

**Houston Department of Health and Human Services
 QUALITY ASSURANCE AND AUDITING BUREAU
 INVESTIGATIVE REVIEW PROCESS FOR PROPOSED RESEARCH**

SECTION I	ROLES / RESPONSIBILITIES
<p style="text-align: center;">IRC</p>	<p>Composition</p> <ul style="list-style-type: none"> A. BC/QA serves as chairperson for the committee B. Chairperson appoints 5 - 8 members to the Investigative Review Committee (IRC) C. BC/QA may change committee members as needed at his/her discretion. D. Committee members will invite subject matter or program expert as indicated. <p>Role / Responsibilities</p> <ul style="list-style-type: none"> A. reviews policies governing Department research activities B. reviews proposed research submissions and arrives at consensus decisions to accept or reject proposal
<p style="text-align: center;">IRC Coordinator</p>	<p>Role / Responsibilities</p> <ul style="list-style-type: none"> A. Ensures that the <i>Pre-Application Request</i> is available on-line and may be completed and submitted electronically B. Requests applicant submit online <i>Pre-Application Request</i> C. Receives and reviews Pre-Application Request and determines feasibility of proposed research for environment. D. Ensures that request is reviewed in the predetermined timeline (14 days for simple, 30 days for complex). E. Upon approval of Pre-Application Request: Instructs applicant to provide hard copies of documents for the Committee meeting (in adequate number for each member to have a set). Documents requested are: Pre-application request, research protocol, all consent forms and attachments, Institutional Review Board (IRB) approval letter (if applicable). F. Places study on agenda for review by the committee. Distributes packets for review prior to the meeting and instructs members to bring packets to meeting. G. Takes minutes of meetings. H. Generates acceptance or denial paperwork to applicants subsequent to meetings. I. Submits a monthly report and an annual summary report of research approved/denied to the Chairperson. J. Retains copies and files of appropriate documents.
SECTION II	STUDY APPLICATION REVIEW PROCESS
	<ul style="list-style-type: none"> A. Applicant completes and submits Pre-Application Request (PAR) online. The Pre-Application Request is used as a screening tool to determine if the research proposed seems feasible for the HDHHS environment. B. IRC Coordinator receives PAR and reviews for feasibility; consults with Chairperson as needed. C. If study is deemed not feasible, IRC Coordinator sends a rejection letter to the applicant and copies any involved HDHHS section/program. D. If study is deemed feasible, IRC Coordinator places on agenda for next Committee meeting and requests the applicant to submit X copies of research protocol, all consent forms and attachments, and IRB approval letter (from Baylor or UT), if applicable. E. IRC Coordinator also schedules applicant or their representative to attend the Committee meeting to address any questions about the proposed study. F. Subject matter expert(s) from the department may be requested to attend as well. G. IRC Coordinator obtains Chairperson's approval of agenda and distributes to Committee members along with packets for each study to be considered. Packets include documents listed in D above.

**Houston Department of Health and Human Services
 QUALITY ASSURANCE AND AUDITING BUREAU
 INVESTIGATIVE REVIEW PROCESS FOR PROPOSED RESEARCH**

	<p>Committee members are asked to review packets and bring to meeting along with any questions.</p> <p>H. IRC Coordinator takes minutes of meetings.</p>
SECTION III	POST REVIEW ACTIVITIES
IRC	<p>A. IRC Coordinator finalizes meeting minutes and obtains signature approval of Chairperson.</p> <p>B. IRC Coordinator generates approval or rejection letter under Chairperson's signature to applicant. Involved department section/program is copied.</p> <p>C. Approval letters may include conditions which must be met prior to initiation of study. IRC Coordinator is responsible to follow-up on any such requirements.</p> <p>D. Conditions of approval for all studies include:</p> <ol style="list-style-type: none"> 1. Applicant is required to notify IRC when study activities are completed. 2. If study activities cannot be completed in the approved time period, applicant must notify the IRC Coordinator. 3. Applicant is required to submit any and all articles/documents related to study results to the IRC prior to publication. HDHHS reserves oversight of accuracy of study results as they pertain to HDHHS. 4. Once a proposal is approved, the investigator or designee must attend orientation on ethical aspects of conducting research within department. 5. For all proposals which involve access to HDHHS data, the applicant must acknowledge that the data is the property of HDHHS and all publications and documents resulting from it must have HDHHS approval. 6. Raw data may not be copied and removed from HDHHS, although reports from that data may be. 7. Published articles must give appropriate written credit HDHHS.
SECTION IV -	POST REVIEW FUNCTIONS: COMPLIANCE
Chairperson	<p>Compliance: Reviews Functional Protocols:</p> <ol style="list-style-type: none"> A. On an annual basis, reviews status of all active protocols. B. Utilizes committee members as well as other subject matter experts within the Department to assist as needed. <p>Compliance: Reviews and Reports Findings</p> <ol style="list-style-type: none"> A. Ensures that all research activities are in compliance with the following: <ol style="list-style-type: none"> 1. Applicable federal guidelines and statutes. 2. Applicable Department and City of Houston policies and procedures. B. Receives, investigates, and addresses all issues related to compliance. Initiates audits as deemed appropriate. C. Generates and distributes findings to the IRC, the QMC Chairperson or other executive level management staff as deems appropriate. D. Recommends corrective actions up to and including termination of research activities. Has final authority in this regard.
Investigator	<p>Compliance: Response</p> <ol style="list-style-type: none"> A. Responds to any issue related to compliance and resolves as requested by HDHHS. B. Takes action on requests made by HSHHS up to and including termination of research activities.

Houston Department of Health and Human Services
QUALITY ASSURANCE AND AUDITING BUREAU
INVESTIGATIVE REVIEW PROCESS FOR PROPOSED RESEARCH

Legend:

BC/QA – Bureau Chief, Quality Assurance and Auditing
IRC – Investigative Review Committee
IRB – Investigational Review Board
QA – Quality Assurance and Auditing Bureau
QMC – Quality Management Committee

Clarification:

HDHHS Consent Form and Informed Consent Checklist – May also use Consent Form and Informed Consent Checklist generated by applicant, as long as these instruments capture all points of information included in the HDHHS documents.