1. PURPOSE
   1. This procedure describes the fee schedule used by the Carilion Clinic Institutional Review Board (IRB) for the initial review and continuing reviews of research
2. POLICY
   1. The IRB charges fees for reviews of fully or partially industry supported research, including chart review studies. These fees are used to:
      1. Offset some of the costs of processing and tracking research protocols
      2. Assign financial responsibility to business or industry for IRB review of protocols they sponsor
      3. Educate IRB members and clinical investigators with respect to Good Clinical Practice Guidelines and federal regulations for research in human subjects.
   2. The IRB fees are assessments of real cost associated with protocol review by the IRB.  If subjects are never enrolled, the study terminates before milestones are met, expenditures exceed revenue, or a contract is never finalized, the investigator and department are responsible for all expenditures not covered by the sponsor, including the initial and any annual IRB fees.
3. RESPONSIBILITIES
   1. Investigators or their staff must incorporate and negotiate applicable IRB fees into the research contract.
   2. Departments should incorporate the IRB review fee in the budget of all business or industry sponsored research studies.
   3. The Office of Research & Development will transfer the review fee to the IRB from the business or industry funds set aside for the conduct of the research project.
4. PROCEDURE
   1. Studies funded by federal or state grants directly to Carilion or by non-profit foundations or internal funds directly to Carilion are not subject to the IRB review fee.
   2. Fees will be waived for investigator-initiated research that receives no support or only minimal support from business or industry sponsors. There is no charge for review of exempt or QA/QI proposals.
   3. When an IRB submission is received and not designated as supported by business or industry but is later determined by the IRB to be supported by business or industry, appropriate IRB fees will be assessed.
   4. The IRB will charge the fee once the research is approved.
   5. Fees can be changed at any time.
   6. All new studies with industry/commercial sponsors with contracts being negotiated on or after June 1, 2023 will include the Carilion IRB fee of $500 for a local-context, administrative review.
   7. The fee schedule for fully or partially industry supported research is as follows, as of June 1, 2023.

* Full Board Initial Review $ 2,500.00
* Full Board Continuing Review $ 1,000.00
* Full Committee Modification $ 300.00
* Expedited Initial Review $ 1,000.00
* Expedited Continuing Review $ 500.00
* Expedited Modification $ 100.00
* Study Closure $ 250.00
* Administrative Review, Carilion is the Relying IRB $ 500.00

1. APPROVAL AND REVISIONS
   1. 3/26/19: Human Research Protections Office Director, Carley Emerson, originally created and approved
   2. 8/23/19: Update to the fee schedule
   3. 8/1/23: Update to the fee schedule with the new addition of Administrative Fee when Carilion is the Relying IRB, Tanner Harmon, IRB Operations Consultant.
2. REFERENCES
   1. None