Standard Operating Procedure (SOP)

SOP number SOP CW AHC 254	**SOP Name** Release of Suppressed Research Notes in the EMR to AdventHealth App (Patient Portal)
Location *Company-Wide Policies	**Responsible Department** Research Services
SOP Owner/Executive Owner Executive Director of Research Services	**Original Creation Date** 11/17/2022
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I. **SCOPE:** This standard operating procedure (SOP) applies to all AdventHealth Investigators and Research Personnel who document research notes in the electronic medical record (EMR).

II. **PURPOSE:** This SOP is intended to explain the process and timing for the release of research specific suppressed notes in the EMR to AdventHealth App (the Patient Portal).

III. **QUALIFIED PERSONNEL:** Research Personnel

IV. **TRAINING:** EMR access and applicable research related training in EMR.

V. **SUPPLIES & EQUIPMENT:** EMR

VI. **PROCESS/PROCEDURE:**

A. The research specific note type in the EMR is intended for documentation related to an individual's research participation. This research visit documentation should only consist of information related to the study and should not include any information required for the diagnosis or treatment of the patient. The research specific note type default setting automatically suppresses any sharing of the note to the AdventHealth App (patient portal). The suppression of research related notes is due to the potential risk of jeopardizing the integrity of the study by sharing study related information that could possibly bias the participant regarding their experience in the study or possibly even inadvertently unblind the participant to their study randomization assignment. During the patient's participation in the study and while the study is active, the suppression of these notes is considered to fall under the "Infeasibility Exception" of the 21st Century Cures Act, as an exception to information blocking provisions for not fulfilling requests to access, exchange, or use electronic health information (EHI). Patients are informed during the informed consent process they will not have access to study related notes until after the completion of the study.

B. The process for releasing the research specific suppressed notes is as follows:

1. When the study is closed and Termination of IRB Approval is finalized, the "Infeasibility Exception" for research no longer applies. The study team must determine if any other exceptions apply to continue to suppress the notes (see Exception(s) section) and only release notes per what is expected and standard in clinical practice. If other exceptions that may affect patient care are suspected, the Principal Investigator should communicate with the treating Physician or Primary Care Provider to make determinations. If no more exceptions apply, the suppressed notes must be released

within 30 days of study closure.

2. Upon Termination of IRB Approval and closure with an external study sponsor, if applicable, the designated study team member may release all research specific notes for a specific study at once in a batch fashion in the EMR.
3. In the EMR, navigate to the report, "Notes Withheld from Patient for Research Reason" and run the report.
4. Filter the report by study, navigate to the closed study of which you wish to release all suppressed notes, select that study and click to select all patients.
5. Click "Update Share with Patient", then select "Accept" in the text box that pops up.
6. These actions will release the previously suppressed notes for all patients to the AdventHealth app for patients in the selected study giving them access to the research notes.

VII. DEFINITION(S):

For capitalized terms not defined in this SOP, refer to CW AHC 107 Definitions in Human Research.

For abbreviations not defined in this SOP, refer to CW AHC 102 Abbreviations in Research.

VIII. EXCEPTION(S): See CW AHC 101 Research Oversight for additional Exceptions.

It should be noted that some research notes could at times include notes that also fall under another exception. For example, if a research study includes a depression scale, or other notes related to mental health or psychotherapy, these notes fall under the "Preventing Harm Exception" due to the nature of the content. At study closure, the "Preventing Harm Exception" would continue to apply and those notes should continue to be suppressed and not released.

IX. REFERENCE(S):

Cures Act Final Rule: Information Blocking Exceptions (healthit.gov)

PUBL255.PS (congress.gov)

X. RELATED DOCUMENT(S) / ATTACHMENT(S):

- Research Oversight
- Definitions in Human Research
- Abbreviations in Research
- Human Research Protection Program
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-413 WORKSHEET - Closure Criteria