Characteristics of Successful SOPs

Purpose: To outline features of comprehensive SOPs using the Burkitt Lymphoma Genome Sequencing Project (BLGSP) SOP manual (https://ocg.cancer.gov/resources/ocg-templates-and-protocols) and Nationwide Children's Hospital Biospecimen Core Resource protocols as models.

Effective SOPs based on the aforementioned models include:

1. Informative Title
2. Introduction: Protocol summary and use (1-2 sentences)
3. Scope and Purpose: Purpose of protocol
4. Safety Precautions: Actions that ensure safety of the person conducting the protocol (PPE use, dangerous material handling, calling out of potential pathogens)
5. Equipment and Materials: Pertinent equipment details, company, and catalog number for reagents, composition for solutions
6. Quality Control: Methodology to reduce sample mix-ups (barcode scan every time a sample is moved to a new tube), contamination, degradation
7. Procedure: Specific details of the protocol, in the order in which they are performed.

Additional SOP Components to be Included

- SOPs should be tailored for a single process and each should have precise title and versioning.
- Emphasis on sterility and personal protection is important.
- Descriptions of set-up of working space is valuable, especially for time-sensitive applications. These should be outlined prior to the active portion of the protocol so that the work area is prepared in full before activities begin.
- Product details should be precise (company, catalog number), especially for products that cannot be substituted. If there are allowable alternatives for a reagent, there should still be an example with specific product details. It is helpful to include the statement *"It is possible to substitute disposable materials and certain equipment from other vendors as long as they are the equivalent of the item described above. *Denotes items for which substitution is not recommended"*. If the protocol does not progress as expected, identifying deviation is essential and reagents can be a source of variability.
    - Even if using a kit, write out all of the protocol, as experience with kits increases insight into tricks to be used and idiosyncrasies of the protocol. Notation of versioning is important here as different versions of kits are released over time.
- Include step-by-step instructions listed in the order in which they occur. Avoid jumping around in the protocol. If something should be prepared or heated or cooled prior to beginning a particular process, ensure that it is listed in the order it should be done or as part of a preparation section.
- To reduce sample mix-ups, include in SOPs when labels should be used and what information the label should contain.
    - If barcodes are used, note that barcode readers are used throughout the process whenever transferring samples from one tube to another.
- Include images and diagrams whenever they are useful.

- Tables and workflow diagrams are always helpful as summaries or references within the protocol.
- Automated vs manual—If the lab has an automated protocol, that is fine to include but an alternative manual protocol should be included for use by labs that may not have the resources/equipment required for the automated protocol.
- Details regarding reagent/solution/product storage (time, temp, humidity, light/dark, as applicable) and stability are important to include.
- It is helpful to have a person (or two) other than the person who prepared the protocol review it. Notate who prepared the protocol, who reviewed it, and who accepted it. It is especially useful to choose someone who is unfamiliar with the protocol as a reviewer so that they can pick up on details that someone familiar with the protocol may have missed.
- Time-sensitive steps should be noted and mechanisms to remain within the acceptable time frames should be included.
- A "Quality Control/Material Use Precautions" section is a useful way to emphasize portions of the protocol when special care should be taken to avoid sample mix-ups, contamination, or deterioration. Including this information within or directly after the Materials section is helpful.
    - For example, insert notes such as the following: "To avoid cross-contamination of cultures, only have one sample in the hood at a time".
- Define lingo/jargon and always define acronyms when used the first time, or include a glossary.