IND WORKFLOW FROM DRUG COMPANY APPROVAL TO TREATMENT

ORAQ

- ORAQ gets approval from drug company and enters into REDCap which sends out email notifications to everyone.
- FDA approval?
  - No: Email all parties. IND ends.
  - Yes: ORAQ enters the approval into REDCap which emails all parties.
- ORAQ will register in institutional database.

COORDINATOR

- The coordinator will work on the IND in the eIRB and submit.
- Coordinator is going to enter into REDCap that IRB has approved.

IRB

- IRB receives the protocol.
- Protocol is reviewed by IRB chair/board.
- IRB chair/board approves the protocol.

IDS AND MAESTRO CARE

- Emergency or Non-Emergency IND?
  - Emergency: Physician will complete the build themselves.
  - Non-Emergency: Maestro Care Analyst can begin building the order set.
- IDS starts drug preparation.
- IDS notifies Physician that the drug is ready for pick up.

ORC

- ORC will know if a contractual agreement needs to be in place based on the answer provided by ORAQ.
- A basic agreement will be put in place for all IND. ORC will reach out to Physician to determine most appropriate agreement needed.
- If the drug company refuses to put an agreement or contact in place, then no data will be released to drug company.

Physician

- Physician picks up drug from the pharmacy
- Physician treats patient.