Problem: Study subject did not sign a HIPAA Form B

Person obtaining consent (POC) did not ask study subject to sign the form

• Why?
Training on the purpose and use of the HIPAA Form B was not conducted

• Why?
There are no departmental SOPs regarding HIPAA procedures

• Why?
Historically small 2-person research team (which only recently expanded)

• Why?
Since study team has grown, there is a need to create SOPs

Example: “5 Whys” Problem Solving Tool