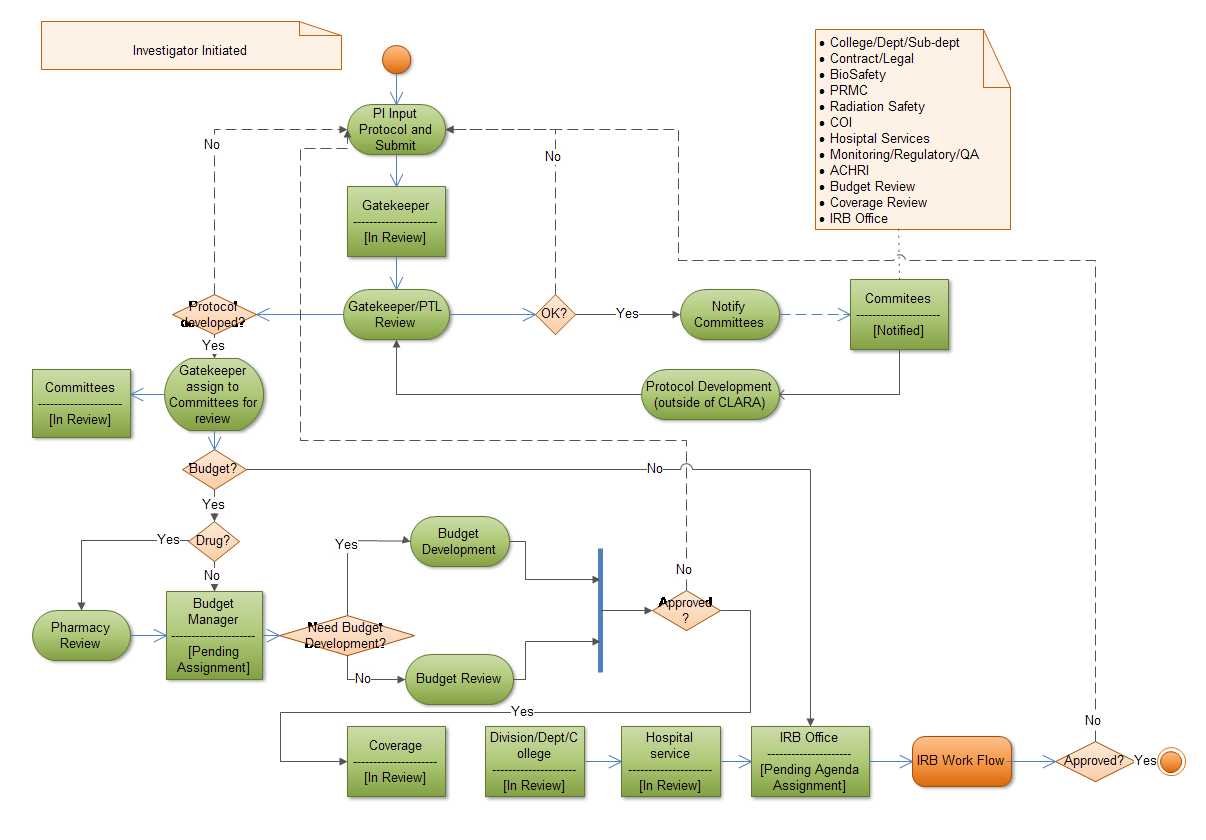
# Investigator Initiated



## PI

* 1. Input protocol and submit when finish.

## Gatekeeper

* 1. Review protocol submitted by PI. If it’s not OK, send back to PI to modify. If it’s OK, notify couple of Committees to develop the protocol.
  2. When all the notified Committees are done with Protocol Development outside of CLARA, check if the Protocol is developed properly. If not, send back to PI to modify. Else, assign the Protocol to couple of Committees for review.
  3. If the Protocol does not have Budget, send to IRB Office. If the Protocol has Budget and investigational drugs, send to Pharmacy for review. If the protocol has Budget and does not have investigational drugs, send to Budget Manager.

## Committees

* 1. When notified by Gatekeeper, start developing Protocol (ref 2.1). Send back to Gatekeeper when done.
  2. When assigned by Gatekeeper, start reviewing Protocol (ref 2.2).

## Pharmacy

* 1. Review Protocol when requested (ref 2.3).
  2. Send to Budget Manager when done with review.

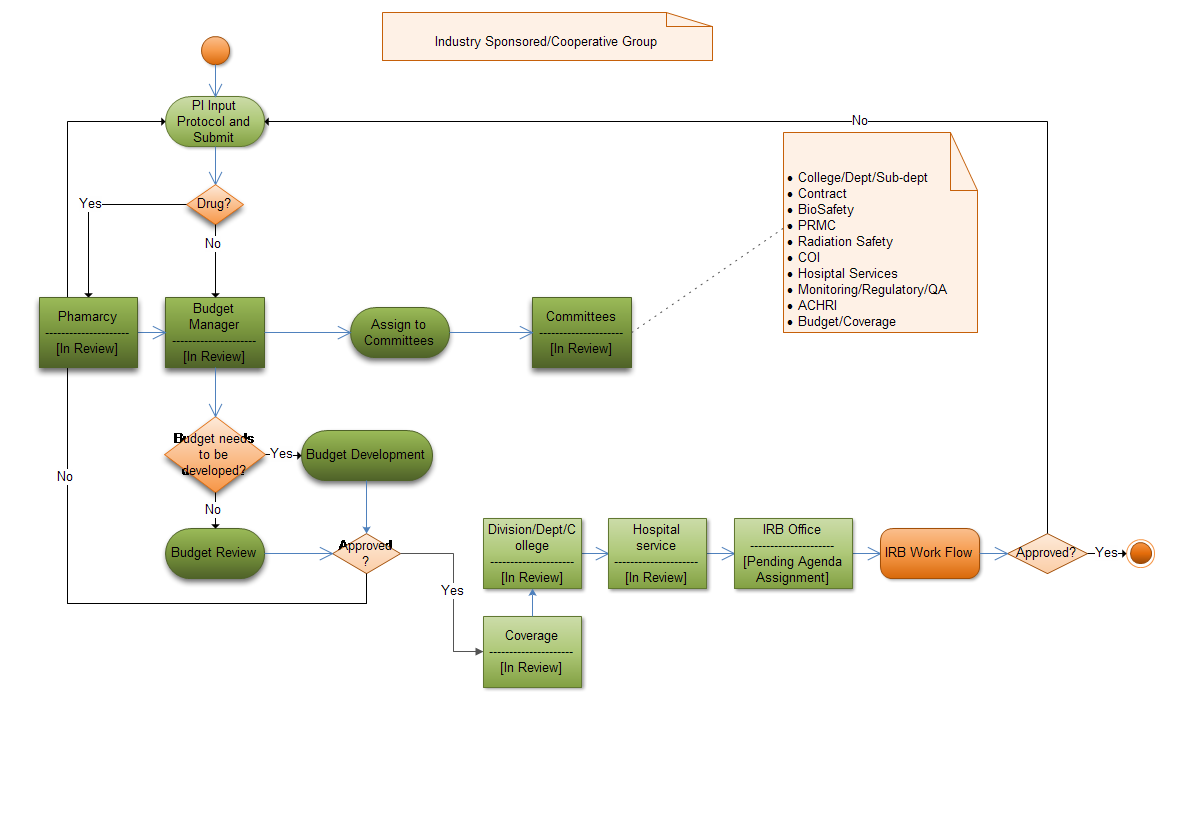
## Budget

* 1. When received from Gatekeeper or Pharmacy (ref 2.3, 4.2), check if the Budget needs developing. If it needs developing, forward to Budget Development, otherwise, forward to Budget Review.
  2. When both Budget Review and Budget Development are done, send to Coverage for review, then Division/Department/College, Hospital Service. When these Committees are done with review, send to IRB Office.

## IRB Office

* 1. When received from Gatekeeper or Hospital Service (ref 2.3, 5.2), assign to Agenda.
  2. Review the Protocol following IRB procedures (ref document IRB Procedures).
  3. Make decision. If approved, the whole work flow ends. If not approved, send back to PI.

# NOT Investigator Initiated



## PI

* 1. Input protocol and submit when finish.
  2. If the Protocol has Drugs, request Pharmacy Review. Otherwise, the Protocol goes to Budget.

## Pharmacy

* 1. Review Protocol when requested (ref 1.2).
  2. Send to Budget Manager when done with review.

## Budget

* 1. When received from PI or Pharmacy (ref 1.2, 2.2), check if the Budget needs developing. If it needs developing, forward to Budget Development, otherwise, forward to Budget Review.
  2. Assign to Committees for review.
  3. When both Budget Review and Budget Development are done, send to Coverage for review, then Division/Department/College, Hospital Service. When these Committees are done with review, send to IRB Office.

## Committees

* 1. When assigned by Budget, start reviewing Protocol (ref 3.2).

## IRB Office

* 1. When received from Hospital Service (ref 3.3), assign to Agenda.
  2. Review the Protocol following IRB procedures (ref document IRB Procedures).
  3. Make decision. If approved, the whole work flow ends. If not approved, send back to PI.