Guide to IRB research milestones for continuing reviews

(Please note: any other combinations of selected milestones than those described below will result in clarifications requested. These milestones are based on current FDA guidance regarding continuing reviews.)

1. Study is open to enrollment:

(Continuing Reviews for greater than minimal risk studies in this state will be reviewed at a Full Committee IRB meeting.)

Research milestones: (select all that apply)

☐ Study is permanently closed to enrollment OR was never open for enrollment
☐ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
☐ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
☐ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
☐ Remaining study activities are limited to data analysis
☐ Study remains active only for long-term follow-up of subjects

2. Study is permanently closed to enrollment but subjects are still actively participating:

(Continuing Reviews for greater than minimal risk studies in this state will be reviewed at a Full Committee IRB meeting.)

Research milestones: (select all that apply)

☐ Study is permanently closed to enrollment OR was never open for enrollment
☐ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
☐ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
☐ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
☐ Remaining study activities are limited to data analysis
☐ Study remains active only for long-term follow-up of subjects
3. Study is permanently closed to enrollment, all subjects have completed all study-related interventions, and activities are limited to data analysis:

(Continuing Reviews for greater than minimal risk studies in this state are eligible for expedited review and do not need to be reviewed at a Full Committee IRB meeting.)

**Research milestones:** (select all that apply)
- ✔ Study is permanently closed to enrollment OR was never open for enrollment
- ✔ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- ✔ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ✔ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ✔ Remaining study activities are limited to data analysis
- □ Study remains active only for long-term follow-up of subjects

4. Study is permanently closed to enrollment, all subjects have completed all study-related interventions, and the study is active only for long-term follow-up of subjects:

(Continuing Reviews for greater than minimal risk studies in this state are eligible for expedited review and do not need to be reviewed at a Full Committee IRB meeting.)

**Research milestones:** (select all that apply)
- ✔ Study is permanently closed to enrollment OR was never open for enrollment
- ✔ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- □ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- □ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- □ Remaining study activities are limited to data analysis
- ✔ Study remains active only for long-term follow-up of subjects
5. Study is permanently closed to enrollment, all subjects have completed all study-related interventions, and the study is active only for long-term follow-up of subjects and data analysis:

(Continuing Reviews for greater than minimal risk studies in this state are eligible for expedited review and do not need to be reviewed at a Full Committee IRB meeting.)

**Research milestones:** (select all that apply)

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g., study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects

6. Study is permanently closed to enrollment, all subjects have completed all study-related interventions, collection of PHI is complete, and analysis of PHI is complete (study closure):

(Checking these milestones is considered a study closure. Closures are done via an expedited review and do not need to be reviewed at a full committee meeting.)

**Research milestones:** (select all that apply)

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g., study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long-term follow-up of subjects