

NIH ETHICS INFORMATION MANAGEMENT SYSTEM (EMIS)

Protocol Review

Clinical protocols require review and clearance by the Deputy Ethics Counselor (DEC) of the protocol Principal Investigator (PI), i.e. the Institute/Center (IC) ethics office, or NIH Ethics Office (NEO) if the PI is senior, “top 5”. If there are two PIs from different ICs, and one is a senior, “top 5” employee, the NEO shall review the protocol. If neither PI is a senior, top 5 employee, the ethics office staff for the first PI listed will conduct the review. It must be clear that the employees involved in the protocol hold no financial interests which can be affected by the protocol being reviewed. Ethics Office staff will identify whether there are real or potential conflicts between the financial interests of NIH employees listed on the protocol and the products being studied. Instructions for conducting the review are available separately. The protocol information shall be entered into the Principal Investigator’s EMIS record only.

Enter a new record each time a protocol is reviewed. Each review may be a different type, e.g., the first review is for a new protocol, then there may be a supplement, and annual continuing reviews.

Add/Edit/Save Data: Instructions for each field are in the table below. When a new record is created and saved, the option at the bottom of the screen is *Save*. When a current record is opened and edited, the option is *Update* at the bottom of the screen.

Delete: To delete a record, open the record and click on *Delete* at the bottom of the screen. Click on *Yes* in the confirmation window.

Name of Field	Enter the Following Information
EMIS ID	Non-editable internal database identification number for the record.
Receipt Date	Enter the date you received the protocol for review. Date format is mmddyyyy or m/d/yy.
Expedited Review?	Choose yes or no from the drop-down list.
Protocol Number	Enter the number from the protocol cover sheet.
Protocol Type	Choose the type as indicated on the Protocol COI Statement: New, Renewal, Amendment, or Supplement Note that an amendment is a type of continuing, but not all continuing are amendments. An amendment means that something changed (investigator, drug, other change).
Type of Study	Choose the type of study as indicated on the COI Statement for Type of Protocol. If no option applies, choose Other. Drop-down list options: Natural History Other Pharmakokinetics Phase 0 Phase I Phase II Phase III Phase IV Screening Training
To Specialist	Date assigned to Specialist; dd/mm/yy format.

Name of Field	Enter the Following Information
Specialist	Specialist's name (last name, first initial).
Spec Review	Date Specialist completes the review; dd/mm/yy format.
Mgmt Review	Date management completes the review; dd/mm/yy format.
To DEC	Date forwarded to the DEC; dd/mm/yy format.
DEC Clearance	Date of DEC's decision and signature; dd/mm/yy format.
COI Identified?	Means initial assessment. Indicate No if no conflict identified. Indicate Yes if conflict identified, even though it is resolved later.
Resolution Type	When first entering data, choose Pending. After DEC clearance, change it to the appropriate option. If No is indicated for the field above, no action is required for this field. Options include: Pending Divestiture: may indicate relevant facts in Notes Waiver Resignation: Normally means resignation from the protocol, though if the employee resigns from the IC due to conflict, it also applies. Annotate in Notes if this happens. Other (See notes) Not Applicable Removal
Returned to PI	Date returned to the protocol PI.
Notes	Add relevant information, e.g., how a COI was resolved. Examples: AI w/ conflict, reassigned off the study. (Note in this case you would also enter an EMIS record for that Associate Investigator under the Other Actions form.) Holds Merck, direct competitor, must divest (Note in this case you would enter divestiture information into EMIS under the Other Actions form.)

Upload Files: This function permits you to upload files and attach them to the open record. At the bottom of the screen, click on *Browse*; locate the desired file; double click the file name; add a description of the attachment. Attachments may be pdf, Word, or other formats. However, pdf is preferred to guarantee that others will be able to open the file in the future. Files shall be named as follows, truncating as needed:
Employee-hyphen-Number-hyphen-Initial for type-hyphen-Clearance date.pdf

Type of protocol identifier:

- N** for new
- A** for amendment
- C** for continuation
- S** for supplement

For example, Dr. Indiana Jones's amendment to protocol number P04212014 is cleared on April 23, 2014. The file will be named: JonesI-PR04212014-A-2014-23-04.pdf

Document History:

File Name: Q:\EMIS\SOPs\Employee-Forms\Protocol-Data-Entry.doc

2/16/08 Original SOP posted. NEO (FEPlyler)

3/18/13 Revised with new fields and naming convention. FEPlyler

4/21/14 Revised. Updated logo and field instructions. NEO (C.Galvin-Combet)