



National Institute of
Neurological Disorders
and Stroke

**OFFICE OF CLINICAL RESEARCH
RECRUITMENT PLANNING & MONITORING**

**STANDARD OPERATING PROCEDURE
FOR
E-MAIL RECRUITMENT ENROLLMENT**

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Version 3.1

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PURPOSE

This Standard Operating Procedure (SOP) supports the electronic e-Mail enrollment process for clinical trials managed by the RPM team. It describes how clinical sites shall submit subject enrollment information from the clinical sites to the RPM for tracking and monitoring purposes.

The NINDS Office of Clinical Research bears the responsibility for overseeing awarded clinical studies and the management of efficient, effective, and expedited clinical research. The defining mission of the RPM project is:

To accelerate the development and delivery of advances in treatments of protocols to individuals suffering from neurological disorders by:

- ***Encouraging and supporting efficient, effective, and expedited clinical research***
- ***Supporting improved ability of PIs to achieve accrual targets and diversity estimates***

The primary purpose of collecting this enrollment data is to allow the NINDS staff responsible for managing the awarded clinical studies to better support PIs in achieving accrual targets and diversity estimates. The clinical site submits e-mail enrollment reports with the required details with specified required syntax at the specified e-mail address for proper and accurate enrollments.

APPROACH

There are many ways in which enrollment data can be collected from the various data collection units (DCUs) supporting clinical trials. The NINDS team examined many options with particular respect to critical selection factors and determined the solution must be:

- Easy for DCU's to implement and maintain.
- Easy for NINDS to process enrollment data in a fashion that conforms to NIH and NINDS security guidelines and restrictions.
- Support many different types of hardware, software, and database platforms.

After careful examination and with the guidance and approval from the NINDS DER Office of Clinical Research, the NINDS team opted for an e-mail submission interface with an encoded data string that will be accessed and interpreted at NINDS for storage and reporting. It addresses all the critical issues raised and lends itself to flexibility, simplicity, and portability. The remainder of this document discusses the data that shall be collected and the specific syntax that must be followed for proper submission.

THE E-MAIL STRUCTURE

The goal of the e-mail is simply to communicate to the NINDS RPM team that a study has enrolled an additional subject at a specified site that meets the noted gender, race, and ethnicity values provided, if known upon submission. The guidelines for formatting the e-mail are as follows:

HEADER:

TO:	NINDSDER-ClinicalTrialsRecruitment@mail.nih.gov This is the target e-mail address for your submission. It is an internal unpublished address.
SUBJECT:	The NINDS would prefer something like "RPM Enrollment", "New RPM Enrollment", or "Today's Subject Randomization"; HOWEVER, you can name the subject with whatever best fits your system for tracking.

BODY:

To provide flexibility and security for reporting, the body of the enrollment email can accept one or more enrollment records per email. Each enrollment record is delimited by a semicolon and must appear in the following format:

SYNTAX: STUDY_ID, SITE_ID, RECORD_ID, GENDER, RACE, ETHNICITY, ENROLL_DATE, RECORD_TYPE;

REQUIREMENTS:

- Individual fields within a row **MUST** be delimited by a comma and **MUST APPEAR IN THIS ORDER**.
- Each row **MUST** be delimited by a semi-colon, ";".

As part of the "encoding" of the email, no indicators as to the order of fields or what they represent should appear in the email or is needed in the email. The format of the data contained in these fields is described below:

FIELD	DESCRIPTION	FORMAT / VALID VALUES
STUDY_ID	MANDATORY. Contains the IC/Serial number for the NINDS awarded grant associated with the clinical study. It is available on the NGA or from the NINDS Recruitment Coordinator.	NS123456
SITE_ID	MANDATORY. Contains the NINDS supplied Site Number . A list of a Study's participating sites and Site Numbers shall be provided to the DCUs for each Study they support.	9999
RECORD_ID	MANDATORY. Contains a number that uniquely identifies this record within this Study and Site combination IN YOUR SYSTEM . It shall identify this record if a record update is necessary to add or correct data. E.g. this can be the Subject Number assigned by the DCU for the patient in the Study and Site.	Alphanumeric up to 10 characters
GENDER	Indicator for the subject's identified gender, if provided. If the subject did not provide one, the system will assume "4" (Not provided)	1 = Male 2 = Female 3 = Unspecified / Unknown 4 = Not Provided (DEFAULT)
RACE	Indicator of the subject's identified race code, if provided. If not provided system will assume "9" (Not provided)	1 = American Indian / Alaska Native 2 = Asian 3 = Black / African American 4 = Caucasian / White 5 = Hispanic / Latino 6 = Native Hawaiian / Pacific Islander 7 = More than 1 8 = Unknown / Withheld

		9 = Not Provided (DEFAULT)
ETHNICITY	Indicator for Hispanic/Latino status. If not provided system will assume "2" (Not Hispanic/Latino)	1 = Hispanic/Latino 2 = NOT Hispanic/Latino (DEFAULT)
ENROLL_DATE	MANDATORY. This indicates the subject enrollment date encoded as the number of days from July 04, 2001. e.g. July 04, 2001 is Day 0, July 5, 2001 is Day 1, etc.	3866
RECORD_TYPE	<p>MANDATORY. Indicates how a given enrollment record is to be processed by the RPM system. The RECORD_TYPE is used along with the STUDY_ID, SITE_ID, and RECORD_ID to record or change a specific enrollment record.</p> <ul style="list-style-type: none"> • NEW (value = 1) is used for a new enrollment record with a new RECORD_ID • UPDATE (value = 2) is used when information previously reported for the RECORD_ID is being changed in some way (e.g. when gender, ethnicity, or race are clarified). • DELETE (value = 3) is used when an existing enrollment record identified by the RECORD_ID is being removed from the system because it was entered in error (e.g. with the wrong Site ID or for a person that did not qualify or other reason). It should not be used for a patient Lost to Follow-up, Withdrawn or otherwise refusing to participate. • EXCLUDED (value = 4) is included as an option to indicate screen failures that have been enrolled (as defined by a particular study) and have since been excluded. <ul style="list-style-type: none"> ○ It is NOT to be used to indicate Lost to Follow-Up, Withdrawn, or otherwise refusing to continue participation. ○ It is not necessary to first submit a record as a "1" and then change it later to a "4". The system can accommodate records that arrive as "4" without having first been submitted as a "1." This allows flexibility for those studies that only submit once or twice per month. 	1 = NEW 2 = UPDATE 3 = DELETE 4 = EXCLUDED*

NOTE:

Study teams are allowed to define enrollment date per the needs of individual studies. For some studies, this may be equal to the date a subject is consented. For other studies, this may be equal to the day a subject is randomized, which may be some length of time after consent has occurred to allow for any necessary screening.

OPERATING TIPS:

1. TO REDUCE ERRORS:

- a. All fields listed as **MANDATORY** in the above table **MUST BE INCLUDED in each enrollment record**. Failure to include any one of the mandatory fields will stop the processing of the enrollment submission.
- b. Field values **MUST APPEAR IN THE EXACT ORDER LISTED ABOVE**. Any deviation from this order will result in a processing error.
- c. To reduce visible meaning to the data, **INCLUDE ONLY THE FIELD VALUE**. **Do not include the field name**.
- d. Separate EACH FIELD with a comma. If a field lacks a value, simply include the comma to save the space.
- e. Separate EACH RECORD (if more than one is included) with a semicolon.
- f. Please ensure that you submit encoded values according to the listed valid values.
- g. Please ensure the email format is "plain text." HTML and Rich text formats cannot be read by the system.
- h. The following characters must not be included in the **subject line** of the email:
\$, @, /, \, ~, !, #, %, ^, *, +, =, {, }, |, or ?

2. SUBMISSION FLEXIBILITY:

- a. The syntax above illustrates how to structure and submit an email for a single enrollment record. However, the e-mail BODY may contain multiple enrollment records provided each conforms to the noted syntax and appears on its own line.
- b. **SUBJECT-LEVEL SUBMISSION:** the simplest implementation of the enrollment recording.
 - i. When a subject is enrolled in a study at a site, the DCU simply forwards an enrollment e-mail according to these guidelines.
 - ii. When a subject record is corrected or enhanced in the DCU, another enrollment email shall be sent with the corrected data where the RECORD_TYPE indicates an UPDATE and RECORD_ID, STUDY_ID, and SITE_ID identify the target record.
- c. **DAILY SUBMISSION:** this flexibility allows you to bulk submit enrollment records added or updated on a given day to minimize the number of emails you send, if desired.
 - i. The HEADER syntax is the same, and while the syntax of each enrollment record in the BODY remains the same also, you can include more than one enrollment record; e.g. one for each subject record added or updated this day.
 - ii. This approach might be desirable to DCUs wishing to minimize the volume of emails sent out or group submissions on a daily basis.
- d. **WEEKLY SUBMISSION:** this flexibility allows you to bulk submit enrollment records added or updated within a given week to minimize the emails you send, if desired.

- i. The HEADER syntax is the same, and while the syntax of each enrollment record in the BODY remains the same also, you can include more than one enrollment record; e.g. one for each subject record added or updated this week.
 - ii. This approach might be desirable to DCUs wishing to minimize the volume of emails sent out or group submissions on a daily basis.
- e. **REPLACEMENT SUBMISSION:** the system shall support the submission of a complete set of enrollment records for a Study as a means of maintaining consistency and data integrity between the NINDS repository and the DCU repository. The replacement submission shall result in a complete replacement of ALL enrollment records at NINDS for the noted Study with the enrollment records contained in the replacement set.
- i. **SYNTAX:** to send a replacement submission, simply preface ALL enrollment records with the following line:
 1. **REPLACE, NS123456;**
where the NS123456 represents the NINDS Study ID whose enrollment data is contained in this email submission.
 - ii. **REQUIREMENTS:**
 - This line **MUST APPEAR BEFORE ANY** enrollment records
 - The fields must be delimited by a comma and **APPEAR IN THIS ORDER.**
 - This line must be delimited by a semi-colon, “;”.
 - Each Replacement Submission shall operate on **ONLY ONE STUDY.**
 - Each enrollment record shall follow the SAME FORMAT noted above.
 - Each enrollment record shall have a RECORD_TYPE of 1 (NEW) or a 4 (EXCLUDED). Since the replacement set will replace all data, records that were deleted will just not appear in the new set and those updated should now contain the updated data in the new set with RECORD_TYPE of 1 (NEW) or a 4 (EXCLUDED).

PROTECTED HEALTH INFORMATION (PHI) & PERSONALLY IDENTIFYING INFORMATION (PII) CONCERNS

For some studies (e.g. those in newborns/neonates), we understand that the date of enrollment may be very close or equal to the date of birth. This may be a cause for concern regarding the sharing of PHI/PII. Therefore, for studies in which this is the case, the NINDS Office of Clinical Research encourages you to consider options for coding the date of enrollment such as:

- Assign all enrollments in a given month to a specific day in that month (e.g. the first day of the month in which they are enrolled)
 - Using the first day of the month will ensure that no enrollments appear to have occurred in the future when they are submitted to the system and will allow the data management team to submit the enrollment data at any time during the month
- Assign random dates in a given month to all enrollments in that month and send a replacement set on the first day of the following month

QUALITY ASSURANCE PROCESS

In order to ensure the highest possible level of data quality, and to ensure that the data in the monitoring system matches the study team's data, it is recommended that a full replacement data set be sent to the system no less frequently than every 6 months.

For studies that choose to use the **REPLACE** function for all submissions, this additional step is not necessary.

However, for those studies that have chosen to submit incremental enrollment data (whether real-time, weekly, bi-monthly or monthly), ***we strongly encourage you*** to select a frequency (quarterly, biannually) to submit replacement data sets to the system. This will serve as both a quality control and quality assurance mechanism.

SAMPLE E-MAIL ENROLLMENT NOTIFICATIONS

Sample #1 – By Subject

From: OUR_COLLECTION_UNIT@UniversityOfClinicalTrials.edu

To: NINDSDER-ClinicalTrialsRecruitment@mail.nih.gov

Subject: New enrollment today

NS027713, 72, 1011, 1, 1, 2, 3866, 1;

Sample #2 – Daily

From: OUR_COLLECTION_UNIT@UniversityOfClinicalTrials.edu

To: NINDSDER-ClinicalTrialsRecruitment@mail.nih.gov

Subject: Daily RPM Entries

NS027713, 72, 1011, 1, 1, 2, 3866, 1;

NS027713, 72, 1012, 1, 1, 2, 3866, 1;

Sample #3 – Weekly

From: OUR_COLLECTION_UNIT@UniversityOfClinicalTrials.edu

To: NINDSDER-ClinicalTrialsRecruitment@mail.nih.gov

Subject: Weekly RPM Enrollments

NS027713, 72, 1011, 1, 1, 2, 3866, 1;

NS027713, 72, 1012, 1, 1, 2, 3868, 1;

NS027713, 72, 1013, 2, 5, 2, 3869, 1;

Sample #4 – Replacement Submission

From: OUR_COLLECTION_UNIT@UniversityOfClinicalTrials.edu

To: NINDSDER-ClinicalTrialsRecruitment@mail.nih.gov

Subject: Replacing Study Contents

REPLACE, NS027713;

NS027713, 72, 1011, 1, 1, 2, 3866, 1;

NS027713, 72, 1012, 1, 1, 2, 3868, 1;

NS027713, 72, 1013, 2, 5, 2, 3869, 1;