

	Human Subjects Institutional Official *	Program Executive Committee	Director, CHR ^A	IRB Co-Chairs *^	IRB Committee	Regulations Specialist	CHR Staff	Investigator
A. IRB Review								
Reviews the scientific and scholarly merits of a proposed research study				o	x			
Has the authority to approve, require modification, or disapprove all research activities, including proposed changes in previously approved human subjects research				o	x			
Conducts continuing review of approved research at intervals appropriate to the degree of risk, but not less than once/year				o	x			
Has the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects		o		o	x			
Ensures continuing review is substantive and meaningful				o	x			
Ensures risks to subjects are minimized; risks are reasonable in relation to anticipated benefit; selection of subjects is equitable; informed consent is sought from each subject; informed consent is appropriately documented				o	x			x
Ensures data collection is monitored to ensure subject safety; privacy and confidentiality of subjects is protected; additional safeguards are included for vulnerable populations				x	x	o		x
Designates protocols for expedited review (minimal risk)			o	x	x			
Presents primary reviewer's findings on behalf of reviewer if reviewer is unable to attend full IRB meeting				x				
Reviews adverse or unexpected event reports; sends response to the investigator; and proposes those events that need to go to OHRP.		o		x				
Designates IRB members as expedited reviewers			o	x				
Conducts research according to the IRB approved protocol					o			x
Submits changes to research plans for previously IRB approved protocol					o			x
Reviews Exempt studies			x					
Provides the IRB with appropriate resources and staff	x	o						
B. Meetings								
Identifies appropriate members to serve on IRB		x						
Identifies appropriate co-chairs for IRB	o	x						
Identifies/addresses issues of IRB members not meeting performance standards	o	x						
Serves on the Executive Committee	x		x	x				
Coordinates semi-monthly IRB meetings			o					x
Facilitate semi-monthly IRB meetings				x				o
Coordinate and Chair Executive Committee meetings	x	o						
Appoint subcommittee to act on behalf of IRB when immediate action is required		o		x				
Ensures a majority of the IRB members are present, including at least one non-scientist			o	o				x
Ensures the IRB meeting minutes include: attendance at the meeting; actions taken by the IRB; the vote on these actions, including the number voting for, against, and abstaining; the basis for requiring changes in or disapproving research; documents specific findings required by regulations; and provides a written summary of the discussion of controversial issues and their resolution						o		x
C. Recordkeeping & Reporting								

* responsibilities separate from those covered under Executive Committee

^ responsibilities separate from those covered under CHR Committee

o = oversight responsibility

x = direct responsibility

	Human Subjects Program Institutional Official *	Executive Committee	Director, CHR ^A	IRB Co-Chairs ^A	IRB Committee	Regulations Specialist	CHR Staff	Investigator
Ensures IRB records/correspondence are maintained appropriately and available upon request to authorized Federal officials	o		o	o			x	x
Ensures prompt reporting of proposed changes in a research activity								x
Ensures that changes in approved research, during a period which approval has been granted, are not initiated w/o prior approval			o		x			x
Ensures prompt reporting to IRB and appropriate agencies of any unanticipated injuries or problems involving risks to the research subjects			o	o				x
Reports to OHRP any serious or continuing noncompliance with the regulations and/or requirements of the IRB	x	o						
Reports to OHRP any suspension or termination of IRB approval for research	x	o						
Maintains copies of all research proposals reviewed, scientific evaluations, approved sample consent documents, progress reports submitted by investigators, reports of injuries to subjects, records of continuing review activities, correspondence between IRB and investigators			o				x	x
Maintains file copies of all IRB meeting minutes			o				x	
Maintains all signed consent documents in the manner approved by the institution					o			x
Reports progress to the IRB on an annual basis, at a minimum (Continuing Review)					o			x
D. Policies & Procedures								
Ensures organization has and follows written policies & procedures for the human subjects protection program	o	x						
Establish procedures for receiving and reviewing grievances	o	x						
Resolve grievances		o			x			
Monitor grievances submitted to Executive Committee to determine whether there is a systematic pattern that requires attention		x						
Develop IRB guidelines		x						
Manages CHR office policies & procedures		o	x					
E. Monitoring & Oversight								
Must comply with all applicable provision of their institution's Assurance	o	o	x	x	x	x	x	x
Monitors compliance with federal regulations	o	o	x	x	x	x	x	x
Suspend enrollment in studies; withdraw approval or perform other action deemed necessary to protect the rights and welfare of research participants		o		x	x			
Ensures all cooperating performance sites have appropriate OHRP-approved assurances			x				x	x
Ensure performance sites in research have, and can document, appropriate mechanisms to protect research subjects						x	x	x
Prepare regular and periodic performance reports on CHR for the School's faculty and administration		o					x	
Contact investigators to resolve committee and/or non-compliance issues or complaints		o		x				
Develop and implement a project quality assurance/improvement program	o					x		
Monitors CHR office performance		o	x					

F. Communication

* responsibilities separate from those covered under Executive Committee

^ responsibilities separate from those covered under CHR Committee

o = oversight responsibility

x = direct responsibility

	Human Subjects Program Institutional Official *	Executive Committee	Director, CHR *^	IRB Co-Chairs *^	IRB Committee	Regulations Specialist	CHR Staff	Investigator
Ensures institution-wide communication & guidance on human subjects research	x	o	x					
Designated as OHRP's primary institutional contact	x							
Sets the "tone" for the institution's culture of respect for human subjects	x	o						
Sends adverse event documentation to OHRP	x	o						
Sign Statements of Approval, IRB mintues, Letters of Non-Compliance to Investigators and Termination Notices to Investigators			o	x				
Initiate and/or compose non-routine correspondence to investigators				o			x	
Provides comments on National, State and local policy announcements on the protection of human subjects		x			x			x
Ensures each potential subject understands the nature of the research and of the subject's participation. Takes all necessary steps to gain that comprehension - this includes communication of associated risks, benefits and the option to participate					o			x
Provides copy of IRB-approved informed consent document to each subject at the time of consent					o			x
G. Education/Training								
Ensures personnel reviewing, conducting or supporting human research demonstrate sufficient knowledge of protection of research participants	o						x	x
Ensures investigator/research team has sufficient scientific expertise to conduct proposed human subjects research		o			x			x
Responsible for educating members of the research community in order to establish/maintain a culture of compliance w/ Federal regulations and institutional policies relevant to the protection of human subjects	x				x			x
Provides training and educational opportunities for the IRB and investigators	x							x
Attend national or local human subjects training conferences for the protection of human research subjects	x		x	x	x	x	x	
Possesses knowledge about the requirements of Federal regulations, applicable state law, institution's Assurance, and institutional policies and procedures for the protection of human subjects	x		x	x	x	x	x	x
H. Authority								
Has authority to speak on behalf of institution	x		x					
Serves as knowledgeable point of contact for OHRP	x		x					

* responsibilities separate from those covered under Executive Committee

^ responsibilities separate from those covered under CHR Committee

o = oversight responsibility

x = direct responsibility

Bloomberg School of Public Health

Human Subjects Program

**Institutional
Official ***

**Executive
Committee**

**Director,
CHR *^**

**IRB
Co-Chairs *^**

**IRB
Committee**

**Regulations
Specialist**

**CHR
Staff**

Investigator

* responsibilities separate from those covered under Executive Committee
^ responsibilities separate from those covered under CHR Committee

o = oversight responsibility
x = direct responsibility