REB Quick Reference Table - for Annual Renewals, Completion of Study, and SAE Reporting

Type of Initial REB Review	Accrual (enrolment of subjects) status	Type of annual review required		Completion of Study Notice may be submitted	SAE Reporting Required
		Full Board	Delegated/ Expedited		
Section A:	**Minimal Risk Studies**				
Studies Initially approved by REB Delegated/ Expedited Review	Studies involving direct human participation ▪ Expedited renewal required until study completed as per Section B (or if US affiliated – Section C).		✓		✓
	Studies NOT involving direct human participation ▪ Data or specimens being added to the study dataset.		✓		
	Studies NOT involving direct human participation ▪ No new data/specimens being added to study dataset. ▪ *Analyses only of already collected data or specimens may continue (if US affiliated, this may only be data/specimens that are NOT individually identifiable).*			✓	
Section B:	**Studies NOT Sponsored or Monitored by the United States (initially approved by the full board)**				
Studies Initially approved by the REB Full Board	Open to accrual		✓		✓
	Closed to accrual ▪ Research-related interventions ongoing, including treatment, diagnostic testing that is not part of standard care, long term follow-up (survival data being collected).		✓		✓
	Closed to accrual ▪ All subjects deceased or follow-up is complete. ▪ All research-related interventions are complete. ▪ Data or specimens are no longer being collected or submitted to the sponsor. ▪ *Analyses only of already collected data or specimens may continue (if US affiliated, this may only be data/specimens that are NOT individually identifiable).* ▪ **and** see 'Study Completion' notes below			✓	
Section C:	**Studies Sponsored or Monitored by the United States (i.e., OHRP- HHS, NCI, NIH, FDA)** (as per; OHRP Dept of Health & Human Services-Guidance on Continuing Review)				
Studies Initially approved by the REB Full Board	Open to accrual ▪ No subjects enrolled and no additional risks identified		✓		✓
	Open to accrual ▪ Subjects enrolled or; ▪ No subjects enrolled but additional risks have been identified either locally or otherwise.	✓			✓
	Closed to accrual ▪ Research-related interventions ongoing, including treatment or diagnostic testing not part of standard care.	✓			✓
	Closed to accrual ▪ All research-related interventions are complete. ▪ Research remains active only for long-term follow-up of subjects or limited to the analysis of individually identifiable data/specimens.		✓		✓
	Closed to accrual ▪ All subjects deceased or follow-up is complete. ▪ All research-related interventions are complete. ▪ Data or specimens no longer being collected or submitted to the sponsor. ▪ *Analyses only of already collected data/specimens that are NOT individually identifiable may continue..* ▪ **and** see 'Study Completion' notes below			✓	

Study Completion:

A study may only be considered "**complete**" when it **no longer requires annual renewal** (see above) **and**

- **Industry sponsored studies -** there has been an official "close-out visit" by the sponsor.
- **NCIC CTG monitored studies** - the lead centre must have been notified by the NCIC CTG.
- **Grant funded studies** – there is no active grant that requires annual ethics approval.
- For details refer to Guidance Notes For Notification Of Study Closure

When a study is complete**;** a **"Completion of Study Notice"** must be submitted to the REB in RISe.