#### **Progress Report Process-**

An alternative to continuing review, where continuing review is not required by regulation, the IRBs have the authority to require that a progress report be submitted to the JHM IRB. A progress report is an institutionally required study update that must be submitted to the JHM IRB at a designated interval. The purpose of the progress report is to ensure the study is being conducted in a compliant manner and there are no issues with the conduct of the research that would prevent continued approval. Progress reports may be required at intervals of one, two or three years from the date of initial approval. The interval will be communicated in the approval notice.

It is important to submit the progress report 6-8 weeks before the study Progress Report Due Date. This allows the IRB time to complete the review prior to the Progress Report Due Date.

### Progress Report Past Due-

If a progress report has been submitted but not approved or has not been submitted before the required progress report due date, then the study will move to a Progress Report Past Due state and no research activities, including data analysis, may continue until approval has been granted.

The Principal Investigator will have 30 days to submit the progress report past the due date before the study is administratively withdrawn.





Create Progress Report

- •PI and Study Team create Further Study Action (FSA)
- •This is the process of creating the progress report. Status of the Progress Report will be "Resercher Prep" until the PI submits the complete application. Only the PI has the ability to submit the application.

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•PI Submits Progress Report

Submit

#### **RSS Review-Pre IRB**

Pre-team IRB Coordinator/Analyst conducts a prereview.

If changes ar required, the application is returned to the study team.

# PI Response-Pre IRB

Pre-IRB reviewer notes (from pre-team IRB Coordinator/Analyst) have been sent to study team; Application requires the study team to respond and resubmit within 60 days.



Waiting Outcome

 When the Progress Report is resubmitted to the IRB, application will be assigned for review and is waiting for post team to record meeting outcome.

RSS Post Review-Post IRB  Meeting outcome has been recorded by post-team IRB Coordinator/Analyst. Post-team performs all post meeting responsibilities.



#### PI Response-Post IRB

• Application received an outcome other than "Approved or Disapproved". Post-IRB meeting reviewer notes have been sent to the study team. Application requires the study team to respond and resubmit within 60 days.

# **RSS Review-Pre IRB**

• Pre-team IRB
Coordinator/Analyst
will review study
team's response to
post meeting reviewer
notes. Once all issues
have been addressed
then application will
go through the
process again starting
at the ""Waiting
Outcome" point.







### **Outcomes**

# Approved/Acknowledged

Application is approved/acknowledged and research may begin.

# **Approved/Acknowledged with Administrative Changes**

The application requires administrative changes and re-review before final approval documents can be issued.

#### **Tabled**

The application does not meet the criteria for approval at the time of review. A letter will be issued to the PI with review issues to resolve.

# **Disapproved**

Application is disapproved. A new application must be submitted to pursue this study