SickKids

GOOD DOCUMENTATION PRACTICES

Full Study Title: A Randomized Comparative Trial of Pediatric Vision Screening Devices and Cost-Effectiveness Analysis of School-age Children Vision Screening Programs in Ontario
Qualified/Principal Investigator (QI/PI): Agnes Wong
REB File #: 1000045972

DOCUMENTATION TIPS

SickKids has a policy outlining documentation practices. See SickKids "Documentation" Policy for further information.

- Use blue or black ink, no erasing so use ink *(do not use pencil)*
- Write legibly and clearly
- Document in a timely manner *(if too much time passes sometimes it may be more difficult to get the data points you need for your study)*
- Avoid blank or white spaces-it may appear that something was deleted *(if field is blank then one is not able to tell if data was missing, not done or not available- if data field is blank- include the reason for this in the data field- i.e. not done, not available or data missing)*
- Write or have a space to document the participant's unique study ID # on each page of the data collection forms
- Ensure data collection form has a field to include signature and date of person who completed the data collection form
- Keep documents easily accessible, private and secure i.e. filing system *(two lock system, locked office, password protected computer, password protected file)*
- Ensure that study documents (both paper and electronic files) that contain participants' identifiable personal health information are accessed only by research team members authorized by the REB for your study.
- Keep a glossary of common acronyms used in the study as well as the definitions. Avoid using acronyms unless the meaning is clear to all readers.
- Use REB approved study forms for documentation i.e. Data Collection forms.
- Version date and paginate all documents, if you amend, submit the revised study document to the REB and update version date.
- Keep complete copies of any documents you submit to the REB for your study files
- Avoid documenting source data on yellow stickers, post-it notes or other materials (e.g. gloves). They are easily misplaced and you will lose that data. If data is collected

on a post-it or other material, that is now a source document and must be maintained with the study records. Transfer this information onto the data collection/case record form as soon as possible and then retain the original as the source document.

- Whenever you send an original document to another person, department and/or agency, keep a complete copy for your study records including email correspondence, shipping/courier records, fax confirmation form, confirmation of receipt etc.
- Ensure Qualified/Principal Investigator QI/PI signs off and dates each completed Data Collection form/Case Report form (CRF) (can be done as the CRF is completed or at the end of the study)

DATE AND TIME

Dates and times are critical data elements in clinical research. They document when key study events occurred or when approvals were obtained and are used to calculate key data elements such as age, time since diagnosis etc.

To keep consistency in documents for both clinical and research purposes, use the date formats outlined in this Policy. Here are some important tips:

SickKids has a policy outlining how dates and times should be recorded. See SickKids "Date and Time Representation Standard Policy" for further information.

- As required by the policy, use descending order for all dates and times. Use hyphens to separate the numbers.
  - Date should be documented as: yyyy-mm-dd. e.g. July 14, 2005 would be: 2005-07-14. This reads as century year-month-day.
  - Time is documented using the 24 hour clock, and is written as hh:mm. E.g. 2:00 in the afternoon is 14:00. This reads as hour: minute.

- Sometimes the date **and** time are important to record. For example, if informed consent and the first drug administration occur on the same day, the date and time of each event should be recorded to ensure that informed consent was signed prior to the first dosing of the study drug.
  - Date should be recorded as yyyy-mm-dd and time should be recorded as hh:mm. e.g: date and time: *1992-08-28* at *17:42*.

DATES AND SIGNATURES

Dates are also important elements of signatures. All key study signatures should include the date that the document was signed.
Note: Back dating of signatures is not permitted

Ensure that the informed consent form is signed **and** personally dated by the participant or their legal guardian and by the person who explained the study and obtained informed consent.

CORRECTION OF ERRORS

Errors should be corrected so that the original information should be clearly visible, as well as the corrected information. Only the PI or the research study staff can make corrections

Note: The sponsor's monitor or auditor cannot make corrections on your documents.

It is expected that errors will occur; the key is to correct the error properly to ensure the data is credible.

Proper Correction of Errors:

- Draw a single line through the mistake
- Write a note clarifying the reason why the data is being changed
- Write in the new data
- Initial and date the change.

Example: The wrong amount of medication was recorded:
Error: 20 tablets
Correction: ~~20 tablets~~ error, wrong amount recorded,
Proper correction of error: ~~20 tablets~~ 40 tablets *RA* 2005-04-19

- Never use white out or corrective tape to correct errors.
- Do not correct errors by scribbling or blacking out the error with ink.

E

~~• B l a c k~~
• .g.: s h o u l d

Adding Information that was Omitted

Occasionally information may be omitted at the time it was require to be entered. This information can still be included in the participant's research record as an addendum or "note to file". The Note (can use the Note to File template) should include the current date the new information was added. Back dating is not permitted.

Re-Writing CRF or other study document

If you decide to re-write a CRF or other study document ensure that you **keep** the old document and attach to the new re-written document. Draw a line across the old document and write "re-rewritten" across it and date and sign the old document.

REFERENCES

- Good Clinical Practice guideline E6
- SickKids Policies and Procedures: *"Documentation" policy*
- SickKids Policies and Procedures: Health Records and Admitting: "*Standardization of Health Records Forms*" policy
- SickKids Policies and Procedures: Information Services Subsection: "*Date and Time Representation Standard*" policy
- SickKids "*Privacy is your Responsibility*" website

The signature and date below are the attestation of understanding the information stated within this document.

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Signature **Date** (yyyy/mm/dd)
