

SUMMARY OF REVIEW PROCESS FOR GHUCCTS PROTOCOLS

Streamlined process with protocols review within a one-month period

SEPCOM review on first Thursday of month
(see website for deadlines)

Depth of review by SEPCOM is determined by protocol type (1-7)
(see table 1)

GHUCCTS IRB review on second Thursday of month
(see website for deadlines)

Review by two committees is independent, but sequential

Protocol **must** be reviewed by SEPCOM prior to receiving IRB review
(see table 2)

Protocols deferred by SEPCOM will be asked to address reasons for
deferral prior to undergoing GHUCCTS IRB review

TABLE 1. REFERENCE GRID FOR PROTOCOL REVIEW BY SEPCOM

(all approved protocols will be forwarded to the RACC for allocation of resources)

#	TYPE OF PROTOCOL			SEPCOM REVIEW PROCESS				
	Source of Funding	GHUCCTS Investigator-initiated?	Prior Level of Review	Scientific Review	Statistical Review	Patient Safety and Ethics Review	Clinical Resources Review	Administrative Review
1	Pilot studies (GHUCCTS-funded)	Yes	No previous peer review	Rigorous <i>(performed by PCS sub-committee)</i>	Rigorous	Rigorous	Yes	Yes
2	Collaborative studies (GHUCCTS-funded)	Yes	No previous peer review	Rigorous <i>(performed by PCS sub-committee)</i>	Rigorous	Rigorous	Yes	Yes
3	Investigator-initiated pilot (no other support)	Yes	No previous peer review	Rigorous	Rigorous	Rigorous	Yes	Yes
4	Federally funded (e.g. R01s with NIH funding)	Yes	Already Peer-reviewed	Abbreviated (major flaws only)	Abbreviated (major flaws only)	Yes	Yes	Yes
5	Foundation-funded	Yes	Already Peer-reviewed	Abbreviated (major flaws only)	Abbreviated (major flaws only)	Yes	Yes	Yes
6	Industry-funded	No	Reviewed by sponsor	Waived <i>(already reviewed, limited possibility of protocol changes)</i>	Waived	Yes	Yes	Yes
7	Multicenter Studies (e.g. cooperative group or industry sponsored)	No	Reviewed by group or sponsor	Waived <i>(already reviewed, limited possibility of protocol changes)</i>	Waived	Yes	Yes	Yes

TABLE 2. SUMMARY OF PROTOCOL REVIEW

PROTOCOL # (SEE TABLE ABOVE)	SOURCE OF FUNDING	FIRST REVIEW (first Thursday of month)	SECOND REVIEW (second Thursday of month)
1	Pilot studies (GHUCCTS-funded)	SEPCOM Full	GHUCCTS IRB
2	Collaborative studies (GHUCCTS-funded)	SEPCOM Full	GHUCCTS IRB
3	Investigator-initiated pilot (no other support)	SEPCOM Full	GHUCCTS IRB
4	Federally funded (e.g. R01s with NIH funding)	SEPCOM Abbreviated	GHUCCTS IRB
5	Foundation-funded	SEPCOM Abbreviated	GHUCCTS IRB
6	Industry-funded	SEPCOM Safety & resources	GHUCCTS IRB
7	Multicenter Studies (e.g. cooperative group or industry sponsored)	SEPCOM Safety & resources	GHUCCTS IRB