

Project Enrollment Tracker



Set-up Procedure

Once a Notice of Award (NOA) is issued for a clinical trial the Sponsored Research Administrator (SRA) will develop a project enrollment tracker template.

Your SRA will be responsible for the following:

1. Create a study specific folder for the project enrollment tracker in the Project Enrollment Tracking Folder on the P drive found here: P:\Clinical Research\Project Enrollment Tracking. The folder will be labeled by PI last name, PI first name, and Short Title.
2. The schedule of events budget will be sheet 1 and should NOT be edited, this will only serve as a reference.
3. The tracker for patient 1 will start on sheet 2. Your SRA will set up sheet 2/ patient 001
4. The budget and the 1st sheet of the tracker will include the following: title, sponsor, patient identifier, activity number, PI name, coordinator name, Period of Performance dates, and the number of patients.
5. A row will be added at the top of the schedule labeled "Date of Visit" and at the bottom of the schedule labeled "Total Due to CHOA".
6. Add legend at the bottom of spreadsheet and use the following acronyms:
Not Completed=NC
Missed Visit=MV
Make up visit =MUV Add comment to the notes section
7. SRA will be in contact with the coordinator to provide the tracker.

The Coordinator will be responsible for the following:

The research coordinator will be responsible for updating the tracker after each patient visit.

Find their Project Enrollment Tracker in the Project Enrollment Folder on P drive P:\Clinical Research\Project Enrollment Tracking

1. The tracker will be located in a folder labeled with the PI last name, PI first name, and Short Title.
2. Keep the approved budget as first sheet in the spreadsheet. DO NOT delete or edit.
3. Start on the 2nd sheet for the first enrolled subject, labeling the name of the sheet with the patient identifier and create a new sheet for each enrolled subject. Update each sheet at the top with the appropriate patient identifier.
4. Be sure to keep the procedure amounts in the cells. (DO NOT use X's)
5. Be sure to keep the CPT codes.

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6. Add notes section at the bottom. (DO NOT use highlights or colors to indicate a note, clearly write out in comments section)
7. For each patient visit, enter the date in the tracker and verify that all procedures were completed. This should be done within 24 hours of the completed visit.
8. If there was a procedure not completed during the visit enter NC = not completed. in the appropriate row that corresponds to the procedure in the appropriate visit date column.
9. There should be NO patient information included on the project enrollment tracker (i.e. date of birth, name, medical record number, etc.)
10. If applicable, add an IRB sheet to track the initial and continuing IRB fees, monitoring visits. Etc. Please confirm with your SRA if this is needed. (See Example below)

Procedure Name	Total Charge	20XX	20XX	20XX	20XX	20XX
<i>IRB Initial Approval Fee</i>	1,500.00	1,500.00				
<i>Continuing Review Fee</i>	750.00		750.00	500.00	500.00	500.00
<i>Monitoring Visit</i>						
<i>Total Due to CHOA</i>		1,500.00	500.00			

11. Coordinators should contact their Research Admin contact for questions about completing the tracker.