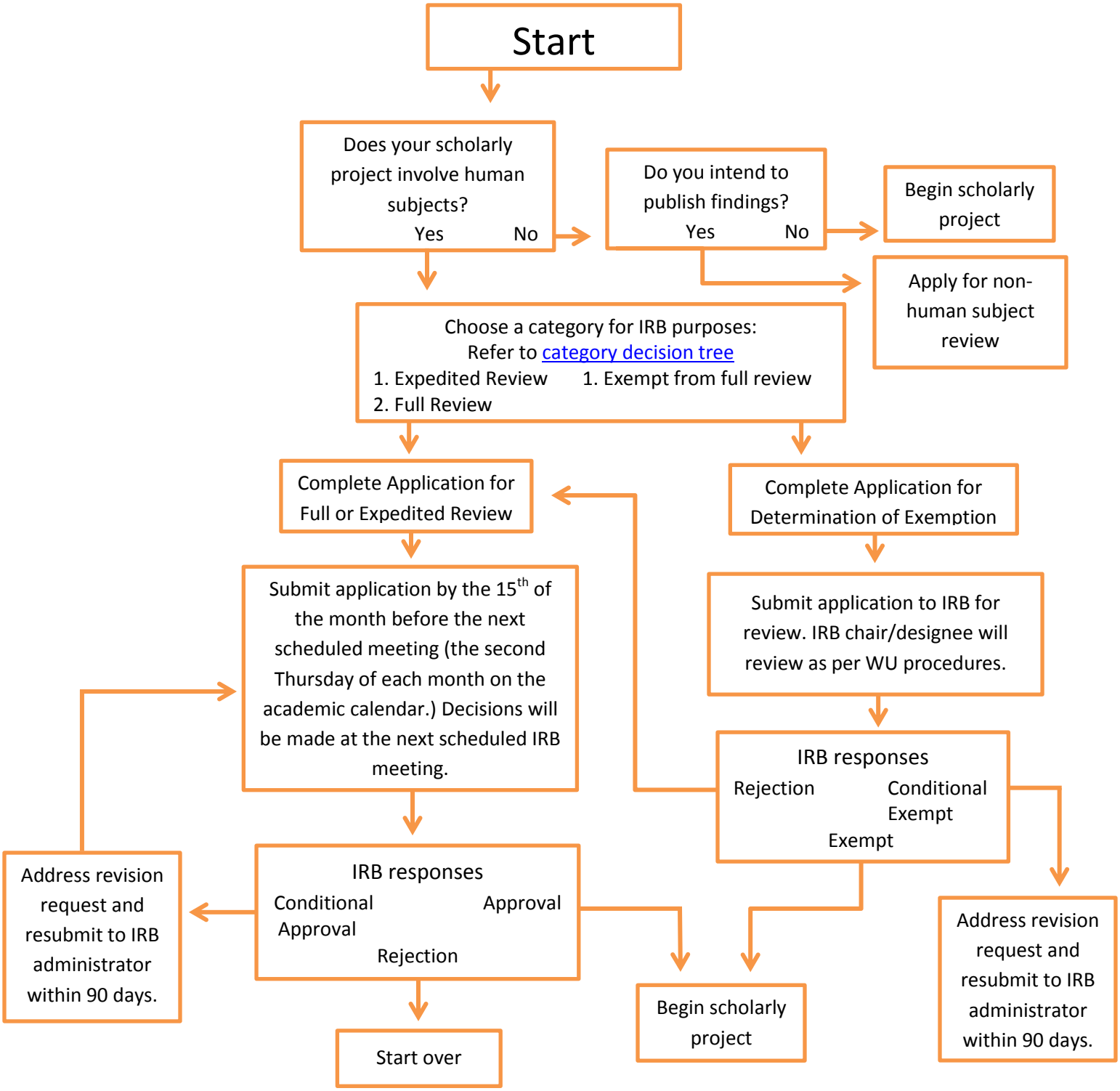Institutional Review Board Process