DEPARTMENT POLICY ONLY COORDINATION SHEET

Subject Matter: Institutional Review Committee (IRC) Policy

Date: 07/10/2025

Division/Bureau/Program:

Contact Person: Deborah Banerjee

Director
Houston Health Department

DocuSigned by: Stephen Williams A8219D332CF4498...
8/11/2025
Stephen Williams, M.Ed., M.P.A.

Chief of Staff/Deputy Director

DocuSigned by: Judy Harris D2683C7695C2433...
8/11/2025
Judy Harris, MBA

Assistant Director- Public Health
Public Health Infrastructure Division
Executive Sponsor/Co-Chair IRC

Signed by: Renita Madu 337B1DCA627041F...
7/21/2025
Renita Madu, Ph.D, PA-C, LSSBB

Bureau Chief
Office of Program Evaluation and Research for Effectiveness
Institutional Review Committee (IRC) Chair

DocuSigned by: Deborah Banerjee 72BE7837BE994D2...
7/21/2025
Deborah Banerjee, Ph.D, MS

STANDARD OPERATING PROCEDURE

HOUSTON HEALTH DEPARTMENT

SOP TITLE:	EFFECTIVE DATE:
INSTITUTIONAL REVIEW COMMITTEE	
POLICY GUIDANCE: INSTITUTIONAL REVIEW COMMITTEE	

1. PURPOSE

The purpose of this policy is to establish the authority of the Houston Health Department's (HHD) Institutional Review Committee (IRC). The IRC policy shall shape, guide, optimize, and protect performance by ensuring that all programs are aware of human subject's research requests that impact their program. This policy is undergirded by The *Belmont Report,* one of the leading works concerning ethics and health care research. It was written by the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, which identifies basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects. These are beneficence, justice and respect.

2. SCOPE

2.1 This policy applies to all HHD employees, and all individuals seeking to collect primary data or use de-identified secondary data belonging to HHD and its programs.

2.2 This policy supersedes all other policies regarding research using data from HHD Programs.

3. ROLES AND RESPONSIBILITIES

FUNCTION OF IRC:

a) ETHICAL PRINCIPLES: Ensure ethical principles are described and followed in all interactions involving human subjects. These are **beneficence, justice and respect**.

b) DATA PROTECTION: Ensure sufficient data protection procedures (confidentiality and security) are described and followed for the project in question.

c) PROGRAM OPERATIONS: Ensure that the proposed project does not disrupt the operations of HHD programs.

d) PROTECT VULNERABLE POPULATIONS: This requirement is based in part on the Belmont Report (see 4.1). Reflecting the principle of respect for persons, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote that "persons with diminished autonomy are entitled to protection. Due to the work that HHD does to serve the Houston areas that are underserved, the IRC will ensure that provisions are described and in place for **vulnerable populations (**Pregnant women, Minors, Incarcerated, People with diminished mental capacity, and People who are educationally or economically disadvantaged**) and sensitive topics (**personal information**) are handled with extra protection.**

The Chairman of the Quality Council (*under which the Investigate Review Committee is nested*) is the Deputy Public Health Authority. The Deputy Director (or designee) determines the membership of the IRC, appointing no more than 7 total number of members. Appointment to the Committee is based on expertise required, familiarity with applicable laws and regulations and knowledge of programs. The IRC has the authority to approve or disapprove all human subjects research projects in consultation with the program manager, program

leadership and Deputy Director (or designee).

3.1 Each IRC application on projects affiliated with a university, educational institution or healthcare facility will require an Institutional Review Board (IRB) approval from the sponsoring institution. The IRC Committee will ensure that a copy of the IRB approval is in place along with the project documentation.

3.2 The IRC is not an IRB. HHD employees and partners seeking to conduct a research project involving data, must obtain prior IRB approval before there is an IRC review. A copy of the IRB approval (if applicable) shall be provided to the Committee.

3.3 In some cases, IRC approval may be granted while the IRB approval is in process. In such cases, the IRC approval is "*contingent*" on receipt of a copy of an IRB approval.

3.4 Each IRC Committee member is responsible for ensuring that the appropriate SME's and stakeholders are consulted (as needed), prior to approval of an application.

3.5 The IRC Committee shall make every effort to approve applications within 30 days.

3.6 In cases where the application is simple and straightforward (no confidential or protected health information is requested), the "IRC Core" may initiate approval and seek approval of the rest of the IRC Committee via email. An added layer of review for TB, STD and TB proposals – these should be reviewed at 2 different points once when it comes in and once data is prepared for release.

3.7 One IRC member will be responsible for managing the IRC Sharepoint site.

3.8 IRC Committee or appropriate designee will copy the program manager, preceptor, bureau chief or assistant director of the applicant via email on approval of their application.

3.9 The IRC Committee will ensure that each student has a preceptor internal to HHD that has full awareness of the project. Data may not be released if certain conditions are not met (see flowchart).

3.10 The IRC Committee will ensure that each non-student applicant has a collaborator/sponsor/mentor/guide internal to HHD that has full awareness of the project and can respond to questions, should they arise.

3.11 The IRC is not responsible for follow-up on the conduct of the project after it has been approved. As such, the IRC will have no knowledge of any misconduct or mishandling of data after the project IRC approval has been granted.

3.12 The Chairman determines the meeting dates, the IRC shall meet on a quarterly basis or as needed.

3.13 Researcher completes a written request that explains the research request with sufficient details for the IRC to consider the request.

3.14 Researcher shall clearly articulate the purpose of the human subject's research, provide the context and purpose and identify all the data sources.

3.15 Researcher conducts the research project upon the approval of the IRC.

3.16 The Researcher submits a progress report to the IRC and requests an extension to the IRC if the approved timeframe needs to be extended.

3.17 Researchers shall forward to the IRC a copy of all final reports and publications and the Houston Health Department shall be appropriately identified and acknowledged in all publications.

3.18 HHD will be invited to participate in the review, write-up and dissemination of any final report or publication.

3.19 Suggestions for student researchers: Formal presentations, one pagers etc.

RESPONSIBILITY OF APPLICANT

a. The IRC applicant (internal or external to HHD) that this policy applies to, is responsible for keeping their program manager, preceptor, bureau chief or assistant director informed of their submission of an IRC application, as appropriate.

b. The applicant will ensure that appropriate consent process is in place and the vulnerable populations are protected.

c. The applicant is responsible for submission of relevant documentation requested by IRC, to avoid delays in approval.

COMPOSITION AND SERVICE DURATION:

The IRC will consist of either 5 or 7 members (not to exceed 7), of which 3 members will be the "IRC Core" that will include the chair of the committee, the privacy officer and the data privacy and confidentiality member.

a. The IRC will meet virtually, monthly, approximately mid-month. The meetings dates will be pre-set in the calendars.

b. An emergency meeting may be called if deemed necessary, in between the regularly scheduled meetings.

c. The IRC membership appointments will be reviewed every 3 years and may/may not be cycled out to allow new members to join.

d. The new IRC appointments will be made through recommendations sent to the Deputy Director (or designee).

e. Please note that the following criterion and roles are recommended in appointing new IRC members:

1) At least one member that is familiar with research protocol development and IRB/IRC processes or designee
2) At least one member that closely works with populations that are termed "vulnerable" or designee
3) HHD Privacy Officer or designee
4) HHD Legal Officer or designee
5) HHD Local Health Authority or designee
6) At least one member to conduct QA for best practices for data confidentiality and storage or designee
7) Data Science designee
8) One member that manages all documentation.

*Note that members 1-7 are voting members.

4. PROCEDURES

4.1 IRC Data Dissemination Workflow

4.1.1. **External Request (from individual external to HHD)** – Sec. 9.1

4.1.2. Locate POC in program with data that is proposed to be used.

4.1.3. Provide details and names of variables to be used in your analysis with your request.

4.1.4. If IRC request is regarding HIV/STI or TB data, additional review or clarification by IRC Committee may be requested.

4.1.5. Checklist of review criteria by IRC Committee prior to approval letter:

4.1.5.1.1. Complete package received

4.1.5.1.2. Data safety and security is ensured

4.1.5.1.3. Data sharing permissions are in place

4.1.6. IRB approval included or contingency

4.1.7. Minimal disruption to program

4.1.8. CITI training completed and certificate is included with application

4.1.9. Data sharing agreement with program.

4.1.10. Work with POC to receive access to data.

4.1.11. Identify at least one HHD staff that will be included in your authorship or acknowledgement statement (preferably from the program, depending on level of contribution) and submit to IRC.

4.1.12. Follow Data Dissemination policy guidelines (policy is undergoing final review), prior to dissemination of the analysis and reports.

4.1.13. Submit final product(s) to IRC/Data Dissemination Committee

4.2 Internal Request (from HHD staff) – Sec. 9.2

4.2.1. Locate POC/Program Manager in program with data that is proposed to be used.

4.2.2. Provide details and names of variables to be used in your analysis with your request.

4.2.3. If IRC request is regarding HIV/STI or TB data, additional review or clarification by IRC Committee may be requested.

4.2.4. Checklist of review criteria by IRC Committee prior to approval letter:

- 4.2.4.1. Complete package received
- 4.2.4.2. Data safety and security is ensured
- 4.2.4.3. Data sharing permissions are in place
- 4.2.4.4. IRB approval included or contingency
- 4.2.4.5. Minimal disruption to program
- 4.2.4.6. CITI training completed and certificate is included with application

4.2.5. Acknowledge, sign and submit document with statements below:

- 4.2.5.1. Create written statement with POC of kinds of dissemination products planned and submit to IRC.
- 4.2.5.2. Create proposed authorship/acknowledgement statement and submit to IRC.
- 4.2.5.3. Submit final products to IRC/Data Dissemination Committee
- 4.2.5.4. Submit acknowledgement from POC/Program Manager agreeing to data sharing (#2)

4.2.6. Work with POC/Program Manager to receive access to data.

4.2.7. Follow Data Dissemination policy guidelines (policy is undergoing final review), prior to dissemination of the analysis and reports.

4.3 External Request (from organization external to HHD staff) – Sec 9.3

4.3.1. Locate POC in program with data that is proposed to be used.

- 4.3.1.1. Provide details and names of variables to be used in your analysis with your request.
- 4.3.1.2. If IRC request is regarding HIV/STI or TB data, additional review or clarification by IRC Committee may be requested.
- 4.3.1.3. Review by IRC Committee prior to approval letter
- 4.3.1.4. Work with POC to receive access to data.
- 4.3.1.5. Identify at least one HHD staff that will be included in your authorship or acknowledgement
- 4.3.1.6. Statement (preferably from the program, depending on level of contribution) and submit to IRC.

5. DEFINITIONS

5.1 Employee means an individuals engaged in the performance of duties for or on behalf of the City whether hired, appointed, elected, full or part time, temporary, volunteers, contractors or grant funded. This category includes temporary employees working for temporary agencies, City Hall fellows, Urban Fellows and interns.

5.2 Human Subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private health information.

5.3 Interaction means any type of communication

5.4 Intervention means physical procedure by which data is gathered and manipulation of the subject or the subject's environment that are performed for research purposes.

5.5 Institutional Review Board (IRB) means a group of individuals formally assigned in accordance with federal regulations to review and monitor research involving human subjects.

5.6 Human Subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private health information.

6. TRAINING

6.1 All researchers and research staff involved in the conduct of human subjects research must complete CITI Human Subjects Research training every 3 years at CITI Training link - UT Health Houston Researchers Training. *See Attachment 9.4.* The CITI Training provides information on principles used to interact with human subjects (beneficence, justice and respect). A certificate is received after completion of the CITI training, which needs to be attached to the IRC request. CITI Training link - UT Health Houston Researchers Training

7. QUALITY ASSURANCE/COMPLIANCE

7.1 Activities contained in this policy are subject to HHD Quality Assurance review and auditing. The Quality Council may request a periodic report on the IRC reviews.

7.2 The Health Insurance Portability and Accountability Act (HIPAA) carries an associated Privacy Rule that can significantly affect the way research can be obtained and used. Only the minimum amount of information needed for any specific purpose can be disclosed.

7.3 Federal Wide Assurance (FWA) is an assurance of compliance with federal regulations for the protection of human subjects. All human subjects research must be guided by a statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.

8 REFERENCES

8.1 Protection of Human Subjects: FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS | HHS.gov

8.2 Vulnerable populations: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7122263/

8.3 What are IRBs: https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/lesson-3-what-are-irbs/index.html

9 Attachments

9.1 IQUE - HHD IRC Flowchart indiv external.pdf - All Documents

9.2 IQUE - HHD IRC Flowchart Indiv Internal.pdf - All Documents

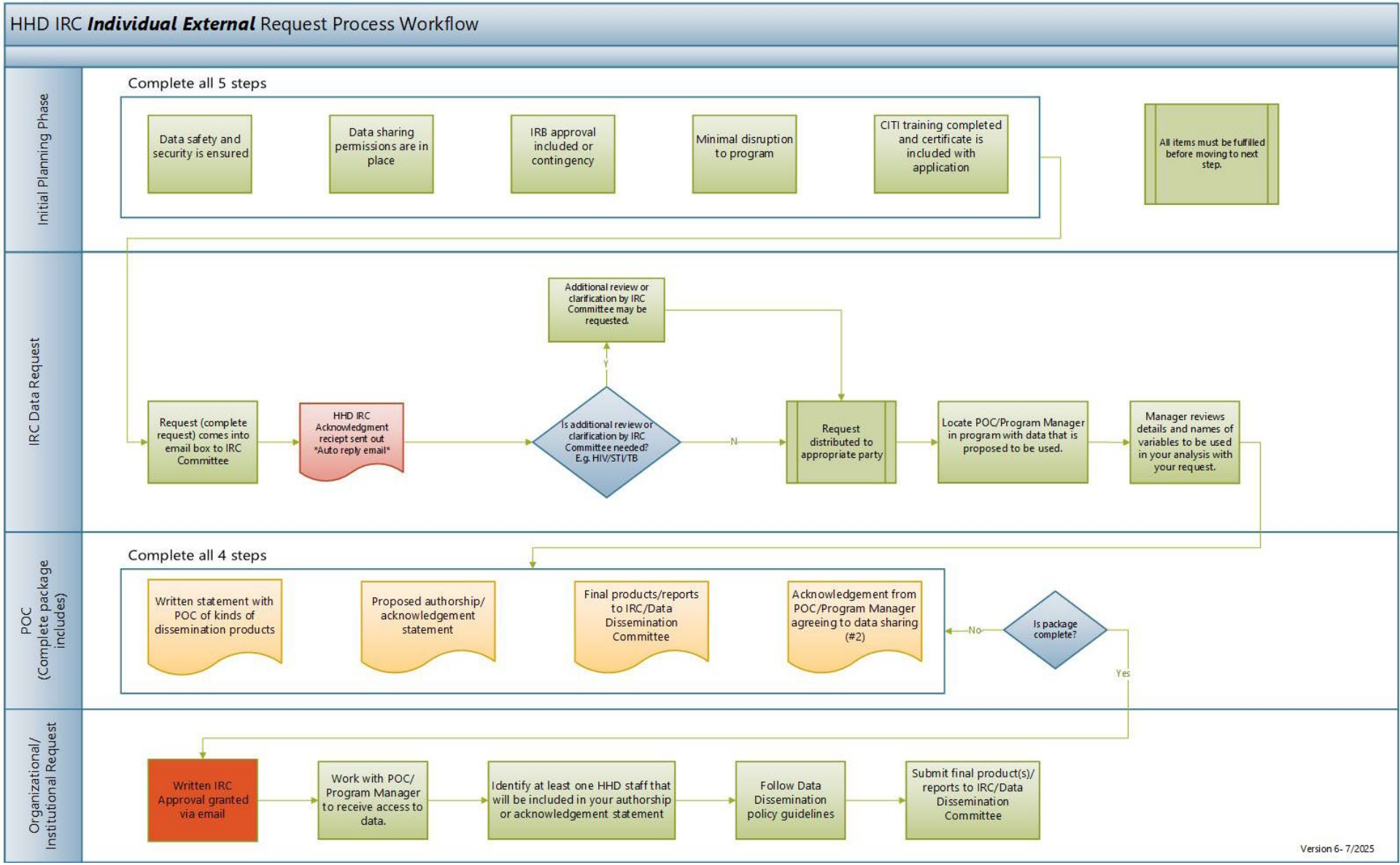
9.3 IQUE - HHD IRC Flowchart Org external.pdf - All Documents

9.4 UT Health Houston Researchers Training (CITI Training)

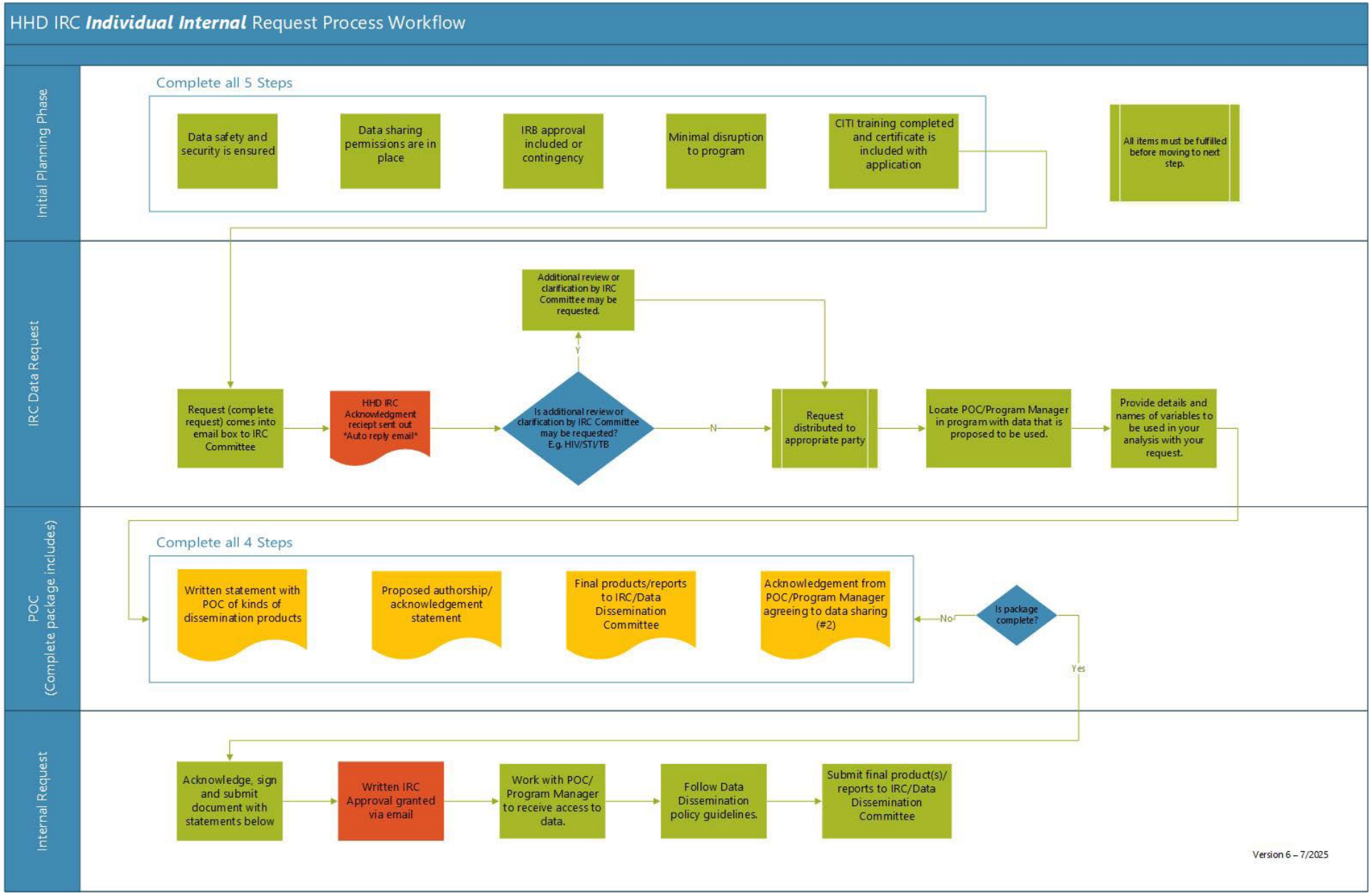
9.5 IRC Workflow Checklist

9.6 Authorship and Dissemination Form (External Workflow)

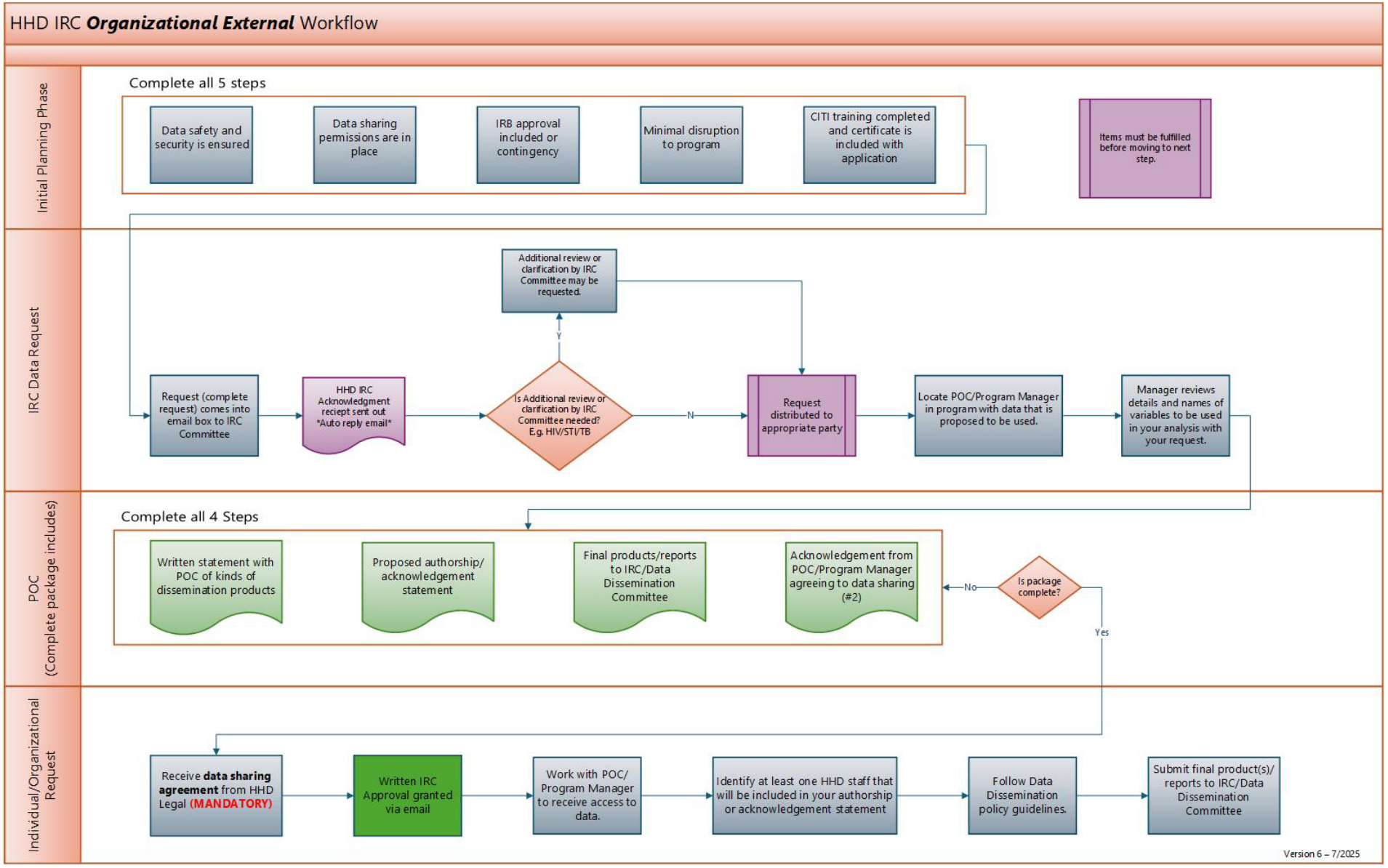
Attachment 9.1 - Refer to Sec. 4.1



Attachment 9.2 - Refer to Sec. 4.2



Attachment 9.3 - Refer to Sec. 4.3



Attachment 9.4 - Refer to Sec. 6.1

CITI Program - Collaborative Institutional Training Initiative (HHD is a collaborative institution of University of Texas Health Science Center at Houston.)

All researchers and research staff involved in the conduct of human subjects research must complete CITI Human Subjects Research training every 3 years.

Log on to CITI www.citiprogram.org and click Register

Step 1 – Select Your Organizational Affiliation. Type University of Texas Health Science Center at Houston. Check both boxes to agree to terms of services and affirm that you are affiliated with UTHealth.

Step 2: Enter your name and email address. Please enter your UTHealth email if you have one, as the **Primary Email.**

Step 3: Create your username and password

Step 4: Enter your country of residence. Type USA - and choose United States from dropdown.

Step 5 - CME/CEU Credits: There is a charge for CEU credits. Select whether you would like to receive CEU credit or not and enter professional affiliation if credit is desired.

Step 6 - Member Information. Apologies in advance for this new screen which will ask for redundant information. You only need to complete required (*) fields. You do NOT need to enter an employee number.

Step 7 - Select Curriculum: This page all lists the courses available on the UTHealth subscription. Humans Subjects Research (HSR) is required for all researchers and research staff conducting human subjects research. Good Clinical Practice (GCP) required for all researchers and research staff conducting clinical trials. All other courses are optional. You can add or remove courses from your curriculum at anytime.

- Human Subjects Research (HSR) - there are two options - **Biomedical and Social Behavioral Educational. Choose the option that is most suitable to your research area.**
- Good Clinical Practice (GCP) - Mandatory for research staff conducting clinical trials
- Conflicts of Interest (COI) - Not required for UTHealth faculty and staff as this is covered in the UTHealth mandatory compliance training
- Data Acquisition and Management - Optional
- Responsible Authorship and Publication - Optional
- Animal Care and Use (IACUC) - Optional
- Clinical Research Coordinator (CRC) -Optional
- Clinical Trial Billing Compliance (CTBC) - Optional
- Responsible Conduct of Research (RCR) -Optional

Once you've made your selection, you will be given choices for each course. Choose the courses you wish to complete based on your research. If you have questions, please do not hesitate to email us at clinicaltrials@uth.tmc.edu or call the IRB office (713-500-7943) or AWC office (713-5003625).

You will now see the screen of selected courses. Click on the word "ENTER" next to a course to begin the modules. You may stop at any time during completion of the modules and your work to that point should be saved.

CITI Training Certificate of Completion is automatically forwarded to CPHS Office when you pass the quiz. If you need additional copies, you may always return to the CITI site and print additional copies.

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IRC Authorship and Dissemination Agreement

The HHD Program Point of Contact (POC) and the researcher have:

Statement	Yes/No If NO, justification is needed.	Details/Notes:
○ Discussed and agreed on types of dissemination products to be created from the data to be shared.		
○ Discussed and agreed on authorship and acknowledgement details for the dissemination products to be created.		
○ Agreed on providing IRC Committee with all final products/reports and other dissemination products.		
○ Agreed on specifics of data sharing ○ (MOUs, MOAs or other)		

Title of Proposed Project _____

Name of IRC Applicant (Researcher) _____

IRC Applicant (Researcher) signature_____

HHD Program Point of Contact/ Assistant Director signature_____

Date _____

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IRC WORKFLOW CHECKLIST

To ensure timely and accurate processing of your IRC data request, please include all required items as specified for your request type. Be sure to provide detailed information and clearly define the names of all variables to be used in your analysis. Incomplete submissions may delay processing.

A. HHD IRC Individual/Organizational Workflow

- ☐ Point of Contact (POC)
- ☐ Types of dissemination products
- ☐ Proposed authorship/acknowledgment statement
- ☐ Final products/reports to IRC/Data Dissemination Committee
- ☐ Acknowledgement from POC/Program Manager agreeing to data sharing
- ☐ Is package complete? Receive **data sharing agreement** from HHD Legal (MANDATORY)

B. HHD IRC Individual Internal Workflow

- ☐ Point of Contact (POC)
- ☐ Types of dissemination products
- ☐ Proposed authorship/acknowledgment statement
- ☐ Final products/reports to IRC/Data Dissemination Committee
- ☐ Acknowledgement from POC/Program Manager agreeing to data sharing
- ☐ Is package complete? Acknowledge, sign, and submit document with statements

C. HHD IRC Individual External Workflow

- ☐ Point of Contact (POC)
- ☐ Types of dissemination products
- ☐ Proposed authorship/acknowledgment statement
- ☐ Acknowledgement from POC/Program Manager agreeing to data sharing
- ☐ Is package complete? Written IRC Approval granted via email.