**NIH or other federally funded projects: pi initiated or departmental studies**

*documents to be maintained:*

* ***copies of the following should be maintained in file or maintained electronically in myIRB system***

**Recommended:** *Curriculum Vitaes for the Principal Investigator and all physician sub-investigators listed engaged in the research. These must be current (less than two years old).*

* Principal Investigator
* Co-Investigators

**Recommended:** *Curriculum Vitaes for all Research Coordinators and Research Nurses involved in the study (less than two years old)*

* All others, ex: PTs, RTs**,** RRTs, RPh

**Recommended:** *Current Medical Licenses for the Research Staff (all applicable):*

* Principal Investigator (if MD)
* Co-Investigators (if MDs, nurses, etc)
* All others, ex: PTs, RTs**,** RRTs, RPh

**IRB Initial Submission Application**

* ***Follow instructions per myIRB and submit applicable documents***
* Current Version ofProtocol (with version number and date)
* Completed irb Application
* Consent Form (with version number and date in footer)

*Include all versions – short forms, verbal scripts, assents, consents*

* All data collection instruments relevant to study
* All other information given to subjects; e.g: diaries, questionnaires
* Grant –funded studies: Entire Grant Application with salaries marked out
* Certificate of Confidentiality, if required

**IRB Correspondence**

* PI Correspondence Report Form
* Approval Memo

 **Study Communication**

* Date of conversation
* Name of people engaged in this conversation & affiliation
* Include brief description of conversation
* Means: email, phone, person to person, fax
* If applicable: copy of email
* Note: any follow-up required (by CRC/PI)
* File correspondence in appropriate location, e.g.: subject record or regulatory binder, appropriate section

**During the Study**

**IRB Modification Update Form**

* Submit and Maintain Modification Update Form
* Approval Memo

**Reportable Event Form**

* Submit and Maintain Reportable Event Form
* Maintain and file Study specific event report form(s): IND Safety Reports; Med Watch Forms, if applicable

**Study Recruitment**

* ***All study recruitment materials need to be submitted to irb***
* E.g. Advertisements, press releases, letters to colleagues, letter to participants

**IRB Continuing Review**

* ***Follow instructions per myIRB and submit applicable documents***
* Complete myIRB Continuing Review Form
* ***Consider the following documentation forms for data collection***
* Inclusion/Exclusion check off
* Case report forms
* Copy of Note-to-File to be used
	+ Screening log
	+ Enrollment log
	+ Master ID list: Code linking participant with a subject ID

**End of study forms**

**Project Close form**

* ***Follow instructions per myIRB and submit applicable documents***
* Submit and Maintain Project Close Form