



**Human Subjects**

*Office of Research*

**UNIVERSITY OF GEORGIA**

# **Noncompliance: Lapse in Approval and Past Due Progress Reports**

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# Which is Which

## Continuing Review

- Has an expiration date
- Usually more than minimal risk
- DOJ funded studies still require continuing review
- Most are STUDYs (pre-2018 Common Rule)

## Progress Report

- No expiration date
- PROJECTs
- Minimal risk
  - Exempt-5 years
  - Expedited-3 years



# Notifications

- 90, 60, and 30 day portal reminders
- Email notification that approval expired or progress report is due now
- IT Report when portal fails to send reminder



# The Process

## STUDY & PROJECT-EXEMPT

1. 2-week reminder
2. 30 days past due-public comment that study will be closed
3. 1-week later-admin close and track (RNI for federally funded)



# The Process Cont.

## STUDY & PROJECT-NonExempt Continuing Review & Progress Report

### Not Federally Funded

1. 2 week- reminder
2. 30 days past due- RNI
3. 1 week later- Dept Head letter
4. 1 week later- Create RNI for board, send to Marie to add to IRB agenda

### Federally Funded

1. 1 week- reminder
2. 1 week later- RNI
3. 1 week later- Dept Head letter
4. 30 days past due- Create RNI for board, send to Marie to add to IRB agenda



# The Process Cont.

## Full Board

### 1. Lapsed 1 day ago but less than 31 days ago

1. Email PI and copy DH
2. RNI required

### 2. 31+ days lapsed

1. Email DH and copy PI
2. RNI required
3. Goes to the board for termination



# IRB Responsibilities

- Suspension
- Termination
- Serious non-compliance
- Continuing non-compliance
- Non-compliance that neither serious or continuing



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# Thank you!



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