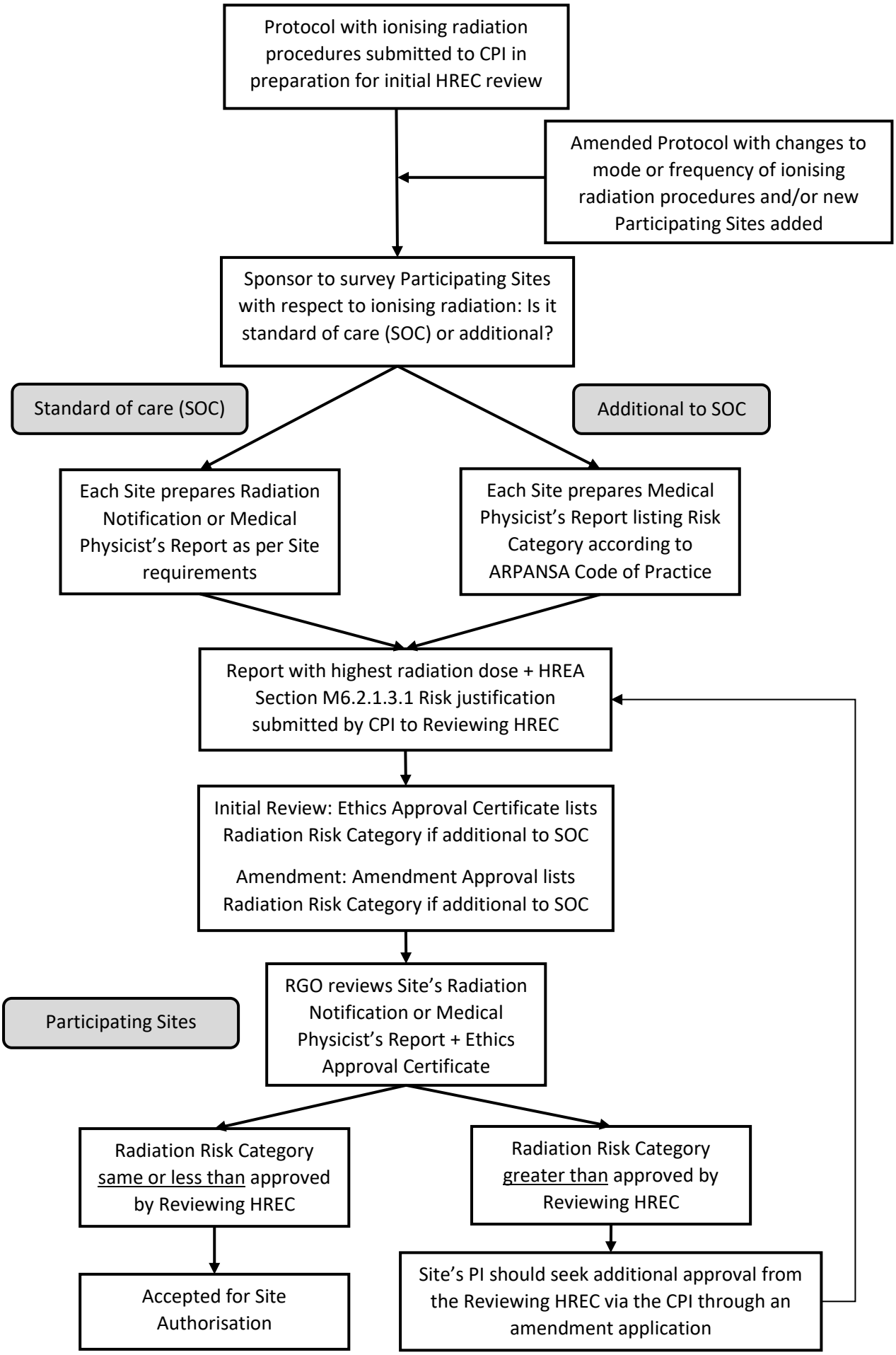
Protocol with ionising radiation procedures submitted to CPI in preparation for initial HREC review
Amended Protocol with changes to mode or frequency of ionising radiation procedures and/or new Participating Sites added
Sponsor to survey Participating Sites with respect to ionising radiation: Is it standard of care (SOC) or additional?
Standard of care (SOC)
Additional to SOC
Each Site prepares Radiation Notification or Medical Physicist's Report as per Site requirements
Each Site prepares Medical Physicist's Report listing Risk Category according to ARPANSA Code of Practice
Report with highest radiation dose + HREA Section M6.2.1.3.1 Risk justification submitted by CPI to Reviewing HREC
Initial Review: Ethics Approval Certificate lists Radiation Risk Category if additional to SOC
Amendment: Amendment Approval lists Radiation Risk Category if additional to SOC
Participating Sites
RGO reviews Site's Radiation Notification or Medical Physicist's Report + Ethics Approval Certificate
Radiation Risk Category same or less than approved by Reviewing HREC
Radiation Risk Category greater than approved by Reviewing HREC
Accepted for Site Authorisation
Site's PI should seek additional approval from the Reviewing HREC via the CPI through an amendment application