**Sentara EPIC Data Access and Request FAQ/Tips for EVMS Learners and Faculty**
Version Date: 06/01/2023 (EVMS Office of Research, EVMSResearch@evms.edu)

## Table of Content

**1. For all types of Sentara EPIC data requests, follow these two steps:**
Step 1: Please complete the EVMS Data Request Intake Form (**EDRIF**)
Step 2: After completing the EVMS Data Request Intake Form please complete the Sentara Health
Research Center submission form.


**2. To access Sentara's EPIC database for chart review**: In order to utilize Sentara EPIC for research purposes, researchers must submit a request for EPIC access to EVMS and then to the Sentara Health Research Center. Please follow the instructions listed below to request an EPIC username and password for research purposes.

Step 1: Please complete the EVMS Data Request Intake Form (**EDRIF**)
Step 2: After completing the EVMS Data Request Intake Form please complete the Sentara Health
Research Center submission form.
   a. Within the submission form please attach the IRB approval document showing that you have been officially added to a research study.
   b. Also for the question "Specific aims of this study" include the statement Request is for EPIC Access Only.
   c. Please enter the EVMS Office of Research Data Request Number (#) that you receive after completing the EVMS Data Request Intake Form.

Once you have completed those steps, please contact researchdata@sentara.com (referencing your research project uploaded into Sentara's Research Request Portal) from your EVMS email account and your EPIC access approval will be finalized.

**3. IRB approval is a must**: EPIC access for research use requires an IRB approval. When the underlying IRB expires, your EPIC research access naturally expires as well…unless your approved study has been officially extended by IRB. When you wish to request EPIC access extension, you will need to send a copy of your IRB-approved continuing review form with an updated expiration date to researchdata@sentara.com.

**4. EPIC research access via the EPIC access for clinical education**: EVMS M3 and M4 students receive an EPIC access for clinical education. However, this EPIC access is strictly for clinical education. Anytime you wish to access EPIC for a research study, there must be an IRB approval covering the study. When Sentara grants an EVMS M3 or M4 student the EPIC access for research, the student will use his/her existing EPIC access for clinical education for the IRB-approved study (there will not be a new/separate EPIC research access issued for the student).

Below are the screenshots and description for accessing the research EPIC template vs the clinical access you will have as an M3 or M4 student. Contact researchdata@sentara.com for questions you may have..

**EPIC Research Login**
   a) Now that you have received approval for your EPIC research login you will see the following branchpoint every time you login to EPIC. You can toggle between job templates (research vs clinical) by clicking on the magnifying glass.
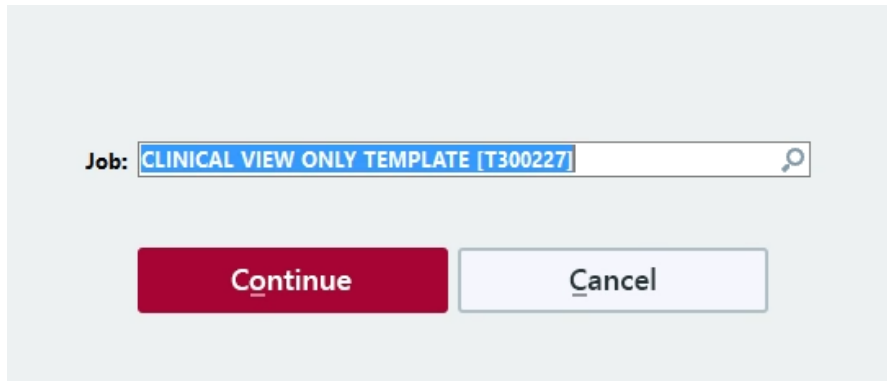
b) If you click on the magnifying glass you will then see the second picture below and you will be able to choose which template is appropriate for your current use. T300227 CLINICAL VIEW ONLY TEMPLATE is the research template. Any EPIC chart review activity for research purposes should be conducted using this login.
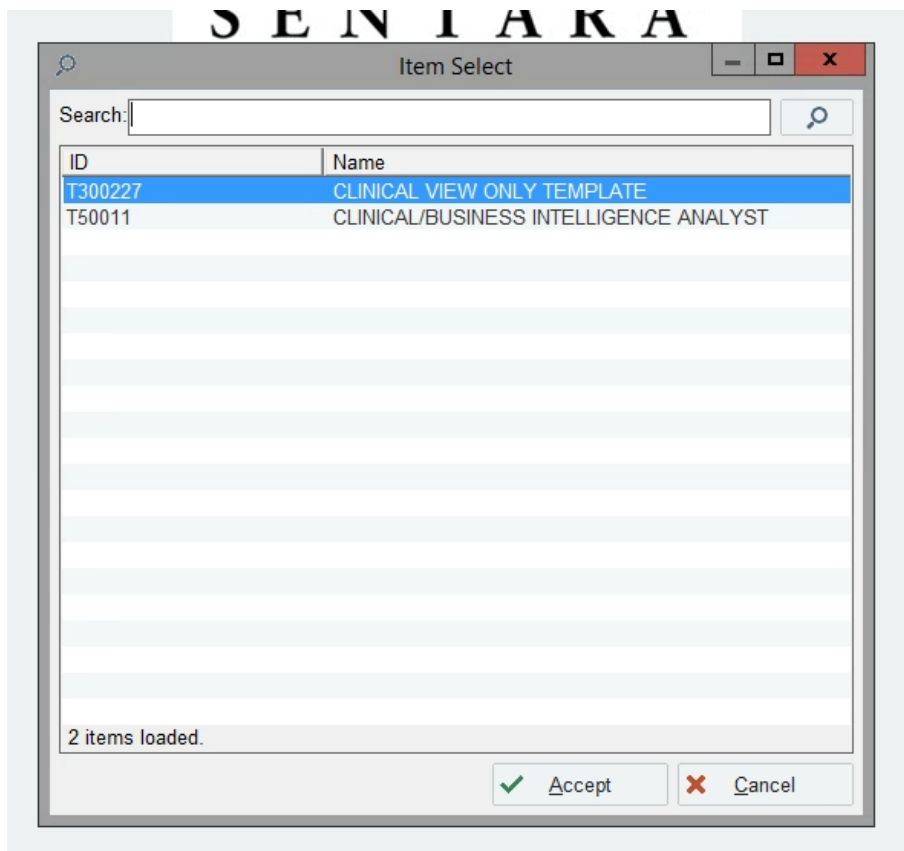


**5. Always communicate with Sentra using your EVMS email address**. Do not use personal email such as gmail, etc…

**6. Project team must include an EVMS person with established and permanent status, e.g. faculty or an attending physician**: The IRB approved project must include **an EVMS person with established and**

**permanent status (e.g. faculty or an attending physician**) who will supervise the project team of learners (students, residents, and/or fellows). Sentara will reject the request from a team without a supervising faculty or attending physician regardless of the project type (an IRB approved research project, an IRB-reviewed Quality Improvement non-research project, or a Case Study project). We understand that a data request may be from a team including EVMS learners and a supervising Sentara physician in place of an EVMS faculty.

**7. Contact EVMS Office of Research for help**: Contact EVMS Office of Research via EVMSResearch@evms.edu

**8. Follow Sentara's instruction**: In the process of establishing EPIC research access, Sentara may require you to set up an MDOffice account and forward the account info back to Sentara. Some EVMS learners do not follow this up, causing a significant delay in establishing the EPIC research access.

**Other notes about asking Sentara's EPIC data for research:**
**9. Time frame of Sentara's EPIC data**: It is very challenging and time consuming to for Sentara to pull EPIC data from before 2015. Please consider working with data from after 2015 to avoid significant delays in EPIC data pulls by Sentara.

**10. Data element specificity**: Be specific about your data inclusion/exclusion criteria for your EPIC data pull request. For example, if you are interested in the patients with "recurrent inguinal hernia". You must provide the ICD-10 codes associated with inguinal hernia for Sentara to identify the patients with such a condition. Just a basic layman description of a procedure or disease may not be actionable for Sentara to abstract data for you. **Imprecise and/or nonactionable data inclusion/exclusion criteria are the most common cause of significant delays for Sentara to pull EPIC data for EVMS data requesters**.

**11. Case study information and consideration (adapted and modified from Sentara)**
**Source: https://www.sentara.com/medicalservices/services/sentara-health-research-center/for-researchers/faqs-clinical-case-reports.aspx**

**Q: What is a case report?**
A: A case report is a clinical presentation about a single interesting or novel patient that is prepared for the purposes of medical education. In this discussion, we are referring to written reports that are prepared for publication in the medical literature. We recognize that verbal case presentations are ubiquitous in medical education and practice and verbal case reports are not the topic of this discussion.

**Q: Does a case report require IRB approval?**
A: A case report does not meet the Common Rule definition of research because it is not a systematic investigation designed to develop or contribute to generalizable knowledge (45 CFR 164.501). A case report is considered an educational process. Therefore, a case report is generally not reviewed by the IRB for approval. At Sentara, a report of two or more individuals is not considered a case report but is considered a case series that requires IRB approval.

**However, please consider securing an official IRB review NOW to determine that your single-patient case study is "non-research". This is quite easy to do. Here is why. Say your case study progresses into a manuscript to be submitted to a journal that requires a case report to have an official IRB review as "non-research". At that time, it will not be possible for IRB to render the "non-research" determination to your study because IRB can't review a completed study retrospectively.**

Generally, patients for case reports are identified during usual patient care activities. Any activity to search medical records for potential case reports would be considered human subjects research and would require prior IRB approval.

**Q: Does a case report require patient consent or authorization?**
A: Direct patient consent is **<u>strongly</u>** advised for all case reports. **<u>Most journals require a statement confirming that patient consent has been obtained</u>**.

Case reports must comply with HIPAA Privacy Rule requirements regarding Protected Health Information (PHI). Compliance with the Privacy Rule can be accomplished by obtaining HIPAA authorization from the patient or patient's representative (in the case of a deceased or incapacitated patient). Sentara's consent and authorization form is available here (LINK). A copy of the signed authorization form should be entered into Epic for permanent storage, filed under the Media tab, and labelled as "Case Report Consent." A copy should be kept in a secure place by the author. A copy of the authorization should not be sent to a publisher because of privacy considerations.

**Q: Are there circumstances when I should involve the IRB?**
A: An author may ask for IRB to review a de-identified case report (if direct patient consent is not obtained) to assure that the information in the case report has been properly de-identified and does not contain Protected Health Information (PHI). Also, if a patient is identified outside of normal healthcare operations and is to be approached solely to obtain information for a case report, IRB should be contacted, and IRB approval may be required.

**Q: Can a case report be prepared without patient consent and authorization?**
A: If a case report does not contain identifying information, it is not PHI and therefore is not regulated under HIPAA and consent is not legally required, although an author should consider the ethical obligation of informing a patient before publishing a case report. **However, almost all journals will require patients' consent even if you use only deidentified data. Get the consent before you start the study.**

The most common way of de-identifying medical data is the "safe harbor" method of deleting 18 identifying elements from a report. It should be noted that element #18 is "Any other unique identifying number, characteristic, or code that could identify an individual." This identifier could apply to patients with rare conditions where the condition itself is a characteristic that could potentially identify the individual. For patients with rare conditions and unique characteristics, the author of a case report is required to obtain a signed direct consent from the patient.

**Q: What are the 18 identifiers that must be deleted from a case report to assure that the report is not PHI?**
A: According to the Privacy Rule (45 CFR 164.514(b)(2)(i)), the 18 identifiers are:
1. Name
2. Address (all geographic subdivisions smaller than a state, including street address, city, county and zip code)
3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Fax numbers

6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/License numbers
12. Vehicle identifiers and serial numbers including license plate numbers
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address
16. Biometric identifiers, including fingerprints and voiceprints
17. Photographic images – including full facial photographs and other comparable images
18. Any other unique identifying number, characteristic, or code that could identify an individual.

**Q: Can a case report include pictures or images?**
A: Yes, but the images cannot include any identifying information. Use of full-face photos, tattoos, or other identifying characteristics is not allowed. A direct patient consent must be obtained for all case reports that include pictures or images.

**Q: I would like to write a case report, but I do not have clinical access to Epic. Can I obtain access to Epic for this purpose?**
A: Access to Epic for pre-clinical EVMS medical students may be obtained by applying through the Sentara Health Research Portal. Students/residents must first complete this EVMS online data request form. EVMS personnel must use their EVMS email addresses and have an EVMS Office of Research request number (issued in the email following the completion of the EVMS online data request form) to make an Epic access request through the SHRC portal. Further questions should be directed to the EVMS Office of Research (EVMSresearch@evms.edu).