

Off-Site Review:	
IRB minutes (3 sets of approved minutes for each committee)	<ul style="list-style-type: none"> • Compare to requirements at 21 CFR §56.115(a)(2) and 45 CFR §46.115(a)(2) • Look for clarifications relevant to the regulatory criteria for approval without subsequent review by the convened IRB. • Look for handling of unanticipated problems involving risk to subjects or others. • Look for handling of serious or continuing non-compliance.
IRB rosters for each committee used to comply with 21 CFR 56.115(a)(5) and 45 CFR 46.103(b)(3).	<ul style="list-style-type: none"> • Compare to 21 CFR 56.115(a)(5) and 45 CFR 46.103(b)(3).
Review tool(s) used by the IRB to determine whether a protocol meets the regulatory criteria for approval. <ul style="list-style-type: none"> • Initial review • Continuing review • Review of modifications to previously approved research 	<ul style="list-style-type: none"> • Compare to 21 CFR §56.111 and 45 CFR §46.111.
Application forms or instructions for investigators to apply for: <ul style="list-style-type: none"> • Initial review • Continuing review • Review of modifications to previously approved research 	<ul style="list-style-type: none"> • Compare to 21 CFR §56.111 and 45 CFR §46.111.
List of currently approved protocols with: <ul style="list-style-type: none"> • Name • Investigator • Type of initial review (exempt, expedited, or convened IRB) 	<ul style="list-style-type: none"> • Reference only
Policies and procedures to identify and manage conflicts of interests of investigators and research staff.	<ul style="list-style-type: none"> • Compare to 42 CFR 50 process.
Financial interest disclosure forms used to identify conflicts of interests of investigators and research staff.	<ul style="list-style-type: none"> • Compare to 42 CFR 50 and 21 CFR 54 disclosure requirements

<p>Off-Site Review:</p>	
<p>Written procedures followed by the IRB for: (Required by 21 CFR §56.108 and 45 CFR §46.103(b)(4)-(5))</p> <ul style="list-style-type: none"> • Conducting initial and continuing review of research • Reporting findings and actions to the investigator and the institution • Determining which projects require review more often than annually. • Determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review. • Ensuring prompt reporting to the IRB of changes in research activity. • Ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects. • Ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration/OHRP of any unanticipated problems involving risks to human subjects or others. • Ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug Administration/OHRP of any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB. • Ensuring prompt reporting to the IRB, appropriate institutional officials, and the Food and Drug 	<ul style="list-style-type: none"> • Look for complete policy

<p>Administration/OHRP of any suspension or termination of IRB approval.</p>	
<p>List of documents provided to all IRB members (i.e., members who are not primary or secondary reviewers) for:</p> <ul style="list-style-type: none"> • Initial review • Continuing review • Review of modifications to previously approved research. 	<ul style="list-style-type: none"> • Compare to 21 CFR §56.111 and 45 CFR §46.111.
<p>List of documents provided to all primary or secondary reviewers (if used) for:</p> <ul style="list-style-type: none"> • Initial review • Continuing review • Review of modifications to previously approved research. 	<ul style="list-style-type: none"> • Compare to 21 CFR §56.111 and 45 CFR §46.111.

On-Site Review: IRB Records <i>(Note: We are willing to review these documents at the IRB office)</i>	
Clinical trials (3)	<ul style="list-style-type: none"> • Compare to 21 CFR §56.115 and 45 CFR §46.115
Protocols that are not clinical trials but were reviewed by the convened IRB (3)	
Protocols that were reviewed by the expedited procedure (3)	
Exempt protocols (3)	
Contracts for clinical trials (3)	<ul style="list-style-type: none"> • Look for statement about ICH-GCP compliance.
On-Site Review: Interviews	
IRB staff (All staff other than the manager - 40 minutes)	<ul style="list-style-type: none"> • Knowledge of regulatory criteria for approval • Knowledge of requirement issues noted in off-site records review
Non-scientific IRB members (3 members - 40 minutes)	
Scientific IRB members (3 members - 40 minutes)	
Investigators (3 – 15 minutes each)	<ul style="list-style-type: none"> • Knowledge of requirement issues noted in off-site records review
IRB chairs (40 minutes)	<ul style="list-style-type: none"> • Knowledge of regulatory criteria for approval • Knowledge of requirement issues noted in off-site records review
IRB manager (40 minutes)	
Legal counsel to the organization for research issue (20 minutes)	<ul style="list-style-type: none"> • Knowledge of definition of LAR, child, guardian.
Individuals responsible for grants and sponsor contracts (20 minutes)	<ul style="list-style-type: none"> • Knowledge of requirement issues noted in off-site records review
Chair of committee that evaluates financial conflicts of interests of clinical investigators (20 minutes)	<ul style="list-style-type: none"> • Compare to 42 CFR 50 process.
Institutional official (20 minutes)	<ul style="list-style-type: none"> • Knowledge of requirement issues noted in off-site records review