DHVI - Protein Production Facility

A Data Management Plan created using DMPTool

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Project abstract:

The Protein Production Facility (PPF) operates as a core facility within the DHVI. The mission of the PPF is to produce and purify, at cost, proteins and antibodies as standardized “Research Use Only” reagents that can be used in vaccine research. The PPF does not claim GMP/GLP or GCLP status, but the facility operates with oversight and routine auditing by the Quality Assurance for Duke Vaccine Immunogenicity Program (QADVIP). All PPF procedures, assays, equipment, operator training, and documentation are governed by Standard Operating Procedures and a Quality Management plan established with the Quality Assurance Unit (QAU). This DMP applies to all data generated and recorded on PPF batch records or worksheets which are completed during the production of proteins, antibodies and related materials by the PPF Core team members. All of the records or worksheets are governed by an associated SOP. The information is retained and archived by the QAU.

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DHVI - Protein Production Facility - Roles and Responsibilities

Roles and Responsibilities

Who will be implementing data management procedures and what are their individual responsibilities?

All employees of the PPF should follow the guidelines within this data management plan as contributing members of their assigned role in the PPF Core.

Prior to the expression of material in the PPF, the technician or analyst will determine the appropriate batch record or worksheet required to complete the process. The batch records or worksheets are associated with a standard operating procedure (SOP) developed in association with and governed by the Quality Assurance Unit. The worksheets outline the process of protein and / or antibody production, purification and testing. They are stored in and accessible through Q-pulse.

All lab members or QA personnel reviewing these records are encouraged to voice concerns regarding the collection of unbiased data and accurate recording of information during the process of expression and purification of all PPF materials. Any lab member or QA reviewer may propose methods for clear and accurate documentation practices.

Any concerns regarding data integrity should be brought immediately to the attention of the Unit/Lab Manager, PI, PPF Director or DHVI Director. It is important to note that some projects, grants, contracts, etc. may have specific requirements for data management that are equal to or better than those described here. In these situations, the data management policies of the sponsor, regulatory agency, etc. will supersede those described here.

How will new people be trained and ongoing communication be encouraged amongst all team members with respect to implementing best practices in data management?

Upon joining the PPF Core all employees will be trained on PPF SOPs which include Good Documentation Practices and the PPFs Quality Management Plan. These SOPs outline best practices for capturing information and documenting data during the production of proteins, antibodies and other reagents expressed by the PPF. The training process will also include instruction on appropriate data management for their position and role in the PPF. The PI and/or Unit/Lab Manager will meet with the new team member during their on-boarding process to explain the expectations of data management and research integrity in the PPF. This will include, but is not limited to, a discussion of the specific practices within that lab for archiving and managing data in compliance with the guidelines as described in this DMP and PPF SOPs. All staff involved in data management activities will be required to acknowledge receipt and understanding of policies and procedures described in this guidance document in paper records or electronic tracking systems (eg. ELN, Q Pulse).

New team members will be asked to consider reviewing the Duke University Library's online data management guidelines and attending an in person data management Responsible Conduct of Research (RCR) forum through the Library or the ASIST program.

Before departing, team members should organize and index the data and research records for which they have been responsible, and discuss with the team leads/unit managers and/or PIs whether it is permissible to retain any copies. No worksheet or record that is part of a packet describing production, purification and testing of any reagent produced in the PPF is to be retained by any PPF or DHVI personnel. In addition, at least one team lead/unit manager and/or PI will be designated to review files with the soon-to-be-departing person, to ensure there is a good understanding of the organization and location of the remaining data and research records.

DHVI - Protein Production Facility - Research Methods and Data Description

Research Methods and Data Description

What type of research does this plan cover? (i.e., briefly summarize your project scope or research unit's focus area that will be covered under this DMP)?

The DHVI's Protein Production Facility expresses and purifies standardized reagents (eg. proteins and antibodies) that are used for vaccine research. These reagents are intended to optimize clinical trial immune monitoring and facilitate immunogen discovery.

How will the research, summarized above, be carried out? (i.e., provide a general, "big picture" overview for the methodologies in practice)

The production of reagents in the PPF is carried out in strict adherence to PPF SOPs which are stored in Q-pulse and are reviewed biennially by PPF team members and members of the Quality Assurance Unit (QAU). The PPF SOPs describe all assays that are carried out in the PPF and a batch record/ worksheet accompanies each SOP. The batch records capture details of all PPF processes used to express, purify and test each protein or antibody produced in the PPF.

What types of data will your research team be generating/using including the format, size, and source?

The data generated by the team is captured on batch records as the process of expressing and purifying proteins and antibodies is performed in real-time. These batch records may consist of paper records which are archived by our Quality Assurance team or records captured in electronic laboratory notebooks.

DHVI - Protein Production Facility - Storage and Organization Workflow

Storage and Organization Workflow

Where and how will the data, documentation, and resources be stored while you are actively using the data?

All information collected for the reagents used in the PPF and steps involved in the expression, purification and testing of proteins and antibodies by the PPF will be captured on the batch record which is associated with the specific SOP for the assay or in a template in an electronic laboratory notebook. All electronic data can only be accessed via secure connection to the Duke network and should not be stored on any personal devices. All laboratory books and electronic files are open to members of the originating laboratory, PI and relevant DHVI leadership, unless restricted by regulatory bodies.

Each individual is responsible for their current working lab notebook which should be stored in the lab or at their desk/office and be made available upon request. These laboratory notebooks are to be used for recording laboratory information when developing or optimizing an SOP and will not be used to record any information in the production of any reagent requested by an investigator through the PPF Core. All completed lab notebooks should be indexed and stored in the lab or with the PI or Unit/Lab manager. Written records and lab notebooks will be kept for at least 10 years. All electronic copies of data are stored on DHVI network servers and located on lab specific network drives, or in a defined archive location, for at least 10 years. Data is backed up and managed by Duke Office of Information Technology (OIT).

How will the data, documentation, and resources be organized within and across file systems?

The Duke PPF Core has a comprehensive folder structure on the DHVI N Drive mentioned above. Folder access and privileges are set by DHVI IT team at the written request and approval of the team lead/unit manager and PI. Unit and project specific directories are established such that persons will know how and where to put new data sets and find older datasets and records. Tools such as DukeBox and Q-pulse are used when appropriate to maintain provenance/version control.

Software such as Unicorn (GE) for chromatography, ELN (LabArchives) and WinKQCL (Lonza) are 21 CFR part 11 compliant creating a audit trail and version control. Information generated by these software is stored in the PPF folder on the N: drive. All other raw data files created by scientific equipment should be preserved in their unaltered state.

DHVI - Protein Production Facility - Documentation and Metadata

Documentation and Metadata

What documentation or metadata will be created during the project and in what format?

During production of a protein or antibody all information relating to expression and purification of the reagent is captured in real-time on a document controlled worksheet (i.e. batch record) or either in electronic format in the electronic laboratory notebook.

All gels (agarose, SDS-PAGE and Western blots) used to visualize expressed plasmids, proteins or antibodies are scanned and stored as a raw image prior to any analysis.

Data generated by the Unicorn or WinKQCL software are stored as raw data and are reported as such.

DHVI - Protein Production Facility - Data Sharing and Archiving

Data Sharing and Archiving

What data will you share at the conclusion of your project? Where will you make it available and under what conditions?

Upon completion of expression, purification and testing of a reagent in the PPF, all information relating to the manufacture of the reagent is compiled into a packet or a folder as either paper records or in electronic format in the electronic laboratory notebook. A Certificate of Analysis (CoA) (template in SOP PPF-M002) will be compiled and will reflect information relevant to the reagent. The CoA is delivered to the requester along with the reagent. All primary data, analyzed data, metadata and documentation will be made available to the service requester upon request via Duke email or other mechanism such as DukeBox. The Core will retain these original files/documents as described in Storage and Organization Workflow and the PPF's Quality Management Plan.

How will you prepare (i.e., "curate") your data to support future access and use?

Archiving of files associated with the production of all reagents generated by the PPF is detailed in the PPF Quality Management plan governed by Duke's Quality Assurance Program. This SOP states that: all original paper and electronic versions of obsolete SOPs (.pdf files and .doc files), all paper versions of raw data and metadata from completed products, all completed QC forms pre-dating one year will be stored in the Archives managed by the Quality Assurance Unit. The Archives remains locked at all times. The Archives are organized to facilitate the retrieval of a document should it become necessary at a future date. All Archive activities are outlined in SOP # QADVIP-M008

Where will you archive your data at the conclusion of the project to ensure collaborators and Duke University research stakeholders can gain access?

If data are NOT deposited in a permanent repository or archived for broader sharing as discussed above, then data will continue to be secured and accessible during the established retention period stipulated by institutional policies and protocols or external sponsor requirements using DHVI network servers and/or cloud options approved by Duke (i.e., DukeBox, LabArchives, and OSF).

If appropriate, describe what data will be destroyed to comply with legal or policy requirements and how you will dispose of the data?

We do not anticipate that any data will be destroyed. If required to destroy data, then we will work with DHVI IT to do so consistent with Duke policies.