Investigational / Post-Market Device Impact Analysis

Baylor St. Luke's Medical Center

Process Begins

Study team submits **Research Device Request Form** and supporting documentation to BSLMC Research Office (RO)

RO reviews packet for completion
2-3 business days

Is this a post-market study?

Legend:
- Study Team
- Research Office (RO)
- Supply Chain (SC)
- Finance

Post-Market / 510K
10 - 20 business days

RO forwards **Form** and supporting documentation to Supply Chain (SC)

No compliance issue

SC reviews for contract compliance / sends confirmation to Finance (cc: RO)

Finance conducts new device purchase analysis and notifies SC / RO of outcome

— Approved →

— Not Approved →

RO notifies study team of outcome. If positive, study team proceeds with administrative application

Process Completed

No →

Is Sponsor providing device and components free of charge?

IDE Expedited Review – Research Device & Components Provided Free of Charge by Sponsor
10 - 20 business days

— Yes →

RO notifies study team to proceed with administrative application

Process Completed

No →

IDE Full Review – Hospital Purchases Research Device and/or Components
20 – 35 business days

RO forwards **Form** and supporting documentation to SC and Finance

SC reviews for contract compliance / sends confirmation to Finance (cc: RO)
2-4 business days

Finance works with Managed Care, Rev. Cycle, Gov. Reporting to prepare financial impact analysis
10 business days

BSLMC CFO review

Finance forwards CFO decision to SC and RO

RO provides study team with status update

SC negotiates price, as outlined by Finance, and engages Legal Affairs, as appropriate

Device agreement negotiation needed?

— No →

— Yes →

Prescribed agreement reached?

— Yes →

— No →

SC executes device agreement with Sponsor/Vendor

SC notifies Finance and RO of outcome

BSLMC CFO reconsideration (as applicable)

— Approved →

— Not Approved* →

SC forwards executed agreement to RO

RO forwards executed agreement to study team and study team proceeds with administrative application

RO provides study team with outcome

Process completed