

OHRP QA Self-Assessment Tool

Date Completed: _____

SECTION A. INSTITUTION'S HUMAN SUBJECTS PROTECTION PROGRAM

This section collects information to assess your institution's or independent IRB's overall human subjects protection program.

1. Name of Institution or Organization:

2. Address:

3. Institutional Review Board (IRB) Organization Number (IORG #):

This number, assigned by OHRP, can be found on the OHRP website at <http://ohrp.osophs.dhhs.gov/>

4. a) Name of Contact Person:

b) Title:

c) Phone:

d) Fax:

e) E-mail:

General Administrative Information on the IRB Component of the Human Subjects Protection Program

5. How many IRBs are operated or supported by your institution?

Include special situation IRBs (e.g., prisoner research, emergency use, etc.).

6. Who oversees the day-to-day operations of the human subjects protection program?

Provide name and title.

7. To whom does the IRB(s) report?

Provide name and title.

8. Does the IRB(s) have its own budget?

9. Who authorizes budget support for the IRB(s)?

Provide name and title or reference previous response (e.g., "same as Question 7").

10. Does the IRB(s) have a written Charter or Charge?

11. Does your institution or organization have an organizational chart for your human subjects protection program?

If yes, please provide a copy as an attachment to this tool.

12. Who appoints the IRB Chair(s)?

Provide name and title or reference previous response (e.g., "same as Question 7").

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13. Describe the criteria used to select the Chair(s).
14. Who selects and appoints IRB members?
Provide name and title or reference previous response (e.g., "same as Question 7").
15. Describe the criteria used to select IRB members.
16. Are conflict of interest issues with IRB members managed and eliminated or minimized?
If yes, how?

General Information on Other Components of the Human Subjects Protection Program

17. Have senior officials ever issued a memo, to any or all of your institution's staff, about the institution's policy on human subjects protections and/or promoting the ethical conduct of human subject research?
18. Does your institution/IRB organization have a separate committee for review of noncompliance incidents?
a) If yes, how are the findings and actions communicated to the IRB?
b) If no, how are noncompliance incidents reviewed?
19. Does your institution/IRB organization have established policies and procedures for disclosure and management of potential conflicts of interest?
20. Does your institution/IRB organization have a separate committee for review of issues related to conflicts of interest?
If yes and when applicable, how are the findings and actions communicated to the IRB?
21. Does your institution/IRB organization have an internal audit, quality assurance, or quality improvement program for human research activities?
If yes, describe what was done in the last year and any changes that were made as a result of an audit, QA, or QI program.
22. Does your institution/IRB organization have an advocacy program or ombudsman accessible to potential or enrolled research participants?

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23. Does your institution/IRB organization ever receive complaints, questions, or concerns regarding human subject protections?

If yes, approximately how many during the past year?

24. Does your institution/IRB organization have a centralized hot line or 800 number for potential or enrolled research participants to file complaints or direct questions regarding human subjects protection issues?

Workload of the IRB(s) and Staffing Resources

The information in questions 25 to 28 is collected to understand the workload of an IRB. This information in summary form can be used to help make recommendations, which may increase not only the performance and quality of an IRB, but also its efficiency.

25. Provide the following general information for each IRB.

For consistency throughout this tool, each IRB should be referenced when appropriate in all further responses by the sequential numbers 1, 2, 3, etc. below. IRB Registration Identifiers, Federalwide Assurance (FWA), Multiple Project Assurance (MPA), and Cooperative Project Assurance (CPA) Numbers assigned by OHRP can be found on the OHRP website at <http://ohrp.osophs.dhhs.gov/>. The table may be expanded if your institution/organization has more than 6 IRBs.

IRB #	IRB Registration Identifier	Type (e.g., biomedical, behavioral, both)	Number Years in Existence	How Often Does the IRB Regularly Meet (e.g., once/mo, twice/mo)	List, by Number, any FWA, MPA, or CPA that Designate this IRB
a) 1					
b) 2					
c) 3					
d) 4					
e) 5					
f) 6					

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26. Please complete the following table to provide information on staffing resources available to the IRB.

Maintain reference to the respective IRBs from table in Question 25.

IRB #	IRB Chair			IRB Administrator			Name(s) of Staff Members Supporting IRB (Indicate Full-Time or Part-Time Staff)
	Name(s)	# Years	% Effort to IRB	Name(s)	# Years	% Effort to IRB	
a) 1							
b) 2							
c) 3							
d) 4							
e) 5							
f) 6							

27. Does your IRB Chair(s) perform administrative functions for the IRB (e.g., prepare or assist in the development of letters to investigators)?

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28. Please complete the following summary table to provide information on the volume of work over the past 12 months for each IRB.

Maintain reference to the respective IRBs from tables in Questions 25 and 26.

IRB Workload Summary Table <i>Enter data for each IRB for the past 12 months</i>	IRB 1	IRB 2	IRB 3	IRB 4	IRB 5	IRB 6
a) Total number of active studies reviewed						
b) Total number of studies reviewed and found to be exempt						
c) Approximate average duration of an IRB meeting: (i.e., hours, minutes)						
d) Number of new protocols reviewed by full committee						
e) Number of new protocols approved by expedited review						
f) Number of continuing review protocols reviewed by full committee						
g) Number of continuing review protocols reviewed by expedited review						
h) Number of amendments requiring full committee review						
i) Number of amendments approved by expedited review						
j) Number of adverse reactions/unanticipated events reviewed						

Educational Training

29. Provide the following information regarding educational training in human subjects protection for each staff member.

	Training rec'd before assuming position? (Y/N)	Training rec'd after assuming position? (Y/N)	How often is training repeated? (e.g., 1/yr, 2x/yr, 1/2yrs, etc.)
a) Signatory Official			
b) IRB Chair(s)			
c) IRB administrator(s)			
d) IRB members			
e) Investigators			

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30. Briefly describe the human subjects protection training each staff member typically received in the last year.

a) Signatory Official	
b) IRB Chair(s)	
c) IRB administrator(s)	
d) IRB members	
e) Investigators	

31. Does your institution/IRB organization maintain a log or in some other way document human subjects protection training received by each individual?

32. Does your institution/IRB organization review the training received by each individual and determine its adequacy for that person's role?

33. Name of person(s) completing Section A:

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SECTION B. INSTITUTIONAL REVIEW BOARD

Complete a copy of this section for each IRB that reviews human subjects research for your institution.

IRB Number(s):

Reference the number (e.g., IRB 2) from Section A, Questions 25, 26, and 28.

1. Who manages the day-to-day operations of the IRB?

Provide name and title.

2. To whom does this person report?

Provide name and title.

3. How often does your IRB usually convene for full committee review of research studies?

___ > once/week ___ once/week ___ twice/month

___ once/month ___ >once/month ___ other: _____

4. Does your IRB have written operating procedures?

5. When were the written IRB operating procedures last reviewed?

6. When were the written IRB operating procedures last updated?

What kinds of changes were made to the procedure (e.g., typographical errors, substantive, policy, etc.)?

7. Do the written IRB operating procedures indicate how frequently they should be reviewed and, if necessary, updated?

8. Who reviews and revises the IRB written operating procedures?

Provide name and title.

9. How long are IRB records (e.g., protocol files, minutes) stored on site and readily accessible to the IRB members and staff?

How are records stored (e.g., paper, electronic)?

10. Are IRB records retained after this period?

a) If yes, how?

b) For how long?

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11. Does your IRB organization use a computerized database for tracking all protocols?
- a) Identify the types of letters that can be produced by the database (e.g., continuing review notice, approval letters).
 - b) Identify the types of reports you can generate from your database.
 - c) What reports do you use routinely?
 - d) Does the database track adverse events?

Submission Process for IRB Review

12. Does your IRB require investigators to use an IRB submission form for initial review of protocols?

If yes, please submit a copy of this form(s).

13. Does your IRB submission form request the name of the sponsor?

14. Does your IRB submission form request the approval and signature of the department chair (or supervisor) prior to submission to the IRB?

15. Does your IRB require the approval and signature of other individuals prior to submission to the IRB (e.g., pharmacy, nursing)?

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16. What items are requested and distributed to each designated IRB member(s) for review?

Check all that apply.

Items Collected for IRB Review		Distributed for Full Committee Review			
Item	Requested by IRB	IRB Chair	Primary Reviewer	Other IRB Members	Alternate Members
a) IRB submission form					
b) Full protocol					
c) Full grant or contract application (if federally funded)					
d) Protocol summary					
e) Informed consent form					
f) Scientific review					
g) Recruitment material (e.g., advertisements, recruitment letters, scripts for telephone conversation or focus groups, etc.)					
h) Investigator's qualifications [e.g., CV, medical license(s), etc.]					
i) Conflict of interests disclosure					
j) List of all investigators					
k) Questionnaires					
l) Other <i>(Describe)</i>					
Additional elements that may apply for biomedical research. <i>Check all that apply.</i>					
m) Investigator Brochure					
n) Package insert providing drug information					
o) Device manual					
p) IND/IDE number					
q) Copy of FDA 1572 form or Investigator Agreement (for device studies)					
r) Copy of case report forms					

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Preparation for Full Committee Review Process

17. Does your IRB have a deadline for investigators to submit protocols that require full committee review?

If yes, how many days are between the deadline and the scheduled IRB meeting?

18. How many days do IRB members have to review materials prior to the date of the IRB meeting?

19. Does your IRB(s) use a primary reviewer system for full committee reviews of new protocols?

- a) If yes, how many reviewers are assigned for each protocol?
- b) Is there an attempt to match the primary reviewer's expertise to the protocol's subject matter?

20. How often does the IRB bring in a consultant to provide scientific or other relevant expertise for review of a particular protocol?

21. Does your IRB ensure that the informed consent document includes input by a non-scientist [e.g., lay person(s)]?

Preparation for Continuing Review

22. Does your IRB request a written status report from the investigator for continuing review?

If yes, how long before expiration of IRB approval? *Select one. If no, go to question 24.*

___>60 days ___45-59 days ___30-44 days ___<30days ___other:

23. What items are requested in the written status report? *Check all that apply.*

- a) ___ Number of subjects enrolled
- b) ___ Number of subjects screened
- c) ___ Number of subjects withdrawn
- d) ___ Reasons for withdrawal
- e) ___ Number of subjects dropped out of protocol
- f) ___ Reasons for drop-out
- g) ___ Number of subjects lost to follow-up
- h) ___ Gender and ethnic/racial breakdown of enrolled subjects
- i) ___ Verification that informed consent was obtained from all subjects and that all signed consent forms are on file (unless requirements were waived)
- j) ___ Number of serious adverse events (SAEs)
- k) ___ Description of SAEs

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23. (cont'd.) What items are requested in the written status report? *Check all that apply.*

- l) ___ Number of unanticipated problems
- m) ___ A description of the unanticipated problems
- n) ___ List of amendments or modifications since last IRB review
- o) ___ Change in study personnel
- p) ___ Change in sponsor
- q) ___ Subject complaints
- r) ___ Summary of progress/preliminary findings
- s) ___ Other: _____

24. What information is requested for continuing review? *Check all that apply.*

Items Collected for Continuing Review		Distributed for Full Committee Review			
Item	Requested by IRB	Chair	Primary Reviewer	Other IRB Members	Alternate Members
a) IRB's written status report form					
b) Full protocol					
c) Copy of informed consent form(s) used during the past approval period					
d) Protocol summary					
e) Protocol/project modifications					
f) Summary of recent literature					
g) NIH Progress Report					
h) DSMB Progress Report					
i) Other:					

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25. How many days prior to the IRB meeting date do IRB members have to review continuing review material?

26. Does your IRB use a primary reviewer system for continuing reviews requiring full committee review?

If yes, how many reviewers are assigned to each protocol?

IRB Review Process

27. After a brief review of three recent IRB minutes, complete the following table.

Start with "Meeting 1" representing the most recent meeting. However, if you convened more than one meeting per month, respond by using information from the first IRB meeting in each of the past 3 months.

IRB Workload Table	1st Meeting	2nd Meeting	3rd Meeting
a) Number of new protocols determined as exempt			
b) Number of new protocols approved by expedited review that were reported to the IRB			
c) Number of new protocols reviewed by full committee			
d) Number of continuing review protocols approved by expedited review that were reported to the IRB			
e) Number of continuing review protocols reviewed by full committee			
f) Number of amendments approved by expedited review that were reported to the IRB			
g) Number of amendments reviewed by full committee			
h) Number of adverse reactions/unanticipated events reviewed by full committee			

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28. Provide information for the following IRB functions:
Check the appropriate boxes for each individual.

	IRB Chair(s)	IRB Administrator	IRB Staff	IRB Member	Other Person; If Other, Specify Who:
a) Performs administrative review					
b) Determines category for review (exempt, expedited, full board)					
c) Performs expedited review					
d) Performs initial review of adverse events					
e) Prepares IRB meeting agenda					
f) Prepares IRB meeting minutes					
g) Maintains IRB database					
h) Maintains IRB files					

29. Does your IRB review the entire grant, contract, or cooperative agreement application for federally-supported research when providing review for the prime awardee of an application?

30. Does your IRB consider whether performance sites are engaged in human subject research supported by the federal government?

31. For federally-supported human subject research, does your IRB inform the investigator of the need to obtain Assurances for performance sites engaged in the research; sites which do not have an appropriate OHRP or federally-approved Assurance?

32. When your IRB reviews research to be conducted at other institutions, does your IRB consider characteristics of the local setting (i.e., race, gender, cultural backgrounds, and sensitivity to issues such as community attitudes, institutional policies and commitments, as well as applicable law and standards of professional conduct and practice)?

33. Who usually determines whether a protocol submitted for IRB review is to be reviewed by full committee or expedited review?

34. Who is authorized by your IRB/IRB chair to approve protocols by expedited review?

35. Approximately how much time does it usually take to review a new protocol by expedited procedures?

36. For each study, does your IRB determine who will be authorized to obtain informed consent from subjects?

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37. Does your IRB require the PI to obtain IRB approval before delegating the responsibility to someone else to obtain informed consent from subjects?

For high-risk studies, does the IRB approve delegation to specific individuals by name?

38. Does your IRB have a sample consent form that investigators may use as a resource?

If yes, please submit a copy to OHRP as an attachment.

39. Does your IRB review the process by which informed consent will be obtained (e.g., conditions under which a subject is approached for recruitment)?

40. How does your IRB ensure that the informed consent document is comprehensible to the subject population (e.g., appropriate reading level)?

41. Does your IRB consider whether a translation to a foreign language (e.g., Spanish language) is needed?

42. Does your IRB ever waive the requirement to obtain informed consent from each prospective subject or the subject's legally authorized representative?

If yes, what criteria does the IRB use to waive the requirement?

43. Does your IRB ever waive the requirement to document informed consent using a written consent form that is signed by the subject or the subject's legal representative?

If yes, what criteria does the IRB use to waive the requirement?

44. How is waiver of informed consent documented for protocols undergoing expedited review?

45. Does your IRB have a policy for review of research involving deception?

46. Does your IRB explicitly consider how to minimize risks to subjects?

47. Does your IRB consider whether risks to subjects are reasonable in relation to anticipated benefits?

48. Does your IRB ever consider the long-range effects of applying the knowledge gained in the research as among the risks that fall within the purview of its responsibility?

49. Does your IRB review recruitment processes to ensure that the selection of subjects will be equitable (e.g., gender, age, race/ethnicity)?

50. Does your IRB review advertisements to be used for recruitment of subjects?

51. Does your IRB include awareness of, through consultation or representation on the IRB as appropriate, the additional concerns or issues of research involving vulnerable populations (such

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as, children, prisoners, women who are pregnant, persons with mental disabilities, or persons who are economically or educationally disadvantaged)?

52. Does your IRB require, when appropriate, that the research plan includes adequate provisions for monitoring the data collected to ensure the safety of subjects?

53. Does your IRB require, when appropriate, that there are adequate provisions to protect the privacy of subjects and to maintain confidentiality?

54. Does your IRB recommend or require, when appropriate, submission of a Certificate of Confidentiality?

If yes, in what situations?

55. When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as, children, prisoners, women who are pregnant, persons with mental disabilities, or persons who are economically or educationally disadvantaged), does your IRB consider and require that additional safeguards be included in the study to protect the rights and welfare of the subjects?

56. Does your IRB determine at the initial review of a study the appropriate interval for continuing review based on the degree of risk?

57. Does your IRB consider and comply with the reporting requirements in accordance with 45 CFR 46?

a) With 21 CFR 50, 56, 312?

b) With 21 CFR 612, 812?

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IRB Minutes

58. After a brief review of three recent IRB minutes, complete the following table.

Start with “Meeting 1” representing the most recent meeting. However, if you convened more than one meeting per month, respond by using information from the first IRB meeting in each of the past 3 months. Maintain reference to the same minutes used in Question 27.

IRB Minutes – Allocation of Time	Meeting 1	Meeting 2	Meeting 3
a) Date of meeting			
b) Time meeting started			
c) Time meeting ended			
d) Length of meeting			
e) Estimated amount of time for full committee protocols/meeting			
f) Estimated amount of time for modifications requiring full committee review/meeting			
g) Estimated amount of time for review of adverse reactions/unanticipated events reported/meeting			
h) Estimated amount of time for continuing review protocols requiring full committee review/meeting			

59. Do the IRB minutes usually record the names of IRB members present?

60. Do the IRB minutes usually record the names of IRB members absent?

60. Do the IRB minutes usually record the names of consultants and visitors present?

61. Does the IRB usually approve the minutes from the prior meeting?

62. Are IRB members notified of all new sponsor- or investigator-initiated modifications/amendments to protocols (i.e., not changes requested by the full committee from a prior review) that were approved by expedited review since the prior meeting?

If not done at the IRB meeting, how are these approvals communicated to IRB members?

63. Are all substantive sponsor- or investigator-initiated modifications/amendments to protocols reviewed and approved by the convened IRB (with quorum)?

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64. Are IRB members notified of all protocols that were approved by expedited review since the prior meeting?

If not done at the IRB meeting, how are these approvals communicated to IRB members?

65. For protocols undergoing continuing review by full committee, does the convened IRB (with quorum) review, deliberate, and vote for each study?

66. Are IRB members notified of all protocols undergoing continuing review by the expedited review process?

If not done at the IRB meeting, how are these continuing reviews communicated to IRB members?

67. Do the minutes document IRB review of adverse events and unanticipated problems?

68. Do the minutes include IRB review of protocol violations or deviations?

Documentation of IRB Reviews in the Minutes

69. For each protocol reviewed by your IRB, do the minutes include written documentation of any discussion of controverted issues and their resolution?

70. For protocols in which your IRB waived the requirement of informed consent, was the justification for waiver documented in the minutes in accordance with 45 CFR 46.116(d)?

71. For research involving pregnant women and/or fetuses, do the minutes document IRB findings required under Subpart B of 45 CFR 46?

72. For research involving prisoners, does the composition of the IRB include a prisoner or a prisoner representative with appropriate background and experience?

73. For research involving prisoners, do the minutes document IRB findings as required under 45 CFR 46.305(a)?

74. For research involving children, do the minutes document IRB findings in accordance with Subpart D of 45 CFR 46?

75. Do the minutes document consideration of additional safeguards for vulnerable subjects when appropriate?

76. Do the minutes document that a quorum was present for all IRB actions requiring a vote?

77. Do the minutes document that at least a majority of the IRB members present voted on all actions requiring a vote?

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78. Do the minutes document that all IRB actions included at least one scientist in the review and vote?

79. Do the minutes document that all IRB actions included at least one non-scientist in the review and vote?

80. Do the minutes document that all IRB actions included at least one non-institutional member in the review and vote?

If no, how frequently has the absence of this member occurred in the past 3 months?

81. Do the minutes record the name of IRB members who abstained from a vote and provide the reason for abstention?

82. Do the minutes record the name of IRB members who were excused from the discussion and vote due to a conflict of interest?

If yes, was the reason for the conflict documented in the minutes?

83. When approval of a study has been deferred by your IRB, do the IRB minutes state who (e.g., chair, reviewers, full committee) will review and confirm that the investigator has completed the modifications requested by the IRB?

Do subsequent minutes document that this review was done?

Post IRB Review

84. Does your IRB notify **investigators** in writing of its decision to approve or disapprove the proposed research activity or to require modifications in order to secure IRB approval?

85. Does your IRB notify the **institution** in writing of its decision to approve or disapprove the proposed research activity or to require modifications in order to secure IRB approval?

86. On average, how much time lapses between an IRB meeting and sending the above written notifications to the investigators?

Who approves these letters before they are sent?

87. If your IRB decides to disapprove a research activity, does it include in its written notification a statement of the reason(s) for its decision and provide the investigator with an opportunity to respond in person or in writing?

88. Does your IRB Chair (or designee) review substantive changes required by the full committee and subsequently made by the investigator?

If yes, in what situations?

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89. Does the IRB monitor or require monitoring of any studies?

If yes, please describe when and how.

Approval Letter

90. Does the approval letter or approval document from your IRB include the title of the study, protocol number, and version (or amendment) date?

If no, what items are included?

91. For federally-supported research, does the approval letter from your IRB include the grant, contract, or cooperative agreement number?

92. For protocols reviewed by full committee, does the approval letter from your IRB reference the date of the IRB meeting at which the protocol was approved?

93. If the IRB approved a study for 1 year, does the approval letter provide an expiration date that is 1 year from the date of the convened IRB meeting in which the study was approved?

94. Does the approval letter reference the requirement to use the IRB-approved informed consent form?

95. Is a copy of the IRB-approved informed consent form attached with the approval letter?

96. Is the IRB-approved informed consent form stamped with an approval date?

97. Is the IRB-approved informed consent form stamped with an expiration date?

98. Name of person(s) completing Section B:

NOTE: If you have any questions regarding this Self-Assessment Tool, please call the Division of Assurances and Quality Improvement at 240-453-8236.