PROCESSES AND SYSTEMS

Standard Operating Procedures

ANZGOG Study Coordinator Workshop

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Sally Dean, Clinical Trial Coordinator
Newcastle Private Hospital

WHAT IS AN SOP?

- Detailed written instructions to achieve uniformity of the performance of a specific function
  - (ICH GCP Sec. 1.55)

WHY DO WE HAVE SOPS?

- SOPs form a single source of reference, so procedures are performed efficiently, effectively and uniformly.

WORKSHOP

PROS & CONS OF SOPS

CONS OF SOPS

- They are restrictive and remove any options for creativity
- They are difficult to follow
- It takes too much extra time and work to comply with them
- They do not fit all situations

PROS OF SOPS

- They ensure uniformity of standards → increased efficiency and performance
- They ensure complex procedures are performed correctly
- Good reference document – aid in interpreting GCP
- They provide a basis for discussion on improvements required
- Assist in planning (daily and project)
- If well written, they allow for flexibility when it is appropriate
- *(They are required by GCP regulations)*

GETTING IT RIGHT *(FROM THE START)*

Creating a good SOP…

- Is this possible?
- Need to understand
  - Our goals and aims in clinical research

    General and specific to your unit/hospital
  - Our customers and what they need
  - What we need to have in place to meet our goals and our customers' needs

WHY DO WE NEED SOPS

Who are we?
What do we do?
Why do we do it?

HANDOUT

CLINICAL TRIAL SITE PROCESSES

CLINICAL TRIAL SITE PROCESSES

- **Study set-up**
  - Feasibility (can we and should we?)
  - subject recruitment
  - approvals (ethics, SSA)
  - budgets
  - document creation/collection, file creation and maintenance (CRFs, tracking tools, trial records)
  - other departments, materials (lab kits, CRFs)
  - non-standard assessments/tests, couriers, training, investigator meetings
- **Study conduct**
  - Subject management, subject medical care, assessments
  - data collection (source and CRF), document collection and maintenance, lab samples, drug supplies, tracking
  - ongoing reporting to Sponsor/HREC, monitoring visits
  - financial management and tracking
  - communication, managing errors, troubleshooting, training
- **Study completion and close**
  - Completion of data clean-up, archiving, final reports (HREC), return of materials, summary of results to HREC and subjects.

CLINICAL TRIAL SITE PROCESSES

- **Quality management**
  - Policies, SOPs
  - Quality control/assurance
    - Subject protection
    - Data integrity
- **Document management (general)**
  - SOPs, staff records, training, equipment maintenance, trial records
- **Facilities and equipment management**
  - Acquisition
  - Service and maintenance
- **Financial management**
  - Contract, invoicing, tracking payments
- **Staff**
  - Training
    - *What, who, when, how?*

CASE STUDY

Gap Analysis for Your Site

BREAK: AFTERNOON TEA

PROCESS IMPROVEMENT

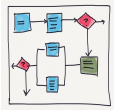
- Defining your (the hospital, department or unit's) strategic goals and purposes
  - Who are we, what do we do, and why do we do it?
- Determining your customers or stakeholders
  - Who do we serve?
- Aligning the business processes to realise the organisation's goals while meeting customer needs
  - How do we do it better?

PROCESS MAPPING: FLOWCHARTS

- Uses of flowcharts
  - Promote understanding of processes and gain consensus on how each one works (visual picture of the process)
  - Provide a tool for training employees e.g. as part of SOP
  - Measure how efficiently the process is working
  - Clearly identify customer/supplier relationships and how these can be improved
  - Identify problem areas and opportunities for process improvement
  - Develop new improved processes to reduce or eliminate inefficiency

PROCESS MAPPING

1. Identify the processes you would like to map i.e. those processes that are highest priority/where you know problems exist
2. Map the process(es)
3. Critically analyse the process and identify areas for improvement
4. Map the "ideal" for that process
5. Compare with current process and identify additional areas for improvement



WORKSHOP

Mapping the informed consent process.

WHAT MAKES A GOOD SOP

- Layout
- Compliance
- Review and approval
- Implementation
- Maintenance and update

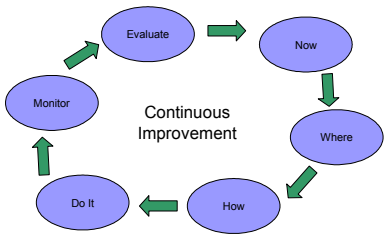
A GOOD SOP

- Uniform structure
- Sufficient detail to complete the process and ONLY sufficient detail to complete the process
- Diagrams and flowcharts
- Step by step instructions in bullet format
- Clear designation of responsibilities
- Appropriate language
  - *Plain English*
  - *will* rather than *should*
- Correct – must reflect the requirements of the applicable standards
- Should reflect reality and not be a wish list i.e. it MUST be possible to comply with it!

MOST COMMON GCP VIOLATIONS

- Non-compliance with the protocol
- Lack of SOPs
- Non-compliance with SOPs
- Inappropriate delegation of responsibilities
- Inadequate supporting source data
- Errors in informed consent
- Safety reporting issues (SAEs and SUSARs)
- Inadequate/incomplete essential documents

COMPLIANCE TO SOPS

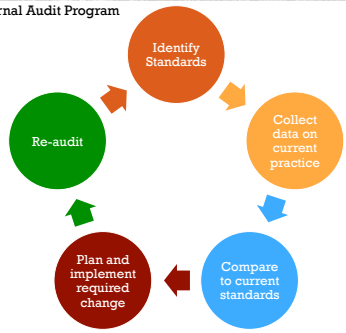


COMPLIANCE TO SOPS

- Are the SOPs used?
- Do they work?
- Who is responsible for ensuring SOP compliance?
- Actions to identify and prevent non – compliance.

COMPLIANCE TO SOPS

eg. Internal Audit Program



"We're going to parachute in and do a surprise audit, but I want to keep the whole thing low key."

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