

|  |  |
| --- | --- |
| **Office of Research Compliance**  Corporate Compliance Jelke Building, 6th Floor  1653 W. Congress Pkwy.  Chicago, IL 60612 | Tel: 312.942.8314 Fax: 312.942.6875  [www.rush.edu](http://www.rush.edu) |
|  |  |

**Documenting a Screen Failure for a Research Study**

* If the Sponsor (or if this is an Investigator Initiated study) did not provide a screening/enrollment log create one for your site.
* Provide a column to document WHY the patient screen failed from the study.
* Document the specific inclusion or exclusion criteria the subject failed to meet.
* Document in the patient’s medical record (EPIC)/research record the screen fail process.
* Make sure you identify the specific study/protocol and the reason the subject did not meet inclusion/exclusion criteria. Document that you explained this to the subject and discussed how they go about their future medical care.
* If the study has an IVRS or IWRS – remember to complete the screen failure process in either the telephone or web study specific system.