Purpose

This document outlines the processes and/or workflow that should be followed in order to receive automatic notifications from Velos to facilitate updating the study record on https://register.clinicaltrials.gov to maintain compliance with federal regulations (42 CFR § 11.64(A)(1)(ii)). Compliance with maintenance of the study record is required for all studies, even those that were voluntarily registered.

Best Practices

- Develop and maintain a workflow that facilitates the updating of participant and study status in Velos throughout the participants study cycle.
- Ensure that participant and study status in Velos is kept current.
- Create a responsibility matrix that describes the handoff process between the individual receiving the automatic notification and the individual who is responsible for updating the record on https://register.clinicaltrials.gov.
- Where feasible include the 'required' participant and study status changes for Velos in the onboarding process for new study team members.
- Indicate the following Participant and Study statuses in Velos to receive all automatic notifications.

Trigger	**Change Recruitment Status in ClinicalTrials.gov** *(when both the participant and study status in Velos are equal to the below and the first participant is **'ICF Signed'**)*	**Change Study Start Date in ClinicalTrials.gov** *(when both the participant and study status in Velos are equal to the below and the first participant is **'Enrolled'**)*	**Change Primary Completion Date in ClinicalTrials.gov** *(when both the participant and study status in Velos are equal to the below and the last participant is **'Off Treatment'**)*	**Change Study Completion Date in ClinicalTrials.gov** *(when both the participant and study status in Velos are equal to the below and the last participant is **'Off Study'**)*
Participant Status	ICF Signed	Enrolled	Off Treatment	Off Study
Study Status	Active / Enrolling	Active / Enrolling	Active / Closed to Enrollment	Study Completed

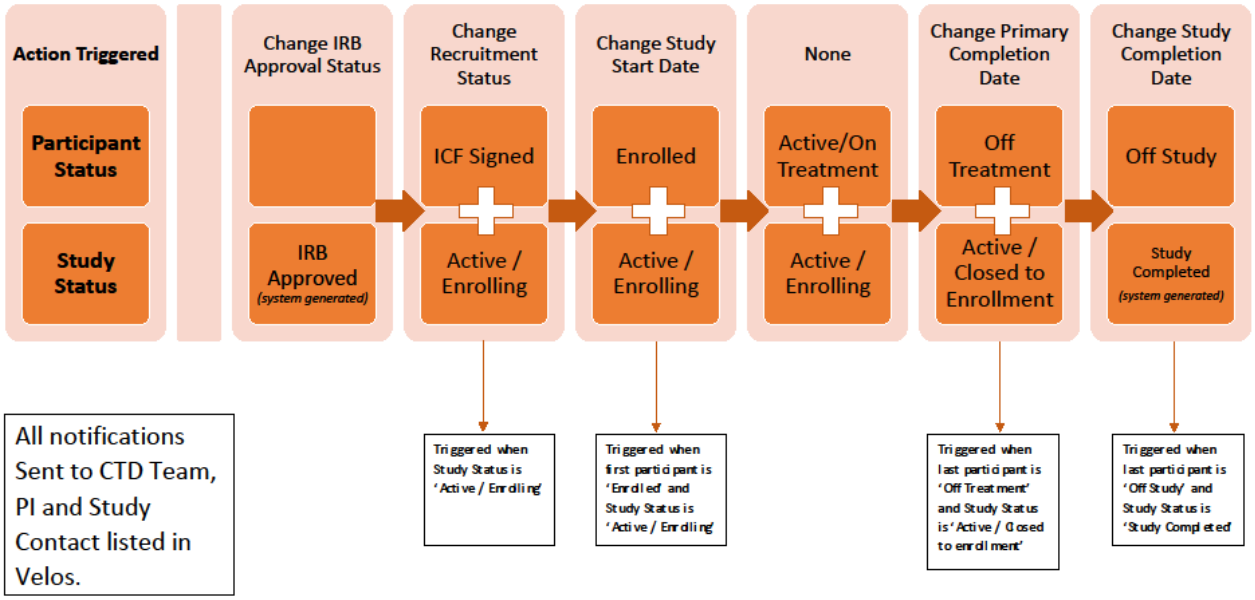

Figure 1 Best Practice Status Flow – double click to enlarge

Minimum Standards

- Identify who should receive the automatic notification by indicating in Velos who is the primary study contact. Ensure that the individual, who is responsible for updating the record, receives the notification if they are not the primary study contact recorded in Velos.
- Ensure that the individual responsible for participant and study updates in Velos is trained on the process.
- Indicate the following Participant and Study statuses in Velos for the minimal triggers

Trigger	Change Recruitment Status *(when both the participant and study status in Velos are equal to the below and the first participant signed ICF)*	Change Study Completion Date *(when both the participant and study status in Velos are equal to the below and the last participant is off study)*
Participant Status	ICF Signed	Off Study
Study Status	Active / Enrolling	Study Completed

- Ensure that the individual who receives the automatic notifications has access to the record on https://register.clinicaltrials.gov.

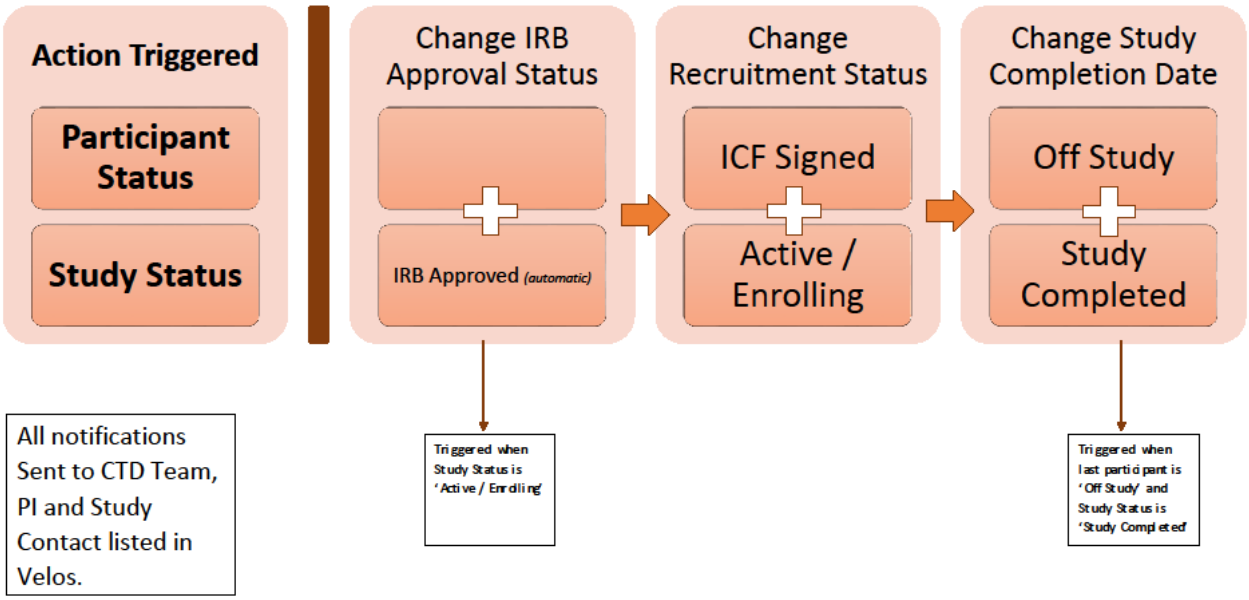

Figure 2- Minimum Standards Status Flow – double click to enlarge

Recommended SOPs, Guidance Documents, or Workflows to facilitate process

The CTD group can assist you with the creation of any of the items below. You can request assistance by emailing them at ctgovum@miami.edu.

- Participant Study Status – *An SOP or guidance document that outlines the minimum participant study status that will be completed in Velos for each participant in a clinical trial.*
- Onboarding Checklist for study coordination – *A checklist that facilitates the process through which new hires learn the knowledge and skills required to function effectively within an organization.*
- Responsibility Matrix – *A document that defines who in the department/center/institution is responsible for individual work elements and deliverables.*

Considerations

- Screening and Enrollment Log can be easily provided from Velos
- Facilitate compliance with Patient Enrollment Policy
- Facilitate billing compliance
- Assist with improving data integrity for your clinical trials

Definitions

Term / Abbreviation	Definition
41 CFR § 11	The Final Rule for Clinical Trials Registration and Results Information Submission, which clarifies and expands the requirements in FDAAA Section 801.
Active / Closed to Enrollment – Study Status	Status that stops patient accrual on the study, while study activities for existing patients continue.
Active / Enrolling – Study Status	Status that allows patient accrual on the study, while study activities are continuing.
Active/On Treatment – Participant Status	First day intervention administered
Best Practices	Additional steps from those indicated in the minimum standards, which might lead to higher efficiency and quality, maintaining compliance with Clinical Trial Disclosure regulations and requirements, while possibly lowering the risks for potential public notices of non-compliance, civil monetary penalties and the ability to publish.
CTD	Clinical Trial Disclosure
CTD Team	Clinical Trial Disclosure Team
Enrolled - Participant Status	Participant met all inclusion/exclusion criteria
FDAAA 801	Food and Drug Administration Amendment Act Section 801 which provides details on clinical trial registration and results submission requirements
GCTDP	Good Clinical Trial Disclosure Practices
Informed Consent Form Signed – Participant Status	Status that indicates the date a research subject consented to participate in the study. This status may also include additional details regarding the consent process (i.e., version of consent signed, study team member involved with consent process, etc.) and is used for re-consenting subjects on the same study.
IRB Approved – Study Status	Status that indicates the Institutional Review Board's determination of approval of the study.

Term / Abbreviation	Definition
Minimum Standards	Steps that at minimum should be taken to facilitate compliance with Clinical Trial Disclosure regulations and requirements
Off Study – Participant Status	When participant completed, withdrawn from, or has been terminated from all predefined study visits or unscheduled visits
Off Treatment – Participant Status	Per protocol, the last assessment of the participant to measure the primary outcome.
Participant	A person who takes part in the clinical trial
Primary Study Team Member	Individual classified in Velos as Primary Contact
PRS	Protocol Registration and Result Reporting System
SOPs	Standard Operating Procedures
Study Completed – Study Status	Status that indicates all study documentation, participant activities, and administrative tasks have been completed, all study related data has been locked and the study is now closed.
Trigger	A change in status that will cause an automatic notification to be sent from Velos to primary study team member
Velos	An electronic Clinical Trial Management System

References

- HSR-P-101 Clinical Trial Disclosure Protocol Registration
- Food and Drug Administration Amendment Act Section 801: 2007
- 42 CFR § 11: Clinical Trial Registration and Result Reporting

Contributors

Yolanda	Davis	*Clinical Trial Disclosure Manager, Research Compliance and Quality Assurance*
Cesar	Gavidia	*IT Project Specialist, Office of Research Information Technology (RIT)*
Thomas	Iglesias	*Clinical Research Coordinator, Clinical Research Center & Regulatory Support*

Cristy	Lage-Rodriguez	*Clinical Research Coordinator, Ophthalmology - Research*
Danny	Leal	*Sr. Programmer, Office of Research Information Technology (RIT)*
Terry	Lynch	*Project Manager, IT, SCCC - Informatics Application Management*
Henry	Manfrediz	*Manager, Information Technology, Office of Research Information Technology (RIT)*
Crystal	Noller	*Post Doctoral Associate, Miami Project to Cure Paralysis*
Heather	Osorio	*Clinical Trial Disclosure Compliance Specialist, Research Compliance and Quality Assurance*
Constanza	Pelusso	*Manager, Research Support, Otolaryngology - Chairman*
Marietsy	Pujol	*Sr. Regulatory Specialist, Interdisciplinary Stem Cell Institute (ISCI)*
Kanchan	Sakhrain	*IT Project Specialist, Infrastructure and Operations*
Smitha	Shetty-Hiliyani	*Sr. Systems Analyst, Office of Research Information Technology (RIT)*
Raquel	Zamora	*Manager, Information Technology, Office of Research Information Technology (RIT)*