Submitting Protocol Under “De Novo Review”

FOR PROTOCOL THAT BEGIN WITH THE 2016, 2017, and 2018

- When protocol is up for “De Novo Review”, the Principal Investigator (PI) will receive ONLY one email notification.
- The PI (or the person designated by the PI to access eSIRIUS) should log into the system.
- Be sure you are on the “Protocol Actions” tab and then click on “Start a New Protocol Application”.
  - Complete all required information and then click on “Submit”. Only the PI may submit the protocol.

FOR PROTOCOL THAT BEGIN WITH 0000

- When protocol is up for “De Novo Review”, the Principal Investigator (PI) will receive ONLY one email notification.
- The PI (or the person designated by the PI to access eSIRIUS) should log into the system and check “In Box” under “De Novo Reviews” (see figure below).
- Click on the hyperlink for the protocol that appears in the In Box.
- Enter information under “Progress Report”
- Next click “Please choose De Novo Review Action” and chose either: “Protocol Will be Renewed” or “Lapse Upon Expiration” and hit the “Save” button.
- If you choose “Protocol Will be Renewed”, the protocol form under de novo review will appear. You should review and update all sections, then click on “Submit”. NOTE: Only the PI may submit the protocol.
- If you choose “Lapse Upon Expiration”, complete all additional tabs that will appear.

NOTE: If you have questions and/or need assistance while complete “De Novo Review Process”, contact Dr. Sunder Shrestha: sunder.shrestha@einsteinmed.org.