IRB Submission Checklist

We encourage you to utilize this checklist before submitting any documentation to DCH IRB office. IRB Contact personnel, Jucel Nazareno, BSN, RN, IRB Monitor @ Juleros.Nazareno@dchstx.org and/or Kevin P. Schooler, IRB chairman @ Kevin.Schooler@dchstx.org

Preliminary Steps:

ALL personnel listed must complete required training and have certificate of Training on IRB file:

- ❑ PIs
- ❑ Co-PIs
- ❑ Research Staff
- ❑ Advisors

Required Training (current/once every 3 years):

- ❑ Completed NIH Training Protecting Human Research Participants (CME Credit Available) **or**
- ❑ Completed CITI Human Subjects Research Training (from other institution/sponsor)

NIH Training:
http://phrp.nihtraining.com/users/login.php

Submission Steps:

- ❑ Create and develop your study documents.
- ❑ **Letter of Intent** (can initially be submitted to determine if your study will qualify for exempt, expedited or full board review).
- ❑ **Research Protocol:** your proposal document.
- ❑ **Informed Consent Documents:** For consent form guidelines and template, waiver of informed consent, contact the IRB.
- ❑ **Instruments:** all data instruments and other materials to be distributed to and/or used with study participants (e.g., surveys, questionnaires, interview guides, etc.).
- ❑ **Recruitment Materials:** all flyers, e-mail scripts, verbal scripts, and other materials to be distributed to and/or used to recruit participants.
- ❑ **Non-English Speakers:** Does your research include Non-English speakers? If so, have you translated the consent form, surveys and questionnaires? Have you included a letter certifying the translations? (For DCH investigators translation support contact: **Department of Patient Relations**
- ❑ **Conflict of Interest (COI) Disclosure form:** fill out form (for further guidance: COI in Research policy).
- ❑ **Other:** Have you checked the spelling, grammar and consistency of your submission?
- ❑ Has your principal investigator/advisor/sponsor approved the final draft for IRB submission and approval?

- ❑ **Department of Planning and Decision Support (for DCH investigator initiated studies):** Will the study involved collection of data by the Department of Planning and Decision Support? (If yes, please consult decision support prior to you having consultation/research meeting with advisor(s) and making your research proposal). Please schedule appointment by email @ DecisionSupport@dchstx.org

- ❑ **Department of Planning and Decision Support (for DCH investigator initiated studies):** When study documents are approved by the IRB. Create a work request. Refer to "How to Create a Report Request" .

- ❑ **Agreements from Outside Institutions:** If you have received permission from an outside agency or organization to receive information, records, or to conduct research activities on site – please provide a letter of support and contact Contract Management (Legal Department).

Copies of research documents required for IRB review:

Exempt Review (New studies that qualifies for exempt approval) Can be scanned and submitted electronically.	YES	N/A
(1) Copy of Letter of Intent		
(1) Copy of presentation/posters (IRB may require)		
(1) Copy of questionnaires and/or surveys, if applicable		
(1) Copy of any proposed advertisement/recruitment materials, if applicable		

Expedited Review (New studies, continuing review, amendments that qualifies for expedited approval) Can be scanned and submitted electronically.	YES	N/A
(1) Copy of Cover memo of submission		
(1) Copy of Letter of Intent		
(1) Copy of the Protocol		
(1) Copy of the Consent, Assent, if applicable		
(1) Copy of Waiver of Informed Consent, if applicable		
(1) Copy of questionnaires and/or surveys		
(1) Copy of any proposed advertisement/recruitment materials		

Full Board Review (New studies requiring full board review)	YES	N/A
(20) Copies of Cover memo of submission		
(20) Copies of Letter of Intent or Abstract/Study Summary (for treatment studies)		
(20) Copies of the Protocol		
(20) Copies of the Consent, Assent		
(20) Copies of study related correspondence (FDA, sponsor(s))		
(20) Copies of any proposed advertisement/recruitment materials		
(20) Copies of the wallet ID card, if required		
(20) Copies of Conflict of Interest and Financial Disclosure form		
(20) Copies of Delegation, Authority and Training Log		
(2) Copies of the Investigators brochure and package inserts		
Payment Receipt (company-sponsored study)		

Amendments/Revisions (Amendments requiring full board review)	YES	N/A
(20) Copies of Letter of Intent		
(20) Copies of the Amendment/Revision		
(20) Copies of study related correspondence (FDA, sponsor(s))		
(20) Copies of Updated Consent and Assent forms		
(20) Copies of any new or updated materials		
Payment Receipt (company-sponsored studies)		

Continuing Reviews (Continuing review requiring full board review)	YES	N/A
(20) Copies of Annual Report form(updated project summary, summary of serious adverse events and unanticipated problems)		
(20) Copies of the current consent and assent forms		
(20) Copies of DSMB result if applicable		
(20) Copies of any new or updated materials		
(20) Payment Receipt (for company-sponsored studies)		

Local Adverse Events	YES	N/A
(20) Copy of Adverse Event Reporting form (one event per form)		
(20) Copy of any new or updated materials		

Non-Local Adverse Events	YES	N/A
(2) Offsite Adverse Event Reporting Form (multiple events may be submitted on one form)		
(2) Copies of new or updated materials		