COMPARISON CHART FOR CLINICAL RESEARCH

Requirements	Clinical Research	Incidental to Research	Registry			HUD – Humanitarian Use Device	CMS- Coverage with Evidence Development (CED) registry studies
			Prospective		Retrospective		
			Registry involving Clinical Intervention	Registry involving NO clinical intervention (only data collection)	Registry involving only data collection		
Definition	**Use of a device, drug or technique that is experimental, or is approved for other use in furtherance of a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge**	**Facility's services to study patient limited to hospital services which routinely performed for regular clinical purposes and do not involve study drug administration, implantation of experimental device or other clinical intervention central to study**	**Registry study that includes a clinical intervention, whether device, drug or technique. Falls into the category of Clinical Research and must meet all the requirements for Clinical Research**	**Study *where data collection or patient-participation does not interfere with choice of treatment, sample collection, procedures & the treatment itself, which should entirely follow standard hospital practices *consent does not list any SOC procedures as part of the study**	**Study or data collection activities that involve only the retrospective collection of data. There is no actual experimental intervention or services related to a study device, drug or technique. May be voluntary or mandated by law.**	**Limited Use of device approved by FDA for use intended to benefit fewer than 4000 patients per year in the US; must be used for accordance with approved indication**	**Approved procedure/device which is covered by Medicare only if data is reported to CMS**

Requirements	Clinical Research	Incidental to Research	Registry			HUD – Humanitarian Use Device	CMS- Coverage with Evidence Development (CED) registry studies
			Prospective		Retrospective		
			Registry involving Clinical Intervention	Registry involving NO clinical intervention (only data collection)	Registry involving only data collection		
Obtain and review full clinical protocol for study	YES	NO	YES	YES	NO	NO	NO
Verify registration in Clinical Trials.gov	YES	NO	YES	NO	NO	YES	YES
Facility cost and/or time analysis	YES	NO	YES	NO to cost analysis Yes to time analysis* (may be waived for academic medical centers with Corporate approval)	NO to cost analysis Yes to time analysis * (may be waived for academic medical centers with Corporate approval)	NO	NO

Requirements	Clinical Research	Incidental to Research	Registry			HUD – Humanitarian Use Device	CMS- Coverage with Evidence Development (CED) registry studies
			Prospective		Retrospective		
			Registry involving Clinical Intervention	Registry involving NO clinical intervention (only data collection)	Registry involving only data collection		
Informed Consent Verification regarding language relating to patient financial responsibility if enrolled in study and subject injury language regarding who will pay for medical treatment required if patient injured	**YES**	**NO**	**YES**	**NO**	**NO**	**NO**	**NO**

Requirements	Clinical Research	Incidental to Research	Registry			HUD – Humanitarian Use Device	CMS- Coverage with Evidence Development (CED) registry studies
			Prospective		Retrospective		
			Registry involving Clinical Intervention	Registry involving NO clinical intervention (only data collection)	Registry involving only data collection		
Facility Research Committee (FRC) review and approval	YES	NO	YES	NO	NO	NO	NO
IRB Review and Approval	Yes	YES* *verification of IRB approval letter required- place IRB name and date of approval by IRB on encounter ticket	YES	YES	YES	YES	NO
Medicare Contractor Preapproval packet	YES, IF A DEVICE STUDY	NO	YES, IF A DEVICE STUDY	NO	NO	YES for Novitas	NO

Requirements	Clinical Research	Incidental to Research	Registry			HUD – Humanitarian Use Device	CMS- Coverage with Evidence Development (CED) registry studies
			Prospective		Retrospective		
			Registry involving Clinical Intervention	Registry involving NO clinical intervention (only data collection)	Registry involving only data collection		
Tenet Entity Contract with IRB Agreement Required	YES	NO	YES	YES	YES if data is identifiable	YES	NO
eCATS approval required	YES	YES if study services are funded by PI or sponsor NO if study services are billed to patient's payor	YES	YES	YES	NO	NO
Qualifying Clinical Trial form	YES	NO	YES	NO	NO	NO	NO

Requirements	Clinical Research	Incidental to Research	Registry			HUD – Humanitarian Use Device	CMS- Coverage with Evidence Development (CED) registry studies
			Prospective		Retrospective		
			Registry involving Clinical Intervention	Registry involving NO clinical intervention (only data collection)	Registry involving only data collection		
Research ID and creation of study in billing software maintenance table	YES	YES	YES	NO- listed on manual spreadsheet for registry studies	NO- listed on manual spreadsheet for registry studies	NO- listed on manual spreadsheet for HUDs	NO
Clinical research database entry (PDR)	YES	YES	YES	NO	NO	Required on separate manual entry spreadsheet	Required on separate manual entry spreadsheet
Bill Hold process for patient account	YES	YES	YES	NO	NO	NO	NO

Requirements	Clinical Research	Incidental to Research	Registry			HUD – Humanitarian Use Device	CMS- Coverage with Evidence Development (CED) registry studies
			Prospective		Retrospective		
			Registry involving Clinical Intervention	Registry involving NO clinical intervention (only data collection)	Registry involving only data collection		
Registrar creates client acct. for study is used to post services that are provided to patient & paid by sponsor/client	**YES**	**YES**	**YES**	**NO**	**NO**	**NO**	**NO**
Facility maintains copies of each enrolled patients' research informed consent	**YES**	**NO**	**YES**	**YES**	**NO**	**NO Unless the IRB mandated use of a particular consent form**	**NO**

Requirements	Clinical Research	Incidental to Research	Registry			HUD – Humanitarian Use Device	CMS- Coverage with Evidence Development (CED) registry studies
			Prospective		Retrospective		
			Registry involving Clinical Intervention	Registry involving NO clinical intervention (only data collection)	Registry involving only data collection		
Facility's Research Coordinator creates "Research Encounter Ticket Involving Studies under Category Incident to Research" & provides to Study Physician, who sends completed form with orders & signature for each patient to Registration	**NO**	**YES, if outpatient services and sponsor or PI will pay**	**NO**	**NO**	**NO**	**NO**	**NO**