**WORKFLOW FOR BSPH INVESTIGATOR: SECONDARY RESEARCH WITH JHM CLINICAL DATA**

For limited data sets and JHM de-identified datasets, PI submits DUA request through JHURA JAWS system.

After completing IRB/HIPAA Privacy Board review and resolving all concerns, BSPH IRB will hold final approval until it has:

* Approval from the JHM affiliate, if required
* Data Trust Research Subcouncil approval, if over 500 records
* BSPH IT approval
* For limited and de-identified datasets, a JHURA-signed data use agreement.

PI contacts JHM data provider, e.g., CCDA or JHM Privacy Office approved Honest Broker to discuss data acquisition.

PI seeks access to JHM PHI for secondary data analysis

PI Actions

IRB/HIPAA Privacy Board Actions

PI initiates internal review and approval from JHM affiliates that require it (JHCP, HCG, JHHC, etc.)

PI submits research application to BSPH IRB with BSPH HIPAA Application for JHM data, JHM data security profile and data security checklist forms, and local approvals from JHM data provider (if required).

BSPH IRB:

* completes ethical/scientific review and HIPAA Privacy Board review
* if over 500 records, sends application to JHM Data Trust Research Subcouncil review
* if under 50 records, and a HIPAA waiver is granted, notifies PI of compliance tracking requirement
* if a limited or de-identified dataset, checks for a fully executed Data Use Agreement