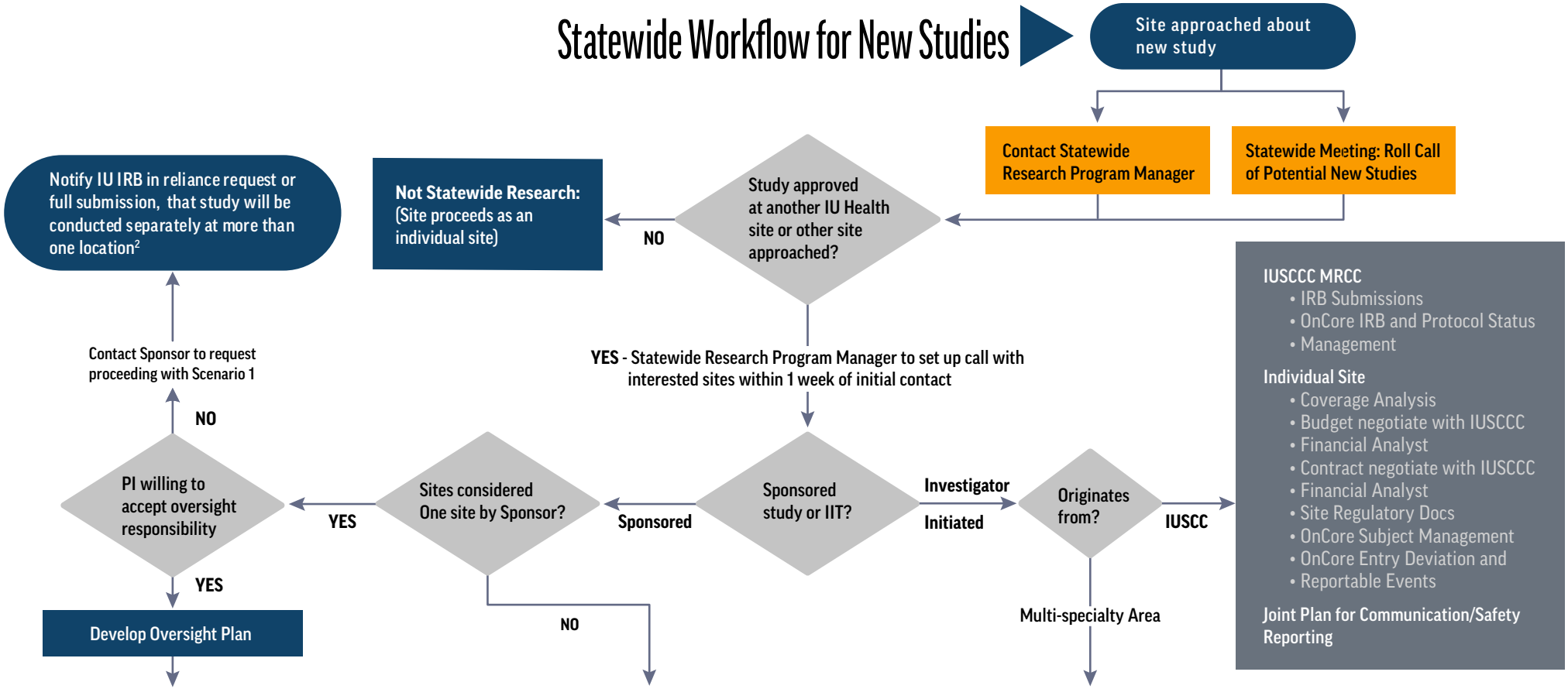
Statewide Workflow for New Studies



Scenario 2

One PI for all Sites
Satellite Sites have Lead Satellite Investigator/Lead Satellite Coordinator

SRCC or MRCC (NCTN studies):
- All IRB Submissions
- OnCore IRB and Protocol Status

Individual Site
- OnCore Subject entry by individual site
- OnCore Deviations and Reportable Events

Joint Develop Plan For:
- PI Oversight of study
- Communication/Safety Plan
- Quality Management
- CA, Budget, Contract

Scenario 1

PI at each Individual Site

SRCC :
- If Central IRB utilized, completes IU reliance request for all sites
- Resource for IRB submissions

Individual Site
- IRB submission (local or central IRB)
- OnCore IRB & Protocol Status Management
- OnCore Subject Management
- Coverage Analysis
- Budget negotiation
- Contract (work order) negotiation
- Site Regulatory Documents

**Potential for Coordination of Budget and Contract negotiation

SRC
- IRB Submissions
- OnCore IRB and Protocol Status Management

Joint Plan for Communication/Safety Reporting

Individual Site
- Coverage Analysis
- Budget negotiation with initiating site
- Contract negotiation with initiating site
- Site Regulatory Docs
- OnCore Subject Management
- OnCore Entry Deviation & Reportable Events

IUSCCC: *IU Simon Comprehensive Cancer Center*
Sponsored: *Any study that is not initiated by investigator within IU/IU Health (ex. Industry, cooperative, NIH, or other federally funded group)*
IIT: *Investigator Initiated trial*
SRCC: *Statewide Regulatory Compliance Coordinator*
NCTN: *NCI National Clinical Trials Network (ex. ECOG, NRG)*
MRCC: *Multicenter Regulatory Compliance Coordinator (IUSCCC)*

[1] *Research Assistant at Ball will complete IRB registration with Ball IRB*
[2] *The IU IRB should be notified so that safety and risk assessment will be consistent.*

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