

CHW Human Research Protections Office (HRPO)
2009 HRPO Program / Research Site Audit

HRPO Manual Reference	Audit Standard	Findings	Comments	Corrective Actions	Due Date	Responsible Party
Audit Date:						
Facility:						
AE:						
IRB For Site:						
Open Studies:						
Identified Accountable Executive						
2.2	Is AE a senior level executive?					
2.2	Is AE clinically trained?					
2.2	Does AE attend each IRB meeting as a nonvoting member or RRC chair?					
2.6.7	Has the AE completed (and documented) completion of the CITI or equivalent training within the last 3 years?					
2.6.8	Does the AE have a copy of the HRPO Manual?					
	How long (Years / Months) has AE been in this role?					
Administrative Review Process and Documentation (Pre-IRB Review)						
2.3.1	Is there a documented Mission Review?					
2.3.2	Is there a documented financial review including:					
2.3.2a	- Identification of research related services?					
2.3.2b	- Identification of all costs to participate?					
2.3.2c	- Has a study budget been created and submitted when costs have been identified?					
2.3.2c(i)	- Are all identified costs included in the sponsorship agreement when applicable?					
2.3.2c(ii)	- Is there a review with CHW Legal and others (e.g. CFO) when all identified costs will not be reimbursed by the sponsor?					
	- Has a billing compliance review been completed?					
2.3.3	Has a billing compliance review been completed and documented?					
2.3.4	Has a Risk Management Review been documented including:					
2.6.6	- Determination the study does not pose an unreasonable risk to the hospital					
5.10	- Documentation that all non-CHW employed physician investigators have obtained professional liability insurance that covers all research activity.					
2.3.5	Has a conflict of interest review been documented including:					
2.6.5	- Completed COI disclosure forms for all investigators and members of the research team?					
2.3.6	Has a HIPAA compliance review been completed and documented including:					
5.8	- Using the appropriate research authorization template?					
	- Using the appropriate waiver of authorization template?					
	- Using the appropriate preparatory to research template?					
2.3.7	Has CHW legal reviewed and approved the following:					
2.6.1	- Sponsorship Agreement signed by sponsor, investigator and CHW?					
	- Other contracts/agreements related to the research?					
5.2	Does this site allow concurrent AE and IRB review? If "yes" how does the AE inform the IRB the study is approved to be placed on the IRB agenda?					
2.4	Has the AE communicated to the IRB in writing (email, copy of AE worksheet, etc) that project has been approved?					
2.4.1	Has the AE communicated to the IRB in writing (email, copy of AE worksheet, etc) that project has <u>not</u> been approved?					
Accountable Executive - Post IRB Approval Responsibilities						
2.5.1	Following IRB approval, is there a process for communicating with PFS when there are research related charges that should not be billed to insurance?					
2.5.2	Following IRB approval, is the person responsible for the CDM notified when there are research related charges that should not be billed to insurance?					

2.6.4	Are copies being maintained of all correspondence between the hospital, IRB, investigators and any governmental agency?					
2.7	Are all records and documentation mentioned above (pre and post IRB) being kept for 7 years after study closure, disapproval, discontinuation or termination of the research project?					
Institutional Review Board Requirements						
3.2	Has all research to be conducted been approved by the IRB of record for this Hospital prior to initiating such research activities or enrolling subjects?					
3.3.1	Is your IRB a committee of the Hospital Medical Staff or an administrative committee appointed in accordance with Hospital policies and procedures?					
3.3.2	Has this site adopted the HRPO Manual IRB Sample Policies and Procedures without modification? If "No" has this site adopted modified policies in a manner that is not inconsistent with the HRPO Manual and all other CHW policies that govern research?					
3.3.3	Have all outsourced IRB's for this site been reviewed and approved by HRPO and CHW Legal?					
3.5	Does this IRB meet the membership requirements?					
2.6.7	Has each IRB member completed and documented (CITI program or equivalent) human subjects protections training within the last 3 years?					
3.8	Has each investigator and research team member completed and documented (CITI program or equivalent) human subjects protections training within the last 3 years?					
5.9	Has each investigator and research team member completed and documented (CITI program or equivalent) human subjects protections training within the last 3 years?					
3.8	Was this training documented prior to participating as a voting member?					
3.11	Is a quorum documented prior to the beginning of each meeting? Is a quorum documented throughout the meeting?					
3.11.1	Are IRB members with a conflict asked to leave the room before final discussion and vote?					
3.12.2	Does the IRB notify the PI in writing of the IRB's decision to approve or disapprove the proposed research?					
3.15.2	Are the IRB minutes prepared with sufficient detail as described in this manual?					
3.15.5	Is a complete list of IRB members, qualifications and education maintained by this facility?					
5.1.1	Does the IRB receive a complete study application before place a new study on the agenda for review including: - IRB application - Entire (and written) study protocol - Protocol summary - Investigator brochure (when applicable) - Proposed consent form – or completed waiver of consent request - Proposed HIPAA authorization – or completed waiver of authorization request - Conflict of interest disclosures from all investigators and research team members. - Pertinent FDA documents, e.g. IDE/IND/HDE determinations and 1572's as applicable. - Subject recruitment materials - Investigator and research team member education documentation.					
5.6.2	Have potential financial conflicts of interest been disclosed in the subject consent form?					
5.6.2	Does each subject consent include the "Experimental Subjects Bill of Rights"?					
5.7	How does this IRB ensure that all elements of informed consent are present in the subject consent document being reviewed for approval?					
3.16	Are IRB records retained for at least 7 years after closure, disapproval, discontinuation, or termination of research project?					
Recent FDA and/or OHRP audit of IRB						
	Has the IRB covering this facility been audited by the FDA and/or OHRP in the last two years? If "Yes" please obtain documentation of the following: - Date of Audit - 482/483 (FDA Notice of Inspection / Notice of Findings) - Other inspection documents - Documentation that all corrective actions have been completed.					
Research Review Committee (RRC) at Hospitals using outsourced (WIRB) or CHW Regional IRB's						

4.1.1	Does the RRC at this facility meet the composition requirements as set forth in the HRPO Manual? Does the RRC approve all proposed research prior to the research being submitted to the IRB?					
IRB File Review Comments						
Accountable Executive Review Comments						
Other Notes / Comments						