are very knowledgeable about IRB procedures and federal policy

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(3) Our IRB that reviews protocols in a timely fashion

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(45) An IRB composed of members who arrive at meetings well-prepared.

Our IRB: 7 6 5 4 3 2 1

Version B: IRB Researchers' Assessment Tool

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Directions: Characteristics and activities of IRBs are reflected in the 45 items. As an investigator, how important is each one to you in your work? First rate how important each item would be to you to do your best work along a 7 point continuum with 7= “Absolutely essential” to 1= “Not important.” Then, rate how well that item described your own IRB on the same item, with 7= “Highly descriptive” to 1= “Not at all descriptive.”

(1) An IRB that reviews protocols in a timely fashion.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(2) An IRB that conducts a conscientious and complete review of protocols.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(3) An IRB that recognizes when it lacks sufficient expertise to evaluate a protocol and seeks an outside evaluator.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(4) An IRB that gives a complete explanation for any required changes to or disapprovals of protocols.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(5) An IRB that includes a complete explanation when it denies or mandates changes in a protocol based on criteria that are more stringent than or different from federal research policy (i.e., application of “local standards”).

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(6) An IRB that is open to reversing its earlier decisions (i.e., willing to carefully listen to investigators' appeals).

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(7) An IRB that invites investigators to present their position whenever a question or concern about a research protocol arises.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(8) An IRB that offers consultation during the development of research protocols or grant applications.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(9) An IRB that offers investigators opportunities to be educated about federal research policy.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(10) An IRB that offers editorial suggestions regarding consent documents and protocols (e.g., typos, grammar, clarity).

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(11) An IRB that offers investigators information to improve the chances of gaining IRB approval.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(12) An IRB that is willing to work with investigators to find mutually satisfying solutions whenever disagreements exist.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(13) An IRB that responds in a timely manner to investigators' inquiries about its processes and decisions.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(14) An IRB that treats investigators with respect.**Importance to you in your work:**

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(15) An IRB that acknowledges full responsibility for its errors or delays in processing protocols and attempts to correct them as expeditiously as possible**Importance to you in your work:**

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(16) An IRB that is open and pleasant in its interactions with investigators.**Importance to you in your work:**

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(17) An IRB that maintains complete and accurate records.**Importance to you in your work:**

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(18) An IRB that monitors the progress of each approved research project in line with federal policy.**Importance to you in your work:**

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(19) An IRB that requires that its Chair be an experienced investigator.**Importance to you in your work:**

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

(20) An IRB that has a diverse membership (i.e., includes women, minorities and both junior and senior members of the institution).**Importance to you in your work:**

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (21) An IRB that is allocated sufficient resources to carry out functions efficiently and thoroughly.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (22) An IRB whose members fully understand and act within the scope of their function.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (23) An IRB that is composed of more than one public member.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (24) An IRB that views its role as being an investigator's ally rather than as being a hurdle to clear.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (25) An IRB that does not use its power to suppress research that is otherwise methodologically sound and in compliance with federal policy whenever it perceives potential criticism from outside the scientific community.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (26) An IRB that shows considerable evidence that the advancement of science is part of its mission.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (27) An IRB that does a good job of upholding participants' rights while, at the same time, facilitating the conduct of research.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
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Highly Somewhat Not at all

(28) An IRB that is empathetic with the difficulties that can present themselves during the design or conduct of research.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(29) An IRB whose membership does not allow their personal biases to affect their evaluation of protocols.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(30) An IRB that requires members to recuse themselves from evaluating protocols whenever there might be a real or apparent conflict-of-interest.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(31) An IRB that holds no preconceived biases against particular research techniques.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(32) An IRB that holds no preconceived biases against particular research topics.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(33) An IRB that is open to innovative approaches to conducting research.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

(34) An IRB that can competently distinguish exempt from nonexempt research.

Importance to you in your work:

7 6 5 4 3 2 1
Essential Moderately important Not important

How descriptive is this item of YOUR IRB?

7 6 5 4 3 2 1
Highly Somewhat Not at all

- (35) An IRB whose membership is very knowledgeable about IRB procedures and federal policy.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (36) An IRB that is composed primarily of highly competent investigators.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (37) An IRB that provides a comprehensive training program for its new members.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (38) An IRB that is composed of members who arrive at meetings well-prepared.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (39) An IRB whose Research Compliance Officer (or staff member in charge of IRB functions) has a background in conducting research.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (40) An IRB that conducts a conscientious, informed analysis of potential benefits weighed against potential risks before making decisions.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (41) An IRB that has at least one member who is knowledgeable about the content domain and discipline of investigators' protocols.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (42) An IRB that views protection of human participants as its primary function.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (43) An IRB that takes timely action when an investigator has violated the specifications of its rulings.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (44) An IRB that applies appropriately flexible standards regarding voluntary and informed consent requirements (e.g., required wording is less demanding for minimal risk research using competent adult participants.)

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all

- (45) An IRB that takes timely and appropriate action whenever scientific misconduct is alleged.

Importance to you in your work:

7	6	5	4	3	2	1
Essential			Moderately important			Not important

How descriptive is this item of YOUR IRB?

7	6	5	4	3	2	1
Highly			Somewhat			Not at all