



MEMORANDUM

TO: Principal Investigator

FROM: Diana Mouton, RN
Manager, Research and Sponsored Programs

RE: HCHD Research Process

Please find attached the following resources to guide you through the HCHD Research Process:

- **Checklist:** BT, LBJ, and Thomas Street Clinic
- **Checklist:** Community Health Centers
- HCHD Research Application
- Health Information Management (medical records) Chart Request Form
- Information Technology Request Form
- Department of Pharmacy Institutional Drug Service (IDS) Brochure
- Contact Information of individuals involved in the HCHD Research Process

The Hospital District values the search for new knowledge. Please feel free to contact me at any time for assistance in acquiring access, reporting problems with research, or suggestions to improve our approval and implementation process:

Research and Sponsored Programs

Harris County Hospital District
2525 Holly Hall, Room 187E
Houston, Texas 77054

research@hchd.tmc.edu

Phone: 713.566.6914

Fax: 713.440.1384



Checklist for BT/LBJ/QM/Thomas Street

- | | |
|--------------------------|---|
| <input type="checkbox"/> | 1. Cover letter requesting approval to conduct study in HCHD facility(s). |
| <input type="checkbox"/> | 2. HCHD Research Application |
| <input type="checkbox"/> | 3. A copy of the IRB approval letter. |
| <input type="checkbox"/> | 4. A copy of the research protocol submitted for IRB approval. |
| <input type="checkbox"/> | 5. A copy of the sponsor's protocol, if funded. |
| <input type="checkbox"/> | 6. A copy of the investigational brochure, if any investigational drug/device is involved. |
| <input type="checkbox"/> | 7. A copy of HIPAA compliant English & Spanish consent forms to be used, if applicable.
<u>If not, a waiver must be requested in writing by letter or email to the HCHD Research Manager.</u> |
| <input type="checkbox"/> | 8. Consent form(s) must include HCHD Injury Disclaimer, if applicable.
"In the event of injury resulting from this research, (your institution) and/or the Harris County Hospital District (name of Hospital District facility or facilities) are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community." |
| <input type="checkbox"/> | 9. A copy of any instrument(s) to be used, including surveys, inventories, assessments, or questionnaires, if applicable. |
| <input type="checkbox"/> | 10. A copy of any subject recruitment materials (advertisements), such as flyers, that will be used to recruit participants from HCHD. (HCHD must review and approve content of materials to ensure adequate subject protection) |
| <input type="checkbox"/> | 11. Research staff must be credentialed by the Office of Physician Services @ 713.873.2309. |

-- Mail **one copy** of the above items to the **Chief of Staff(s)** of the affected HCHD Hospitals(s): or via email to the Chief of Staff assistant

Kenneth Mattox, MD
Chief of Staff, Ben Taub General Hospital
1504 Taub Loop, 1CS11006-A-G
Houston, Texas 77030
lpalomo@bcm.tmc.edu

Steven Brown, MD
Chief of Staff, Lyndon B. Johnson General Hospital
5656 Kelley Street, Room 1EC 73 029
Houston, Texas 77026
mary.f.fabrizio@uth.tmc.edu

-- Mail one copy of the above items:

-- Mail two copies of the above items if your study involve drugs to:

Research and Sponsored Programs
Harris County Hospital District
2525 Holly Hall, Room 187E
Houston, Texas 77054
research@hchd.tmc.edu



Checklist for Community Health Centers

- ☐ 1. Cover letter requesting approval to conduct study in the Community Health Center(s).
- ☐ 2. HCHD Research Application
- ☐ 3. A copy of the IRB approval letter.
- ☐ 4. A copy of the research protocol submitted for IRB approval.
- ☐ 5. A copy of the sponsor's protocol, if funded
- ☐ 6. A copy of the investigational brochure, if any investigational drug/device is involved.
- ☐ 7. A copy of HIPAA compliant **English & Spanish consent forms** to be used, if applicable.
If not, a waiver must be requested in writing by letter or email to the HCHD Research Manager.
- ☐ 8. Consent form(s) must include HCHD Injury Disclaimer, if applicable.
"In the event of injury resulting from this research, (your institution) and/or the Harris County Hospital District (name of Hospital District facility or facilities) are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities emergency treatment and professional services will be available to you, just as they are to the general community."
- ☐ 9. A copy of any instrument(s) to be used, including surveys, inventories, assessments, or questionnaires, if applicable.
- ☐ 10. A copy of any subject recruitment (advertisements/flyers) that will be used to recruit participants from HCHD. (HCHD must review and approve content of material to ensure adequate subject protection)
- ☐ 11. Research staff must be credentialed by the Office of Physicians Services @ 713.873.2309.

-- Mail **one copy** of the above items to the **Chief of Staff(s) of the affected HCHD Hospital(s)**; or via email to the Chief of Staff assistant

Carlos Vallbona, MD
Chief of Staff, Community Health Program
3701 Kirby Drive, Suite 601.26
Houston, Texas 77098
parraare@bcm.tmc.edu

-- Mail one copy of the above items:

-- Mail two copies of the above items if your study involve drugs to:

Research and Sponsored Programs
Harris County Hospital District
2525 Holly Hall, Room 187E
Houston, Texas 77054
research@hchd.tmc.edu

A Presentation must be made to the individual Health Center(s) Council Meeting or in lieu of presenting to multiple Health Centers, the investigator may choose to present to the Council at Large, prior to HCHD final approval, for evaluation from consumer's standpoint as well as to give input to researcher.

-- Contact Yolanda Zermeno @ 713.566.6852 to schedule presentation date

-- Researcher will prepare a one page abstract, in layman's terms, for Council to review in advance of presentation.

-- Researcher may request that presentation be made by Drs. Vallbona, Gavagan, and Bayona.



RESEARCH APPLICATION

GENERAL INFORMATION: Use this form when submitting a protocol to the research office that will include HCHD patients, personnel, and/or facilities. All protocols must receive Chief of Staff approval before initiation.

If you require assistance in submitting your protocol for approval to HCHD, please contact:

Research Services
Harris County Hospital District
2525 Holly Hall, 187E
Houston, Texas 77054
Phone: 713.566.6914 Fax: 713.440.1384
research@hchd.tmc.edu

PROJECT INFORMATION

Protocol Number:

Protocol Title:

Sample Size: (HCHD subjects ONLY)

INVESTIGATOR INFORMATION

Name:

Credentials:

Department:

Mailing Address:

City:

State

Zip Code:

Phone:

Fax:

Pager:

Email:



RESEARCH APPLICATION

STUDY COORDINATOR

Name:		Title:
Mailing Address:		
City:	State:	Zip Code:
Phone:	Fax:	Pager:

SOURCE OF SUPPORT/FUNDING

<input type="checkbox"/> Federal - Sponsor:	<input type="checkbox"/> Commerical - Sponsor:
<input type="checkbox"/> Other (Specify):	<input type="checkbox"/> No Support

LOCATION (Check all that apply)

<input type="checkbox"/> Ben Taub General Hospital	Specific Department:		
<input type="checkbox"/> Lyndon B. General Hospital	Specific Department:		
<input type="checkbox"/> Quentin Mease Hospital	Specific Department:		
<input type="checkbox"/> Thomas Street Clinic	<input type="checkbox"/> Acres Home Clinic	<input type="checkbox"/> Aldine Clinic	<input type="checkbox"/> Baytown Clinic
<input type="checkbox"/> Casa De Amigos	<input type="checkbox"/> Gulfgate Clinic	<input type="checkbox"/> MLK Clinic	<input type="checkbox"/> Northwest Clinic
<input type="checkbox"/> Peoples Clinic	<input type="checkbox"/> Settegast Clinic	<input type="checkbox"/> Squatty Clinic	<input type="checkbox"/> Strawberry Clinic
<input type="checkbox"/> School Based Clinic	<input type="checkbox"/> Homeless Programs	<input type="checkbox"/> Dental Program	

DISTRICT RESOURCES

Will this study involve use of any resources or services at HCHD? If yes, check required service below:	
<input type="checkbox"/> Pharmacy Services	<input type="checkbox"/> Pathology/Laboratory Service
<input type="checkbox"/> Nursing Service	<input type="checkbox"/> Radiology Service
<input type="checkbox"/> Information Technology (IT) Download	<input type="checkbox"/> Nuclear Medicine Service
<input type="checkbox"/> Health Information Management (Chart Review)	<input type="checkbox"/> Other (Specify):

Signature: _____

Date: _____



HEALTH INFORMATION MANAGEMENT

Chart Request Form

DATE REQUESTED

DATE REQUIRED

PROTOCOL NUMBER

REQUESTOR NAME

DEPARTMENT/ORG.

PHONE NUMBER

BEEPER NUMBER

FAX NUMBER

E-MAIL ADDRESS

TITLE OF STUDY/PURPOSE OF REQUEST:

PRIMARY PHYSICIAN:

PERSONS REVIEWING CHARTS:

PERSONS WITH ACCESS TO INFORMATION:

INTENDED USE/RE-DISCLOSURE:

TYPE OF REVIEW (CHECK ONE): ☐ PUBLIC HEALTH ☐ OPERATIONAL ☐ BILLING
☐ RESEARCH ☐ QUALITY IMPROVEMENT ☐ EXECUTIVE REQUEST ☐ CASE MANAGEMENT

ACCESS TO PROTECTED HEALTH INFORMATION (PHI): ☐ Total Access (All PHI including MRN, SS#, Address Phone #, DOB, Age, Age Range >80, Zipcode)

☐ Limited Access _____

☐ Comment _____

PROCESSING TIME: ☐ Standard (5-10 business days) ☐ STAT for Patient Care (needs HIM approval)

Signature _____

00	10	20	30	40
50	60	70	80	90

TOTAL NUMBER OF RECORDS REQUESTED

DATE COMPLETED

TIME COMPLETED

ACCOUNTABILITY SIGNATURE _____

RECEIVED BY IN HIM

DATE RECEIVED BY HIM

TIME RECEIVED BY HIM



INFORMATION TECHNOLOGY RESEARCH REPORT REQUEST

DATE REQUESTED

DATE REQUIRED

PROTOCOL NUMBER

REQUESTOR NAME

DEPARTMENT/ORG.

PHONE NUMBER

E-MAIL

TITLE OF REASERCH REPORT:

PURPOSE OF REPORT:

INTENDED USE/RE-DISCLOSURE:

PERSONS WITH ACCESS TO INFORMATION:

FREQUENCY OF REPORT ☐ One Time ☐ Monthly ☐ Annually ☐ Other:OUTPUT FORMAT OF REPORT ☐ Excel ☐ PDF ☐ MS Word ☐ Other:

DATE RANGE OF REPORT:

DEMOGRAPHICS☐ MED. RECORD # ☐ NAME ☐ SOCIAL SECURITY ☐ ADDRESS ☐ PHONE # ☐ DOB ☐ AGE☐ AGE RANGE >80 ☐ ZIP CODESEX ☐ Both ☐ Male ☐ FemaleMARITAL STATUS ☐ All ☐ Married ☐ Single ☐ Divorced ☐ WidowedRACE ☐ All ☐ Asian ☐ Black ☐ Hispanic ☐ Indian American ☐ White ☐ Other:LANGUAGE ☐ All ☐ English ☐ Spanish ☐ Vietnamese ☐ Chinese ☐ Other:AGE RANGE ☐ All ☐ 0-4 ☐ 5-14 ☐ 15-19 ☐ 20-44 ☐ 45-64 ☐ 65-80 ☐ Other:LOCATION ☐ All ☐ CHPs ☐ Acres ☐ Aldine ☐ Baytown ☐ Casa ☐ Gulfgate ☐ MLK ☐ NW☐ Peoples ☐ Settegast ☐ Strawberry ☐ Squatty ☐ Ben Taub ☐ LBJ☐ Quentin Mease ☐ Thomas Street ☐ School-Based ☐ Dental Center ☐ Other:☐ Other:**FINANCIAL STATUS**INSURANCE GROUP ☐ All ☐ Self-Pay ☐ Commercial Insurance ☐ Medicare ☐ Medicaid☐ PAY CLASS ☐ EMPLOYMENT STATUS**VISIT INFORMATION**☐ ADMIT DATE ☐ DISCHARGE DATE ☐ PHYSICIAN NUMBER ☐ RESOURCE TYPEPAVILION ☐ All ☐ CHPs ☐ Acres ☐ Aldine ☐ Baytown ☐ Casa ☐ Gulfgate ☐ MLK ☐ NW☐ Peoples ☐ Settegast ☐ Strawberry ☐ Squatty ☐ Ben Taub ☐ LBJ ☐ Quentin Mease☐ Thomas Street ☐ School-Based ☐ Dental Center ☐ Other:PATIENT TYPE ☐ All ☐ Inpatient ☐ EC ☐ Observation ☐ Day SurgeryAPPT TYPE ☐ All ☐ New Patient ☐ Outpatient ☐ Returning Patient☐ Primary ☐ Any Existing☐ Primary ☐ Any Existing☐ Primary ☐ Any Existing

PROCEDURE CODES

CPT CODES

DIAGNOSIS CODES

☐ OTHER:

OTHER SPECIFICATIONS:

RESEARCH OFFICE APPROVAL:

DATE:

REMARKS:

HARRIS COUNTY HOSPITAL DISTRICT RESEARCH PATIENT REGISTRATION FORM

General Information: This form is to be completed by research personnel and faxed to the Benefits Coordinator in the Pre-Registration Office @ 713.440.1102.

<u>CONTACT INFORMATION</u> (For person completing the form)		
Name:		
Phone:	Fax:	Email:
LOCATION: <input type="checkbox"/> BTGH <input type="checkbox"/> LBJGH <input type="checkbox"/> QM <input type="checkbox"/> CHP:		
<u>CLINIC/UNIT LOCATION</u> (Enter unit name or clinic specialty and contact name , phone and email address)		
Unit Name/Clinic Specialty:		
Clinic Contact:	Phone:	Email:
SCHOOL AFFILIATION: <input type="checkbox"/> UTSHC-Houston <input type="checkbox"/> BCM <input type="checkbox"/> Other: _____		
<u>RESEARCH STUDY ACCOUNT</u> (This information is needed at the intial set-up)		
Protocol Number:		PI Name:
Billing Address:		
Phone:	Fax:	Email:
Adminstrative Contact:		
Insurance Plan Assigned:		
<u>PATIENT REGISTRATION FOR RESEARCH ACCOUNT</u> (This information is needed for each patient enrolled in the study) (Missing information will delay your ability to implement the protocol)		
Patient Name:		MRN:
SSN:		
Date of Birth:	Race:	<input type="checkbox"/> Male <input type="checkbox"/> Female
Billing Address:		
Mother's Name:		
Date Sumited:	Enrollment Date:	Length of Time on Study:
PATIENT REGISTRATION USE ONLY		
Date Received: _____		Received By: _____
Date Entered: _____		Entered By: _____

HCHD RESEARCH CONTACTS						
FUNCTION	FACILITY	NAME	TITLE	PHONE	FAX	EMAIL
Director, Research	HCHD	Julie Thompson, PhD	Director	713.566.6473	713.440.1383	julie_thompson@hchd.tmc.edu
Manager, Research	HCHD	Diana Mouton	Manager	713.566.6225	713.440.1272	diana_mouton@hchd.tmc.edu
Project Staff Assistant	HCHD	Tamineshia Perkins	PSA	713.566.6914	713.440.1384	tamineshia_perkins@hchd.tmc.edu
CEO Designee	HCHD	Beth Cloyd	Administrator	713.566.6821	832.487.2092	elizabeth_cloyd@hchd.tmc.edu
Administrator	BT/QM	Jeff Webster	Administrator	713.873.2300	713.873.2305	jeff_webster@hchd.tmc.edu
Administrator	LBJ	Lester Martinez-Lopez	Administrator	713.566.5101	713.566.5106	lester_martinez-lopez@hchd.tmc.edu
Administrator	CHP	Michelle Fowler	Interim Sr. VP	713.566.6856	713.495.3738	michelle_Fowler@hchd.tmc.edu
Charge Capture	HCHD	Jamie Smith	Auditor	713.566.6713	713.440.1207	janie_smith@hchd.tmc.edu
Patient Registration	HCHD	Myle Pham	Manager	713.566.6632	713.440.1102	myle_pham@hchd.tmc.edu
Clinical Studies Unit	BTGH	Melissa Brock	Nurse Manage	713.873.8772	713.852.4965	mbroc@bcm.tmc.edu
Investigational Drugs	HCHD	Sara Ruppelt	Coordinator	713.873.4457	713.873.4455	sara_ruppelt@hchd.tmc.edu
Credentialing	HCHD	Sharon Wardsworth	Physician Service	713.873.2309	713.873.8878	sharon_wardsworth@hchd.tmc.edu

HCHD CHIEF OF STAFF CONTACTS						
FUNCTION	FACILITY	NAME	ADDRESS	PHONE	FAX	EMAIL
Chief of Staff	BT/QM/TS	Kenneth Mattox, MD	Ben TaubGeneral Hospital 1504 Taub Loop, 1CS11006-A-G Hosuton, Texas 77030	713.873.3440	713.796.9605	kmattox@aol.com
Chief of Staff	LBJ/TS	Steven Brown, MD	Lyndon B Johnson General Hospital 5656 Kelley Street, 1EC 73 029 Houston, Texas 77026	713.566.4646	713.566.4655	steven.d.brown@uth.tmc.edu
Chief of Staff	CHP	Carlos Vallbona, MD	Family & Community Medicine Baylor College of Medicine 3701 Kirby Drive, Suite 601.26 Houston, Texas 77098	713.798.3643	713.798.3644	vallbona@bcm.tmc.edu