Attachment 2 - Requirements for Checking Opt Outs for Genetic Research – Anonymous or Coded Specimens/Data Previously Collected for Research Purposes

Research study proposed to collect specimens/genetic information

IRB approval obtained

Data/Specimens collected with consent/authorization

Researcher wishes to analyze specimens/data for genetic research

Consent included genetic research

Consent form did not include genetic research

IRB approval obtained

Anonymous data/specimens collected <7/29/05

Cannot use for genetic research

IRB approval obtained

Anonymous specimens/data collected >07/29/05

Data/specimens analyzed

Anonymous specimens/data collected >07/29/05

Cannot use for genetic research

IRB approval obtained

Coded data/specimens

IRB approval & waiver of consent & authorization obtained

Privacy Office checks opt out on OHSU data/specimens

Researcher analyzes data/specimens without opt out