Communication Plan After Protocol Is Approved by WIRB

- **Initial Protocol Approval**: UVM PI must submit approval notification to the UVM IRB electronically.
- **Amendments**: Amendments and any corresponding consent changes are submitted to WIRB only. UVM IRB does not need to track amendments.
- **Continuing Review**: UVM PI is responsible to collect summary data from all sites and submit a continuing review report to WIRB. UVM IRB does not need to receive the continuing review report.
- **Unanticipated Problems (UAP)**: UVM PI must submit any local UAPs meeting UVM IRB criteria to the UVM IRB electronically.
- **Noncompliance**: UVM PI must notify UVM IRB staff regarding any local or study-wide noncompliance issue that potentially affects risk to subjects or others.
- **PI or Key Personnel Changes**: Any UVM key personnel changes must be submitted electronically and approved by the UVM IRB.
- **Protocol Closure**: UVM PI must notify the UVM IRB when the protocol closes.
- **UVM PI is required to send to WIRB all the submissions in yellow. UVM PI is required to submit a subset of these submissions to UVM IRB as well to meet our oversight responsibilities.**

**UVM**

- UVM PI must submit approval notification to the UVM IRB electronically.