

## *eSource Documentation Procedures*

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### General Administration

1. A specific login in will be given to every staff member accessing the eSource. This will be done by the site personnel assigned as eSource administrator and will have specific rights assigned (data-entry, read-only, etc.). Only studies that staff member is currently working on will be assigned.
2. When a particular staff member ceases working on the study user permissions will immediately be withdrawn from the eSource administrator.
3. As entry into the eSource is date and time stamped with the user, only activities actually performed by that user will be entered. There will be NO SCRIBING for another site personnel.
4. All data will be entered as it is performed though “cleaning” up of the data is allowed prior to completing and publishing the visit. This includes writing progress notes and checking to ensure all source pages are completed.
5. Progress notes will be entered for all AEs to document conversation with PI regarding causality and severity of AE. When PI eSigns the visit he/she is attesting to the accuracy of the progress note.
6. Progress notes will also be entered for the visit as a whole and for any abnormal events during a procedure (i.e.. Making sure PI is made aware of an unusual vital sign outside of the norm and documenting the conversation between PI and CRC).

### Paper Source

1. If source was recorded outside of the eSource software (either due to internet being down or because paper source was necessary as in the case of patient questionnaires) then these paper documents will be scanned into the eSource, redacted for any patient PHI, checked for completeness (total number of pages matches, scans were readable, etc.) and will then be uploaded and eSigned by personnel performing this task. This effectively constitutes a certified copy of the paper source and allows for destruction of paper documents.
2. Our policy is to keep Informed Consent forms in a binder for easy source data verification by the CRA. All other supporting source documents will be scanned into the corresponding visit where the assessment took place and made a certified copy and then shredded. Anything measurable by a ruler will not be retained. (eg. VAS)

### PI Review

1. PI will e-sign off on every study visit to document his/her review and acceptance only after it has been completed and published by the CRC(s) conducting the visit. If a major change to the eSource is completed after PI has already eSigned then the CRC will send a request to PI to re-sign the study visit.