Post-Approval Auditing for Studies Subject to Single IRB Review

Post-Approval Auditing Working Group
of the SMART IRB Harmonization Steering Committee

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OBJECTIVE

The Post-Approval Auditing Working Group of the SMART IRB Harmonization Steering Committee aims to identify, propose, and harmonize best practices and tools for research oversight through for-cause and not-for-cause audits of research studies being conducted under an IRB reliance agreement.

AUDIENCE

- **Reviewing IRBs**
- **Relying Institutions**
- **Reliance Staff at Reviewing IRBs and Relying Institutions**
- **Quality Assurance/Quality Improvement Staff at Reviewing IRBs and Relying Institutions**
- **Overall Principal Investigators (PIs) & Study Teams**
- **Site Investigators & Study Teams**

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INTRODUCTION

There are currently thousands of studies reviewed and approved using IRB reliance agreements. In these cases, while the Relying Institution retains compliance oversight of local activities, the Reviewing IRB has the overall responsibility for the oversight of study conduct. However, there is little consistency among IRB policies or guidance as to how this oversight should be executed. Differences include consent procedures, definitions of noncompliance, expectations for reporting these events, and others. It is difficult for investigators and their study teams to keep track of the different policies and requirements when working with a variety of IRBs.

Oversight of a study under an IRB reliance agreement is challenging. Evaluating a study at a distance, even for IRBs with experience serving as a Reviewing IRB, is difficult. The Reviewing IRB may have limited knowledge of the Relying Institution or its investigators and may not be able to perform an on-site audit from afar. Conversely, the Relying Institution's knowledge of the approved study protocol and of the Reviewing IRB's expectations may also be limited; they rarely have access to all study documents such as amendments, progress reports, or reports of unanticipated problems. Finally, enforcement is difficult since the responsible Reviewing IRB does not have authority over investigators whom it does not employ.

There are also differing considerations for when and how not-for-cause and for-cause audits are conducted. When for-cause audits are requested, they are prompted by the Reviewing IRB because of specific concerns regarding the conduct of the research. Not-for-cause audits are typically initiated by the Relying Institution as part of an institution's routine post-approval monitoring program.

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SMART IRB MASTER COMMON RECIPROCAL INSTITUTIONAL REVIEW BOARD AUTHORIZATION AGREEMENT (SMART IRB AGREEMENT)

The SMART IRB Agreement provides clear direction on the responsibilities for the both the Reviewing IRB and Relying Institution in handling study compliance and audits.

Section 4.4 of the SMART IRB Agreement outlines a number of expectations with regard to compliance oversight and auditing:

- **Participating Institutions must, "…maintain, implement or have access to a human subjects research QA/QI process function, program or service that can conduct and report to the Participating Institution the results of for-cause and not-for-cause audits of the institution and its Research Personnel's compliance with human subjects' protections and other relevant requirements."**
- **"Participating Institutions that do not have access to a QA/QI process or function must have an alternate means of monitoring the conduct of Research as appropriate to ensure compliance."**
- **"…any Participating Institutions agreeing to participate in a Ceded Review may agree between or among themselves to waive the requirement to have access to a QA/QI process, function, program or service or alternate means of monitoring with respect to the Research that is the subject of the Ceded Review."**

Section 5 of the SMART IRB Agreement further requires the following of Reviewing IRBs with regards to oversight:

- **Section 5.3 indicates the Reviewing IRB should "[m]ake available to the Relying Institution(s), when applicable and upon request, the Reviewing IRB's policies and procedures, including policies and procedures of the Reviewing IRB/Reviewing IRB Institution regarding exemption determinations."**
- **Section 5.12 requires the Reviewing IRB to "[p]romptly notify a Relying Institution with respect to which it is conducting an audit or investigation of an allegation or matter relating to the Ceded Review, and report its findings of fact to such Relying Institution within a reasonable timeframe."**
- **Section 5.12 states, "…the Reviewing IRB may request the Relying Institution to conduct its own audit/investigation and report its findings of fact back to the Reviewing IRB, or the Reviewing IRB and the Relying Institution may work cooperatively to conduct an audit/investigation."**
- **Section 5.12 further requires, "The Reviewing IRB shall inform the Relying Institution of any corrective actions in connection with the audit, investigation, or resolution of any matter under Sections 5.9 through 5.12 hereof that are required by the Reviewing IRB but shall not prevent the Relying Institution from adopting its own more stringent additional corrective actions."**
- **Section 5.13 states that the Reviewing IRB will "[n]otify a Relying Institution in advance if the Reviewing IRB determines that under applicable regulation or under the terms of the Relying Institution's FWA a report is required to a regulatory agency (e.g., OHRP, FDA), sponsor, funding agency, and/or other oversight authority of any unanticipated problems involving risk to human subjects or others, serious or continuing noncompliance with applicable human subjects protection regulations or with requirements of determinations of the Reviewing IRB, and/or any suspensions or terminations of IRB approval."**
- **Section 5.13.1 goes on to state, "Unless an alternate reporting arrangement is agreed upon, the Reviewing IRB/Reviewing IRB Institution will draft the report and will provide the involved Relying Institution(s) the opportunity (no fewer than five (5) business days, whenever possible) to review and comment on the draft report before the Reviewing IRB/Reviewing IRB Institution sends the report to external recipients."**

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Section 6 of the SMART IRB Agreement requires the following for Relying Institutions with regard to oversight:

- **Section 6.1 states that a Relying Institution must ensure that its research personnel, "…accept the decisions and requirements of the Reviewing IRB. A Relying Institution or its Research Personnel may not initiate any Research or change to the Research, except where necessary to eliminate apparent immediate hazards to subjects, without first receiving prior approval from the Reviewing IRB."**
- **Sections 6.11 and 6.12 require the Relying Institution to promptly notify the Reviewing IRB of any unanticipated problems that may involve risk to human subjects, other noncompliance, and/or restrictions or suspension of research.**
- **Section 6.13 requires the Relying Institution to "[c]ooperate, and require its Research Personnel to cooperate, with any audit or investigation by the Reviewing IRB/Reviewing IRB Institution of any matter under this agreement." It requires, "If the Relying Institution is asked by the Reviewing IRB/Reviewing IRB Institution to conduct its own audit/investigation, or to work cooperatively with the Reviewing IRB/Reviewing IRB Institution to conduct an audit/investigation, then the Relying Institution will do so and will report its findings of fact to the Reviewing IRB/Reviewing IRB Institution within a reasonable timeframe."**

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COMMUNICATION

When sites enter into a reliance arrangement, communication is essential. During the initial reliance exchange of information, the Relying Institution provides its local context information (e.g., institutional policies, state and local laws) to the Reviewing IRB. At that time, it is also important for the Relying Institution to communicate its ability to provide quality assurance/quality improvement activities for ongoing studies. This should include information such as whether the Relying Institution has its own QA/QI program or an alternative arrangement and, if so, the nature of that arrangement. Any financial considerations or resource issues should also be clarified. Having this information early in the conduct of the research will help ensure the study has appropriate QA/QI monitoring in place and is ready to perform a for-cause audit in a timely manner if and when asked. This information could be shared as a part of the SMART IRB Communication Plan.

In addition, communication is important throughout the processes of for-cause and not-for-cause audits. Many issues may be resolved by prompt communication.

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FOR-CAUSE AUDIT

A for-cause or directed audit is an in-depth, generally onsite review of the conduct of the research or investigators that is initiated at the request of the IRB or an institutional official to obtain or verify information necessary to ensure compliance with the protocol, regulations, and/or institutional requirements. At the initiation of a for-cause audit, the Reviewing IRB must define the scope of the audit and communicate the level and urgency of concern that prompted the request. The request should be as specific as privacy and confidentiality will permit.[1] Such specificity informs the Relying Institution of the documentation the Reviewing IRB needs in order to determine the merits of the concern.

When an audit is requested and initiated, each site's responsibilities must be clear. The Reviewing IRB should communicate the expected timing of the audit and the level of urgency and required completion date. In addition, the Reviewing IRB should communicate any suggestions or requirements for methodology and/or required information to be reviewed. It is important for the Reviewing IRB to understand that the Relying Institution may have limited resources with which to conduct the audit, as the request will be unanticipated and not part of the work plan of the Relying Institution. Concessions may be made to limit the scope of the audit to accommodate requests of the Relying Institution, but the scope should be sufficient to satisfy the concerns prompting the audit. It may be necessary at times for the Reviewing IRB to conduct the audit remotely and/or in-person rather than rely upon the Relying Institution to perform the audit; if so, the reasons should be made clear. The Relying Institution is of course free to extend the audit beyond what is requested by the Reviewing IRB.

If the Relying Institution's QA/QI program routinely assists investigators and study teams in the development of draft corrective action plans, such plans should be submitted with the audit findings for consideration by the Reviewing IRB. The Reviewing IRB has the authority to require additional corrective actions and must be satisfied that the corrective action plan is sufficient.

Purpose

The Reviewing IRB may require a for-cause audit be performed for a variety of reasons. During the course of research, events and information may be reported to the Reviewing IRB that cause concern and prompt the audit of a specific site(s), specific investigator(s), or all participating sites involved in a study or studies. The Reviewing IRB will determine the best method by which to perform this audit, including whether and which specific documents (e.g., consent documents, pharmacy records or other source material) or information could be provided from the Overall PI, Relying Institution, or study team members; whether an audit is required; and the appropriate scope of the audit to investigate the concern.

It is within the Reviewing IRB's authority to require a for-cause audit, and nothing in this guidance is meant to limit that authority. However, because the Relying Institution will not have anticipated the audit and any audit will be incremental to its work plan, a for-cause audit should reasonably be requested only for substantive reasons.

A for-cause audit is warranted when a Reviewing IRB has reason to suspect serious and continuing noncompliance; examples include:

- **Information in the submission indicates suspicion of possible serious or continuing noncompliance with protocol and/or with the policies of either the Relying Institution or Reviewing IRB.**
- **Report of an investigator or other member of the study team of possible serious or continuing noncompliance to the IRB.**
- **Report of noncompliance and/or concerns from a third party; for example, participant or sponsor complaints, requests from institutional officials, or concerns from government agencies (e.g., FDA, NIH, OHRP).**
- **A need to verify that the Research is being conducted in accordance with the IRB-approved protocol (e.g., protocols conducted by Investigator(s) with a history of noncompliance; questionable study performance; complex, multisite protocols where substantial portions of study are conducted off-site).**

1. Under certain circumstances, execution of a confidentiality agreement may be necessary.

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Procedures

The Reviewing IRB will send a written notice of the requested audit to the SMART IRB Institution Point of Contact (POC), with a copy to the Overall PI and Site Investigator, when appropriate. The "Sample For-Cause Audit Notification Checklist" (Appendix A) has been developed for this purpose. If the Reviewing IRB is requesting that the Relying Institution conduct the audit, it is expected that the Relying Institution Point of Contact (POC) will then forward the audit request to the appropriate QA/QI staff at their institution or to another body charged with conducting the audit.[2] The POC may also inform the director of the human research protections program, director of the IRB, or institutional official consistent with institutional policy and confidentiality requirements.

When requesting a for-cause audit, a Reviewing IRB should communicate:

- **What concerns prompted the request for an audit.**
- **What information and source documentation should be reviewed for the Reviewing IRB to make a decision regarding non-compliance.**
- **What is the time frame in which the audit should be conducted and communicated back to the Reviewing IRB.**
- **The expectation of how information and documents, including relevant policies if necessary, will be communicated between the Reviewing IRB and the Relying Institution (e.g., Reviewing IRB's electronic system, summary report of submissions, pdf/zip file of relevant documents).**
- **Confirmation as to whether the Reviewing IRB is requesting that the Relying Institution perform the audit or plans to perform the audit directly.**

The Relying Institution will submit a report of the audit to the Reviewing IRB within the expected timeframe of the request. The "Sample Audit Checklist," (Appendix B) has been developed for the QA/QI team to complete as they perform the audit. Any delay or change from the expected timeframe should be communicated to the Reviewing IRB. The "Sample Audit Report Template" (Appendix C) has been developed to help the auditing QA/QI team summarize audit report findings.

The Reviewing IRB will review the submitted report and, if there are further questions and if necessary, request any additional information or source documentation for verification to be submitted. Upon receipt of all the information, the Reviewing IRB provides written notification that they have completed their review of the audit submitted by the Relying Institution. This notification should be made to the Relying Institution's POC, with a copy to the Overall PI and Site Investigator(s) as appropriate, typically within 30 calendar days of receipt. Notification may be in the form of an email and should identify the protocol, reason for the audit, findings, and, if required, plans for external reporting. The Reviewing IRB will make available a summary of their review process of the audit report if requested by the Relying Institution.

If findings suggest that a corrective action and preventive action plan (CAPA) is warranted, the Reviewing IRB should request the Relying Institution to work with the investigator and study team on a draft CAPA that the Reviewing IRB will then review and finalize. Further, the Relying Institution will work with the investigator and study team to implement the CAPA and report any challenges with its implementation to the Reviewing IRB. The Reviewing IRB may request follow up or further information.

2. Clarification and documentation of the necessary path for communication is particularly relevant when the Relying Institution has made arrangements for another group or entity to conduct its audits and/or oversight functions.

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NOT-FOR-CAUSE AUDITS

Not-for-cause audits are conducted at the discretion of the Relying Institution as part of their on-going post-approval monitoring program. Some institutions have well-developed QA/QI programs and a system by which to select studies for these routine audits. Relying Institutions may select studies for audit in a variety of ways.

Examples of requested not-for-cause audits:

- **QA/QI-requested audit: The protocol meets criteria as outlined in the Relying Institution's policies and procedures for a not-for-cause audit (for example Sponsor-Investigator, clinical trial with vulnerable population, off-site research site, study being conducted under a reliance agreement). Such triggers depend on the Relying Institution's policies and may or may not be at random.**
- **Investigator-requested audit: An investigator may request a not-for-cause audit for education and quality improvement purposes. The Relying Institution's QA/QI program will determine the appropriateness and feasibility of the requested audit and execute the audit at its discretion.**

We recommend that Relying Institutions develop a process to track those studies that have ceded IRB review to a different institution's IRB under a reliance arrangement. When auditing reliance studies, issues and concerns may arise regarding: accessing the relevant study documents and interpreting the Reviewing IRB's policies, conduct of the study according to institutional policies, and the expectations established in the reliance agreement. The Relying Institution will work with the study team and, if necessary, the Reviewing IRB, to obtain the necessary documents in order to perform the audit. Reviewing IRBs are expected to provide materials requested by the Relying Institution in a timely manner or verify that the materials provided by the investigator(s) are true and accurate. It may also be necessary for the Relying Institution to work with the Reviewing IRB on the interpretation of the Reviewing IRB's polices.

Reports of the results of not-for-cause audits will be provided to the investigator per the policy of the Relying Institution. Issues of suspected serious or continuing noncompliance or other potential reportable events identified by the not-for-cause audit will be communicated to the Reviewing IRB in a timely manner consistent with the SMART IRB Agreement. In the event that no reportable events, including serious and continuing noncompliance, are discovered, notification that the audit has been completed may also be provided to the Reviewing IRB, but such notification is not required.

The Relying Institution will report any findings of serious or continuing noncompliance or other reportable events to the Reviewing IRB. If the Relying Institution's QA/QI program routinely assists investigators and study teams in the development of corrective action plans, such plans should be submitted with the audit findings for consideration by the Reviewing IRB. The Reviewing IRB will be responsible for determining whether further investigation is necessary via a for-cause audit or other means and will determine whether the corrective action plan is sufficient and make further determination regarding required reporting of the event to external parties. In situations where additional corrective and preventative actions are required, those plans should be developed by the Reviewing IRB and sent to the Relying Institution for comment before they are finalized.

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RESPONSIBILITIES OF THE PARTICIPATING INSTITUTIONS

Reviewing IRB Responsibilities:

- **Communication, typically written, to the Relying Institution of the concerns that prompted a for-cause audit request, as clearly and completely as possible, while remaining consistent with any applicable confidentiality provisions. That communication will be sent to the POC of the Relying Institution, usually with a copy to the Site Investigator at the Relying Institution and a copy to the Overall PI. A confidentiality agreement may be necessary to permit appropriate communication.**
- **Determination, after consultation with the Relying Institution, of who will perform the for-cause audit (e.g., Reviewing IRB, Relying Institution, or a designated third party).**
- **The time frame for completion of a for-cause audit, and any reasons for urgency to the audit.**
- **A process for sharing study documents in a manner that is efficient and effective for the institution conducting the audit, either initiated by the Reviewing IRB, in the case of a for-cause audit, or initiated by the Relying Institution, in the case of a not-for-cause audit. The process could include the Reviewing IRB providing the QA/QI personnel with site-specific study documents directly or the Reviewing IRB providing access to their electronic IRB system. Only those documents relevant to the audit and to the site should be shared. It is anticipated that the Reviewing IRB will request study documents first from the Overall PI and/or Site Investigator. The Reviewing IRB's policies should be made available to the Relying Institution, if requested.**
- **Notify the Relying Institution of completion of its review of the audit report.**
- **Develop an appropriate corrective action plan (or make any required modifications to the Relying Institution's proposed corrective action plan) and share with the Relying Institution for comment before finalizing.**

Relying Institution Responsibilities:

- **Conduct for-cause audits as requested by the Reviewing IRB, maintaining privacy and confidentiality as necessary.**
- **Obtain and provide relevant study documents and policies to the Reviewing IRB when requested.**
- **Provide a written report of a for-cause audit to the Reviewing IRB, with a copy to the Site Investigator and Overall PI, as appropriate.**
- **Communicate any issues of potential serious and continuing noncompliance with the Reviewing IRB for further action or investigation.**
- **Provide feedback to the Reviewing IRB and investigator(s) on the corrective action plan, if necessary.**
- **Regularly conduct not-for-cause audits as part of their post-approval monitoring program, and, at a minimum, report results of the not-for-cause audit consistent with the reportable events policies of the SMART IRB Agreement (or other applicable reliance agreement) and institutional expectations.**

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NOTES

Questions often arise during the course of a study, either from the Reviewing IRB or Relying Institution, that require consultation but do not, at least initially, rise to the level of requiring an audit. This may include the Relying Institution being notified of participant complaints or allegations against an investigator. Depending on the situation, it may be appropriate for the Relying Institution to initiate a preliminary investigation to determine whether the allegation has merit. Once the preliminary investigation has been completed, and if there is merit, that information should be communicated to the Reviewing IRB to determine what further action is necessary.

Generally, we recommend maintaining open communication between the Participating Institutions, as often clarification or simple verification of some documentation may suffice, without rising to the level of a for-cause audit. Cooperation and good intention will advance the purpose of reliance while avoiding unnecessary work or undue burden.

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APPENDIX A

SAMPLE FOR-CAUSE AUDIT NOTIFICATION CHECKLIST

FOR USE BY THE REVIEWING IRB REQUESTING THE AUDIT

STUDY TITLE: _____

PRINCIPAL INVESTIGATOR: _____

PARTICIPATING SITE FOR AUDIT: _____

SITE INVESTIGATOR: _____

RELYING INSTITUTION POINT OF CONTACT: _____

SPONSOR: _____

Funding Sources *(check all that apply)*: ☐ Industry Sponsor ☐ Foundation ☐ Government/NIH ☐ Internal Funds

Type of Study: ☐ Drug/Biologic ☐ Device ☐ Tissue/Sample Repository ☐ Genetics ☐ Vaccine
☐ Questionnaire ☐ Chart Review/Database ☐ Other: _____

WHAT CONCERNS PROMPTED THE REQUEST FOR AN AUDIT?

☐ Reviewing IRB has reason to suspect serious or continuing noncompliance based on information received in a submission or upon report of an investigator or other member of the study team.

☐ Report of concerns from a third party (e.g., participant or sponsor complaints, institutional official request, or government agencies (e.g., FDA, NIH, OHRP).

☐ Reason to need verification that the Research is being conducted in accordance with the IRB-approved protocol [including known/suspected issues with study conduct, data integrity, etc].

Comments and additional information:

DOCUMENTS AND INFORMATION THAT THE REVIEWING IRB REQUESTS TO BE REVIEWED IN ORDER TO MAKE A DECISION REGARDING NON-COMPLIANCE?

☐ Current Protocol in use by site

☐ Current Consent Documents in use by site

☐ Investigator/Study Team Training Documentation

☐ Source Documentation *(Specify)*: _____

☐ Other (e.g., Relying Institutions Policies, Study Manuals, Investigator Brochures, Notes to file, Adverse Event and Deviation logs, etc.) *(Specify)*: _____

☐ Additional information *(Specify)*:

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Time frame in which the audit should be conducted and communicated back to the Reviewing IRB.

How will information and documents, including relevant policies if necessary, be communicated between the Reviewing IRB and the Relying Institution (e.g., Reviewing IRB's electronic system, summary report of submissions, pdf/zip file of relevant documents)*?

Will the Reviewing IRB or the Relying Institution perform the audit? If a shared responsibility, specify what aspects will be audited by the Reviewing IRB and what aspects will be audited by the Relying Institution.

** Secure file transfer requirements, if any, should be followed as per IRB-approved protocol and Reviewing IRB and Relying institutional policies.*

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APPENDIX B

SAMPLE AUDIT CHECKLIST

FOR USE BY AUDITING QA/QI TEAM

A. REGULATORY DOCUMENTATION

1. Is the approved protocol on file? (Original and all previously approved versions?)	☐ Yes	☐ No	
1.1 Is the IRB Approval Letter(s) on file?	☐ Yes	☐ No	
1.2 Is this an FDA regulated study? (If no, go to 1.3)	☐ Yes	☐ No	☐ N/A
1.2.1 Is there a signed FDA 1572 on file?	☐ Yes	☐ No	
1.2.2 Are all versions of the Investigator Brochure or package insert on file?	☐ Yes	☐ No	
1.2.3 Are all versions of the package insert or device manual on file?	☐ Yes	☐ No	
1.2.4 Is all correspondence to and from the FDA on file?	☐ Yes	☐ No	
1.3 CVs of PI/Co-PI and all study staff on file?	☐ Yes	☐ No	☐ N/A
1.3.1 For all CVs on file, are they current in alignment with applicable requirements?	☐ Yes	☐ No	
1.3.2 For all CVs on file, are they signed and dated, if required?	☐ Yes	☐ No	
1.3.3 Is there a staff training log?	☐ Yes	☐ No	
1.3.4 Is the staff training log complete and up-to-date?	☐ Yes	☐ No	
1.4 Is there a subject enrollment log?	☐ Yes	☐ No	
1.4.1 Is the subject enrollment log complete?	☐ Yes	☐ No	
1.5 Is/will the site (be) monitored?	☐ Yes	☐ No	
1.5.1 Who is the monitoring body? _____			
1.5.2 How often? _____			
1.5.3 Is there a monitoring log?	☐ Yes	☐ No	
1.5.4 If yes, is the monitoring log complete?	☐ Yes	☐ No	
1.6 Is there a staff signature and delegation of responsibilities log?	☐ Yes	☐ No	☐ N/A
1.6.1 Is the staff signature and delegation log complete and up-to-date?	☐ Yes	☐ No	
1.7 Is all correspondence to and from the sponsor on file?	☐ Yes	☐ No	☐ N/A
1.8 Are lab tests required?	☐ Yes	☐ No	☐ N/A
1.8.1 If yes, is a copy of normal lab values on file?	☐ Yes	☐ No	
1.8.2 Is a copy of the lab certification on file?	☐ Yes	☐ No	

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REGULATORY DOCUMENTS COMMENTS/ISSUES:

B. SUBJECT RECRUITMENT PROCEDURES

2. How are participants identified for the study?_____

2.0.1 Are there recruitment materials for this study? ☐ Yes ☐ No

2.0.2 Are all recruitment materials IRB approved? ☐ Yes ☐ No

2.0.3 Are all currently approved recruitment materials on file? ☐ Yes ☐ No

SUBJECT RECRUITMENT PROCEDURES COMMENTS/ISSUES:

C. INFORMED CONSENT PROCESS

☐ Section not applicable (consent waived)

3. Is written consent required to be obtained by the IRB approved protocol? ☐ Yes ☐ No

3.1 If yes, how many versions of the consent form are there? _____

DATE APPROVED	EXPIRATION DATE	MASTER COPY OF APPROVED CONSENT FORM ON FILE? (Y/N)

3.2 Have any eligible subjects been enrolled in this study? ☐ Yes ☐ No

(If no, skip the remaining questions in this section and D. SUBJECT SELECTION)

For the consent forms and documentation reviewed, complete the following questions:

3.3 How many subjects are/were enrolled to date? _____

3.4 How many subjects is/was the site approved to enroll? _____

3.5 How many subjects were chosen for review? _____

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3.6 Did each subject or their LAR sign his/her own consent form? ☐ Yes ☐ No

3.7 Did each subject date his/her own consent form? ☐ Yes ☐ No

3.8 Was the current approved consent document used for each subject? ☐ Yes ☐ No

3.9 Are any participants minors? *(If yes, answer the following; if no, go to 3.10)* ☐ Yes ☐ No

3.9.1 Is there evidence of assent? ☐ Yes ☐ No

3.9.2 Did the parent(s) or guardian sign and date properly? ☐ Yes ☐ No

3.10 Did the study staff sign the consent? ☐ Yes ☐ No

3.11 Did the signing study staff date the signed consent? ☐ Yes ☐ No

3.12 Did anyone not approved by the IRB to consent subjects sign as study representative? ☐ Yes ☐ No

3.12.1 If yes, who?_____

3.13 Does the signature date prior to all approved research procedures? ☐ Yes ☐ No

3.14 Did each subject receive a copy of the signed and dated consent form? ☐ Yes ☐ No

3.15 Is subject's receipt of a copy of the signed consent form documented? ☐ Yes ☐ No

3.16 If consent was revised were subject re-consented or notified as required by the IRB? ☐ Yes ☐ No

INFORMED CONSENT PROCESS COMMENTS/ISSUES:

D. SUBJECT SELECTION

☐ Section not applicable (no subjects enrolled)

4. Is there documentation of subject eligibility (note format used)? ☐ Yes ☐ No

4.1 Did all subjects meet eligibility criteria? ☐ Yes ☐ No

4.2 If no, were they excluded appropriately? ☐ Yes ☐ No

4.2.1 If no, was a protocol deviation submitted to the IRB? ☐ Yes ☐ No

SUBJECT SELECTION COMMENTS/ISSUES:

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E. IRB REPORTING AND OVERSIGHT

5. Were study procedures conducted following initial IRB approval? ☐ Yes ☐ No

5.1 Were changes to study procedures only implemented after IRB approval was received? ☐ Yes ☐ No

5.2 Were study procedures conducted during a period of expiration or suspension? ☐ Yes ☐ No

IRB REPORTING AND OVERSIGHT COMMENTS/ISSUES:

F. STUDY CONDUCT

6. Were study assessments/evaluations performed according to protocol? ☐ Yes ☐ No

6.1 Were study tests/procedures completed at the time intervals described in the protocol? ☐ Yes ☐ No

STUDY CONDUCT COMMENTS/ISSUES:

G. ADVERSE EVENTS

7. Were adverse events monitored and recorded as described in protocol and Reviewing IRB's policies and assessed by appropriately qualified and delegated individuals? ☐ Yes ☐ No

ADVERSE EVENTS COMMENTS/ISSUES:

H. DATA MANAGEMENT & SECURITY

8. Is source documentation and data collection accurate, complete and appropriately transcribed? ☐ Yes ☐ No

8.1 Is the data store and transmitted (if applicable) securely? ☐ Yes ☐ No ☐ N/A

8.2 Does documentation support that the DSMP is being followed and that safety/data reviews are occurring according to the approved schedule? ☐ Yes ☐ No

DATA MANAGEMENT & SECURITY COMMENTS/ISSUES:

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

SUMMARY OF COMMENTS AND ADDITIONAL ISSUES:

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

APPENDIX C

SAMPLE AUDIT REPORT TEMPLATE[1]

PROTOCOL TITLE: _____

PRINCIPAL INVESTIGATOR: _____
Name

_____
Department, School

FUNDING SOURCE: _____

DATE OF REVIEW: _____

AUDITORS: _____

_____

_____

DATE OF REPORT: _____

DISTRIBUTION: _____
PI Name

1. Howes, L. M., White, S. A., & Bierer, B. E. (2019). Quality Assurance and Quality Improvement Handbook for Human Research (1st ed.). Johns Hopkins University Press.

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

I. INTRODUCTION: *(include brief introduction; suggested details to include: purpose of site review, who was present, etc.)*

II. STUDY SUMMARY: *(include brief summary of the study being audited)*

III. SCOPE OF REVIEW: *(include all material reviewed including regulatory documentation, consent forms, subject files, etc.)*

THE FOLLOWING DOCUMENTS WERE REVIEWED DURING THE AUDIT:

☐ Enrollment log

☐ Delegation of responsibility

☐ Staff qualifications (CV, medical/clinical licensure)

☐ Laboratory certification and normal value ranges

☐ Sponsor correspondence

☐ IRB documentation (all significant correspondence submitted to or received from the IRB, including submissions, investigator responses, notification letters, and approved consent forms)

☐ Documentation of data and safety monitoring, including log of monitoring activities, meeting agendas, minutes and reports of the data monitoring committee

☐ Participant files for the following subjects: _____

☐ Consent forms ☐ Eligibility ☐ Protocol Compliance ☐ Adverse Events

☐ Events requiring IRB reporting ☐ Other: _____

☐ Other:

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IV. REGULATORY REVIEW HISTORY:

OVERALL FINDINGS: *(include summary of observations in bulleted format with sufficient detail and outline any specific findings below)*

SPECIFIC AUDIT FINDINGS:

Regulatory Documentation:

Corrective Action: _____

Best Practice Recommendation: _____

Informed Consent:

Corrective Action: _____

Best Practice Recommendation: _____

Participant Files:

Corrective Action: _____

Best Practice Recommendation: _____

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V. CONCLUSIONS: *(summarize the site review and provide contact for questions; if response from site is required, identify timeline for response)*

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CONTRIBUTING AUTHORS

Barbara Bierer, MD
Director, Regulatory Foundations, Ethics, and Law Program Harvard Catalyst
Harvard Medical School

Jackie Do, MPH
Regulatory Affairs Operations Officer
Harvard Medical School

Kathy Lawry, MSSA, CIP, CIM
Senior Consultant
Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Neala Lane, MS, CCRC
Associate Director, Quality Improvement Office
Indiana University

Jason Malone, MPA, CIP
Assistant Director, Regulatory Affairs
University of Washington

Megan Kasimatis Singleton, JD, MBE, CIP
Assistant Dean/Director, Human Research Protections Program
Johns Hopkins University School of Medicine

Sarah White, MPH
Executive Director
Multi-Regional Clinical Trials (MRCT) Center

Jessica Williams, MA, MS, CIP
IRB Reliance Manager
University of Kentucky

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SMART IRB HARMONIZATION STEERING COMMITTEE LEADERSHIP

Barbara E. Bierer, MD
Director of Regulatory Policy, SMART IRB
Co-chair, SMART IRB Harmonization Steering Committee

Valery Gordon, PhD, MPH
Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health
Co-chair, SMART IRB Harmonization Steering Committee

Aaron Kirby, MSc
Director, Regulatory Affairs Operations, Harvard Catalyst
Deputy Director of Regulatory Operations, SMART IRB

Polly Goodman, CIP
Associate Director of Regulatory Affairs Operations, SMART IRB

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