1. Purpose

This SOP is intended to standardize the documentation practices used in the Office of Sponsor and Regulatory Oversight (OSRO) for creating, correcting, and presenting data generated during Quality and clinical activities.

2. Scope

2.1. This SOP is designed to ensure that documentation of all Quality Management System (QMS) and Good Clinical Practice (GCP) activities in OSRO is kept in a consistent, transparent manner that will assure the integrity and traceability of data.

2.2. Limitation

2.2.1. Nothing in this document will supersede NCI, National Institutes of Health (NIH) or Health and Human Services (HHS) requirements.

3. Responsibilities

3.1. OSRO personnel shall follow the good documentation practices defined in this SOP.

3.2. Clinical study staff are required to follow this procedure when they are providing documents to the Sponsor for Center for Cancer Research (CCR)-held Investigational New Drug applications (INDs) and Investigational Device Exceptions (IDEs).

4. References

4.1. 101 Good Documentation Practices Policy

4.2. 21 CFR Part 11 Electronic Records; Electronic Signatures

5. Definitions

Refer to the OSRO Lexicon.

6. Procedure

6.1. For the purposes of this SOP, documentation shall refer to

6.1.1. All records, in any form that describes or records the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

6.1.1.1. Documentation forms include but are not limited to, written, electronic, magnetic, and optical records, scans, X-rays and electrocardiograms.

6.1.2. OSRO Quality Management System documents.

6.2. Redaction of documents

6.2.1. All Personal Identifying Information (PII) must be redacted from medical forms provided to OSRO.

6.2.2. Any document which shows PII will be returned to the submitter for redaction.

6.3. Electronic source document systems should be verified for completeness, accuracy, reliability, validation, controlled access, audit trail, appropriate SOPs on its use and availability of data backup procedures.

6.4. Electronic Records

6.4.1. Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine.

6.4.1.1. A closed system is one in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

6.4.2. Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt.

6.4.2.1. An open system is one in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

6.5. Data recording shall follow the ALCOA-C principle for data integrity.

6.5.1. Attributable – information is captured in the record so that it is uniquely identified as having been executed by the originator (e.g. a person or computer system).

6.5.2. Legible, traceable, and permanent – information is readable, understandable, and allows a clear picture of the order of steps or events in the record.

6.5.3. Contemporaneous – recorded at the time data are generated or observed.

6.5.4. Original (or "True Copy") – data in the format in which it was originally generated, preserving the integrity (accuracy, completeness, content and meaning) of the record.

6.5.5. Accurate – data are correct, truthful, complete, valid and reliable.

6.5.6. Complete – adequate, accurate and complete source documents and source data are maintained.

6.6. Signatures and Initials

6.6.1. Signatures affixed to electronic document files must follow the regulations contained in 21 CFR Part 11 (Reference 4.2).

6.6.1.1. Per 21 CFR Part 11 Section 11.50, signed electronic records should contain information associated with the signing that clearly indicate all of the following:

6.6.1.1.1. Printed name of the signer,

6.6.1.1.2. Date and time when the signature was executed, and

6.6.1.1.3. The meaning associated with the signature, e.g. review, approval, responsibility, or authorship.

6.6.2. Persons who use electronic signatures shall employ controls to ensure their security and integrity.

6.6.3. Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.

6.6.4. The use of a JPEG image of a handwritten signature is not acceptable unless the attributes in Step 6.6.1.1 are present.

6.7. Record Keeping Practices.

6.7.1. All original hand-written entries shall be:

6.7.1.1. Written legibly.

6.7.1.2. Written using a blue or black permanent ballpoint pen.

6.7.1.3. Written concurrently with work being performed.

6.7.2. All data shall be labeled with identifying information.

6.7.2.1. Computer generated printouts should be labeled on at least the first page with project ID, test article, etc.

6.7.2.2. If the printout does not include the date and time on each page, then the reporter's initials and date of signing are required on every page.

6.7.3. All data shall be signed and dated concurrently with the work being performed.

6.7.3.1. Back dating entries is not allowed.

6.7.4. The abbreviation "NA" or "N/A" for not applicable should be used in a document in the instance where data is not relevant or not required, such as when there are no comments to include in the comments section.

6.7.5. To correct errors in written documents:

6.7.5.1. Place a single line through the incorrect entry; this should permit reading of the original information.

6.7.5.2. Write the correct entry near the error.

6.7.5.3. Annotate the reason for the correction. Assure that a clear and concise explanation is provided for the correction. For example: date error, spelling error, late entry.

6.7.5.4. Initial and date the correction. If space is not available next to the correction for initials and date, indicate by notating next to the correct entry and explain using the same notation where space is available, e.g. using an ampersand, *. Be sure to notate sequentially when multiple errors occur on the same page of a document, e.g. using 1, 2, 3, etc.

6.7.5.5. Example:

~~01Apr18~~ 02Apr18 Date Error
Initials and date

6.7.6. The following actions are not permitted.

6.7.6.1. Line-out hard-typed information. If a hard-typed error is found in a document, write a comment in the comments section (if available) clearly identifying the error, its location in the document and the correction. Use notation at the error's location to reference the correction in the comments section.

6.7.6.2. Erase or scribble out mistakes to obscure an original entry.

6.7.6.3. Write correct entries over incorrect entries to obscure the original entry.

6.7.6.4. Write entries on scrap paper, skin, or other mediums to be transferred later to the permanent record.

6.7.6.5. Use pencil or ink other than blue or black. Use any type of pen other than ballpoint with indelible ink.

6.7.6.6. Use White-Out or correction tape.

6.7.6.7. Leave uncorrected mistakes.

6.7.6.8. Pre-date or post-date entries. All entries must be made concurrently with the work being performed. If an entry was not made at the time of occurrence, complete the entry noting the current date and document an explanation. Initial and date the notation. Using the statement, "Late entry for work performed on [date]" is acceptable. OSRO Quality will determine if a deviation is required.

6.7.6.9. Use arrows, brackets or ditto marks for recording redundant information (e.g. data, dates, initials). The use of arrows, brackets or ditto marks is not fully informative or descriptive and cannot be directly related to the recorder.

6.7.6.10. Correct entry errors made by another person. Corrections must be done by the original recorder unless the person is unavailable. In this case, the correction is made by the supervisor provided they have supporting data.

6.7.6.11. Discard a record just because you might have made a mistake, it is still required for traceability.

6.7.6.12. Deliberately amending or destroying a GCP record to hide or falsify data is fraud.

6.8. Date and time formatting

6.8.1. Dates should be formatted using either the first 3 letters of the month or the complete spelling instead of the numerical representation of the month. Because of country differences in recording dates, the use of numbers can cause confusion and possibly errors.

6.8.1.1. Example: The written date of 7/12/19 means July 12 in the USA and December 7 in Europe.

6.8.1.2. Two-digit day of the month, three-letter month abbreviation, and either four digits or the last two digits of the year is recommended.

Example: If today is June 24, 2019, then the correct way to record the date in the record is either 24Jun2019 or 24Jun19.

6.8.2. Note: some computer programs are not configured for this date format. In this case, the program setting must be used.

6.8.3. The time should be formatted based on a 24-hour clock or military time. Examples are shown in Table 1. Colons are not used to separate the hour and minute. No units are used.

Table 1. Comparison of Standard Time and Military Time.

Standard Time Format	Military Time (24-hour clock)
12:00 am, midnight	0000
8:30 am	0830
12:00 pm, noon	1200
1:00 pm	1300
4:30 PM	1630
9:00 PM	2100

6.9. Copies of original documents

6.9.1. Copies of original documents must be marked as “COPY” by stamping or legibly handwriting “COPY” on every page to assure that the integrity of the original document is preserved. The first page of a copy must be initialed and dated by the person making the copy.

6.9.2. Copies should be made from the original document and not from another copy.

6.9.3. Changes or additions may not be made to documents marked “COPY.”

6.9.4. Original documents will always be considered the “official” record when available.

6.10. Standard units

6.10.1. Measurement units should be used consistently, pertain to the quantity being measured and the procedure performed.

6.10.1.1. In general, all data values have an associated unit which must be recorded with the number.

6.10.2. Always use the same units that are referenced, hard-typed into a document or given by an instrument. For example, if the pressure setting on a pump is given in psi, then the recorded pressure reading should also be in psi.

6.10.3. When measuring a quantity, e.g. time, that has several unit options, choose the unit that is appropriate to the size of the measurement. For example, one day may be recorded as either 1 d or 24 hr; however, it typically would not be recorded as 86,400 s.

6.10.4. Some examples of commonly used units are listed in Table 2.

Table 2. Common Standard Units.

Quantity	Unit	Symbol
Length	meter	m
Volume	liter	L
Temperature	Celsius	°C
Time	second	s
	minute	min
	hour	hr
	day	d

6.10.5. Prefixes

6.10.5.1. Prefixes should be used to appropriately indicate the size of what is measured. For example, the volume of a drop of liquid would usually be recorded in microliters (1 µL) instead of liters (10-6 L).

6.10.5.2. See Table 3 for some examples of prefixes.

Table 3. Common Metric Prefixes.

Prefix	Symbol	Equivalent
kilo-	k	10^{3}
–	–	10^{0}
centi-	c	10^{-2}
milli-	m	10^{-3}
micro-	µL	10^{-6}
nano-	n	10^{-9}
pico-	p	10^{-12}

6.11. Significant figures and rounding

6.11.1. All data should be reported to the same number of significant figures as the specification or limit that applies to the attribute being measured.

6.11.2. Where raw data is manipulated through calculations to provide a final result, no rounding of the raw data or any intermediate value should take place. Only the final result should be rounded to the number of significant figures defined by the specification or limit.

6.11.3. Rounding of 5 should default to the higher value. For example, 1.5 is rounded to 2.

6.11.4. Examples:

6.11.4.1. If the specification is 2 - 8°C, and a reading of 1.8°C is measured, then the result should be recorded as 2°C and is considered acceptable.

6.11.4.2. If the specification is 2.0 – 8.0°C, and a reading of 1.8°C is measured, then the result should be recorded as 1.8°C and is considered unacceptable.

6.12. This SOP shall be reviewed periodically and updated as necessary.

7. Associated Forms

7.1. N/A

8. Change Summary

Revision Number	Effective Date	Description of Change
1	01SEP2021	New Document