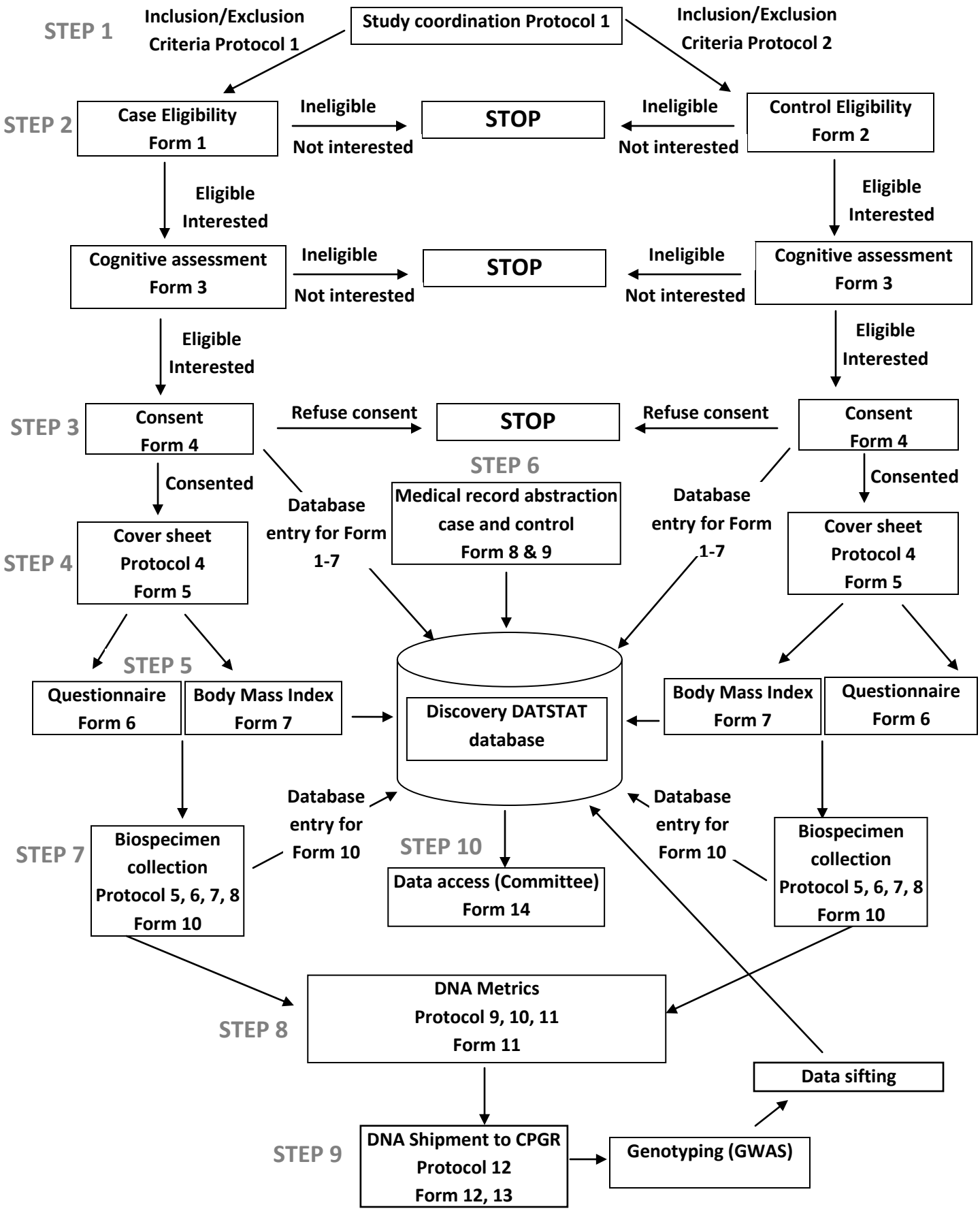U01-CA184374 OVERVIEW OF STUDY