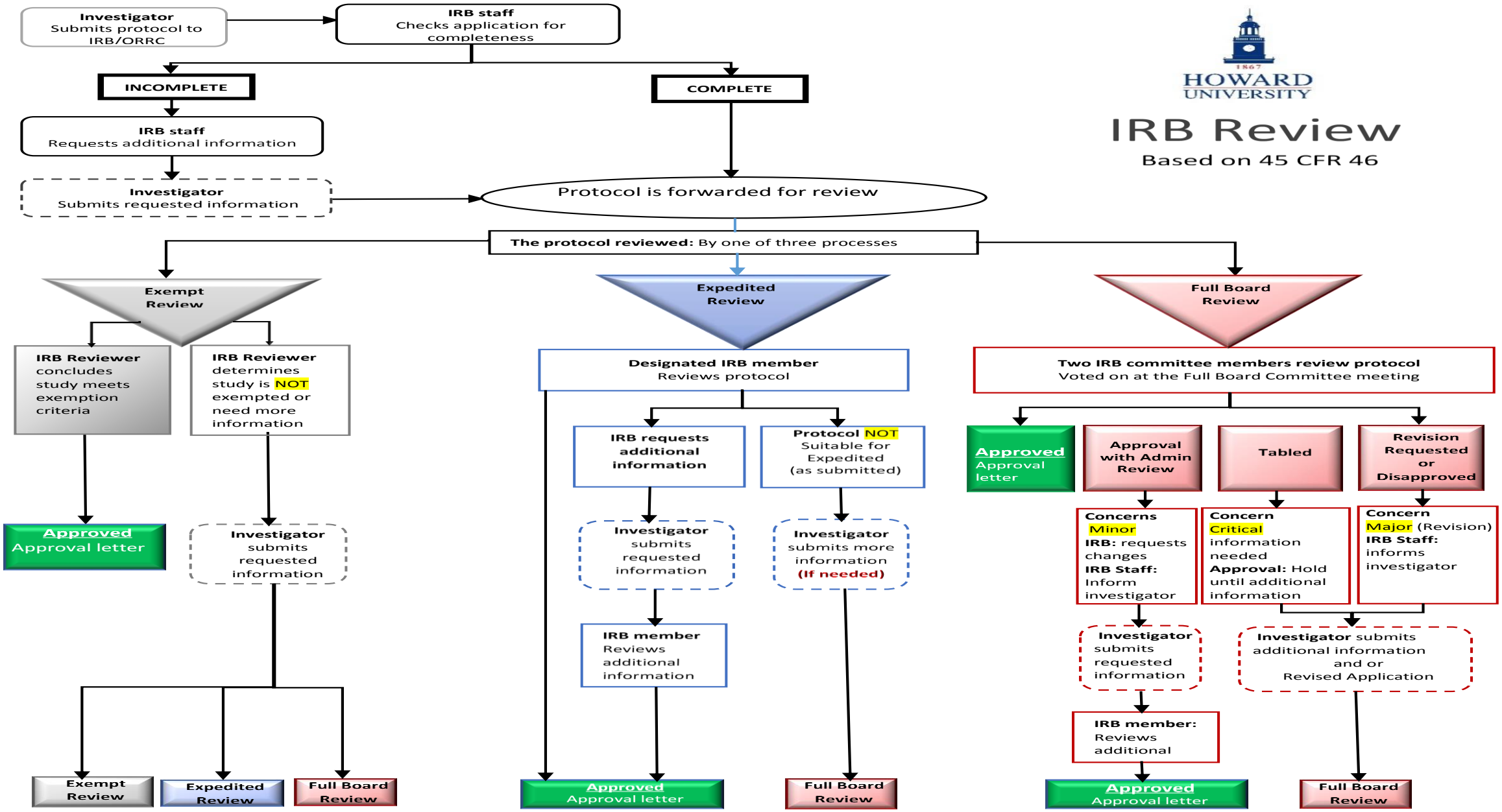IRB Review Process