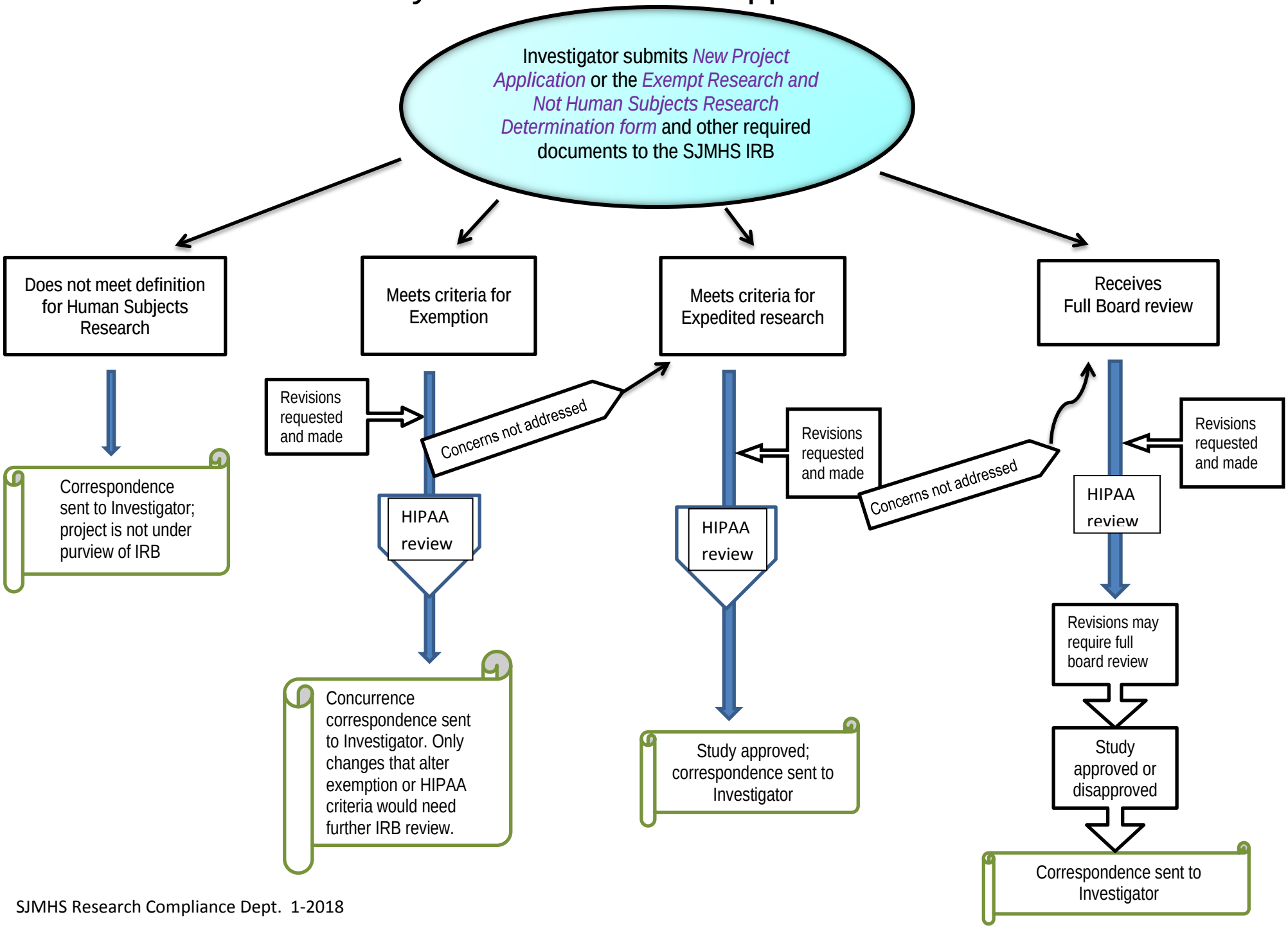New Study Review and IRB Approval Process