



# VCHRI

# Human Research SOPs

# Information Session

Tuesday, July 20<sup>th</sup>, 2010

# Presentation Outline:

- The need for Standard Operating Procedures (SOPs)
  - SOPs for research studies or clinical trials involving human subjects.
- N2 SOPs
- VCHRI review of N2 SOPs
- How to access and use the VCHRI SOPs

# What are SOPs?

ICH GCP Definition:

= “Detailed, written instructions to achieve uniformity of the performance of a specific function”.

In simple terms an SOP is:

- A written process.
- A way for the study site to perform a task the same way each time it is completed.

# SOPs are used to:

- Identify the person responsible for each task.
- Describe actions (what is to be completed and how).
- Train staff.
- Monitor site performance.

# Why SOPs?

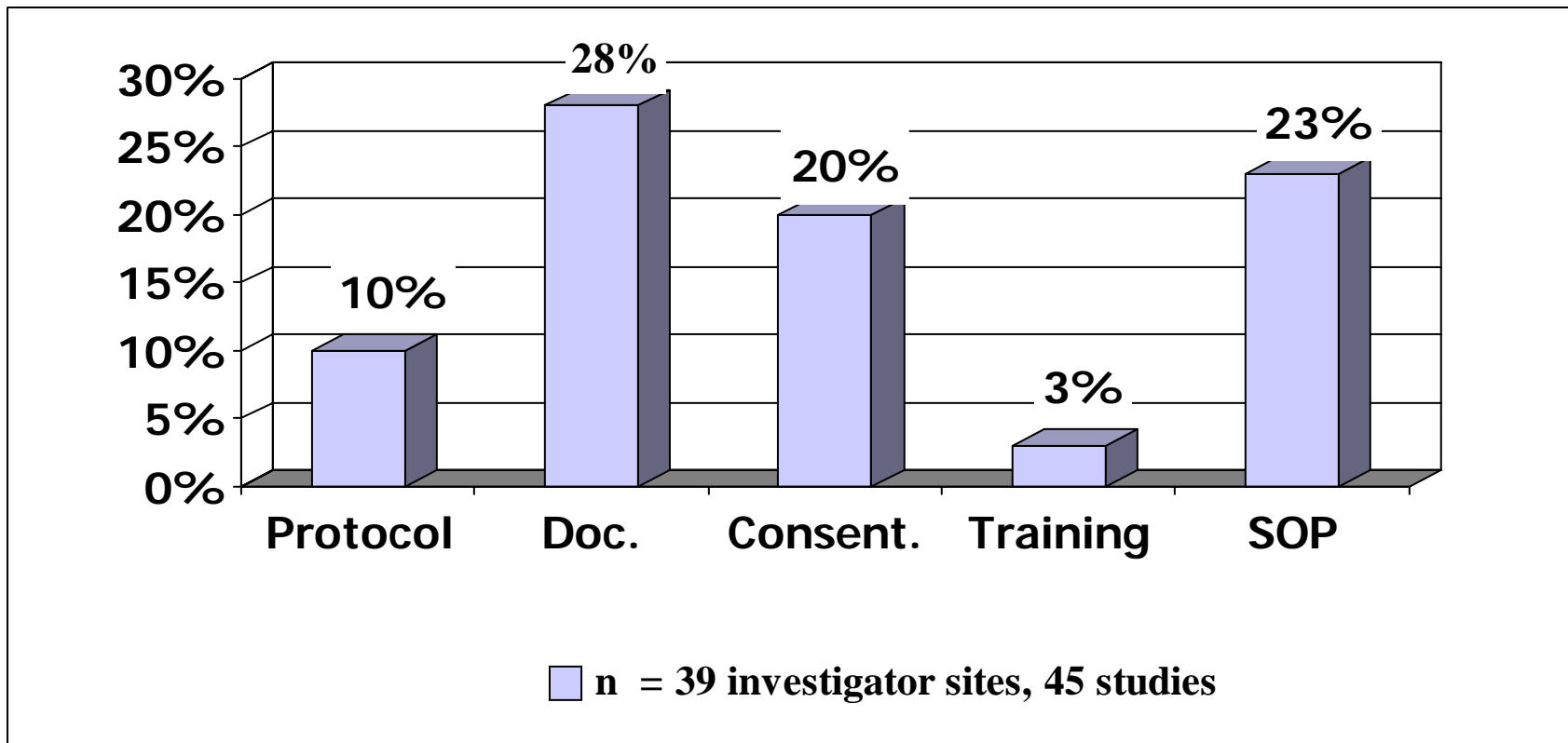
- Consistency;
- Compliance;
- Accountability; and
- Efficiency.

# Are SOPs required by Law/Regulation?

- ICH GCP Guidelines:
  - **ICH GCP 2.13: “Systems with procedures that assure the quality of every aspect of the trial should be implemented.”**
- Tri-Council Policy
- Health Canada regulations: Division 5 of the Canadian Food & Drugs Act:
  - **C.05.010: “Every sponsor shall ensure that a clinical trial is conducted in accordance with good clinical practices.....” (c) systems and procedures that assure the quality of every aspect of the clinical trial are implemented;**
- FDA CFR: SOPs

# Health Canada Inspectorate Report: *Main Deficiencies at Investigator Sites*

Adapted from Health Canada's HPFB (Health Products and Food Branch) Inspectorate Report (December 2004)



# Health Canada Inspection Findings: *Inspections at Sites Sponsored by Commercial Sponsors*

## C.05.010 (c) Quality Systems and Procedures

Training on systems and procedures is an integral element verified during inspection

Example

- *There was no written Standard Operating Procedures on the criteria to be used in the classification of adverse drug reactions and the reporting time limits for reporting to the Research Ethics Board the Serious Adverse Drug Reactions and the Serious and Unexpected Adverse Drug Reactions, and to Health Canada the Serious and Unexpected Adverse Drug Reactions*

Ref: Health Canada Summary Report of Inspections of Clinical Trials Conducted in 2003 / 2004

# Health Canada Inspection Findings: *Inspections at Sites Sponsored by Commercial Sponsors*

## C.05.010 (h) Informed Consent Deficiencies

Sponsors, Qualified Investigators and Research Ethics Boards should help promote compliance with informed consent process requirements by adopting and adhering to written standard operating procedures covering all aspects of the informed consent process, including how to inform, obtain and maintain the informed consent of subjects.

Example:

- *There is no written procedure specific for trial under review that specifies who, how and when written informed consents are obtained and explained.*

Ref: Health Canada Summary Report of Inspections of Clinical Trials Conducted in 2003 / 2004

# Health Canada Inspection Findings: *Inspections at Sites Sponsored by Commercial Sponsors*

## C.05.010 (h) Informed Consent Deficiencies

The Qualified Investigator is responsible for the process used to explain to potential subjects the risks and anticipated benefits of participating in a clinical trial. This process should be well defined and supported with written standard operating procedures, including how to inform, obtain and maintain the informed consent of subjects, and to ensure consistency in the information provided to every subjects. Examples of such deficiency include

Example:

- *There was no written Standard Operating Procedures for the process and responsibilities pertaining to obtaining Informed Consents so as to assure uniformity among the sub-investigators*

Ref: Health Canada Summary Report of Inspections of Clinical Trials Conducted in 2003 / 2004

# Benefits of SOPs

- Regulatory and organizational policy requirements.
- Training.
- Audits/Inspections.

# Network of Networks (N2)

- A National alliance of members with common interests
- Multiple existing disease networks, institutions and other research stakeholders willing to join forces to enhance Canada's research capability and capacity.
- A virtual clinical research hub
  - self-governed, with “self-help” environment to share best practices, tools and resources)

# N2 SOPs

- Currently have **22** Standard Operating Procedures available to N2 members
- Compliant with Health Canada and US Food and Drug (FDA) regulations, the ICH-GCP Guidelines and the Canadian Tri-Council Policy Statement on Research Involving Human Subjects
- Approved SOPs audited by external auditor for compliance with regulations and ICH/GCP requirements
- Available to all members of N2, across institutions, networks and therapeutic areas
- Continue to work on developing SOPs and training tools to support conduct of research

# N2 Agreement with Research Institutions and Networks

- N2 is the sole owner of all title and IP rights for SOPs
- N2 members can distribute and use SOPs **within the boundaries of their Network / Research Institution**

# Why did VCHRI Conduct a Review of the SOPs?

The purpose of VCHRI's review of the N2 SOPs was twofold:

1. To ensure that the SOPs were consistent with VCH and UBC research policies; and
2. To ensure that from the researchers' and research coordinators' perspectives, the SOPs were accurate and reflected our actual processes.

Significant changes were made to:

- SOP 08 Informed Consent Process
- SOP 12 Adverse Event Reporting in Research Studies
- Glossary and Acronyms

# VCHRI SOP Committee Members

The VCHRI SOP Committee comprised the following members:

- Jan Buchanan, Manager, Research Office, VGH Emergency Department
- Cheri Chalmers, Financial & Regulatory Research Administration, VGH Cardiology Research
- Rayone Christante, Clinical Research Administrator, Dermatology Clinical Trials Unit
- Jill Clark, Coordinator, Hematology Clinical Trials Unit (and previously, Tanis Nelson)
- Cheryl Davies, Research Coordinator, Joint Preservation Program, UBC Hospital
- Wendy Morrison, Research Nurse Coordinator, Multiple Sclerosis Clinical Trials, UBC Hospital
- Daniel Rogers, Research Manager, VGH Nephrology
- Kerri Abramson, Coordinator, Research Education, VCHRI
- Stephania Manusha, Regional Manager, Clinical Trials Administration, VCH

# How was the review conducted?

- ~5 meetings a year for 2 years.
- Each committee member was assigned 2-3 SOPs.
- SOPs reviewed in detail at the meeting.
- Issues were raised.
- Agreed upon changes were incorporated.

# VCHRI SOPs

- **SOP 01** Standard Operating Procedure (SOP) Administrative Management
- **SOP 02** Research Team Roles and Responsibilities
- **SOP 03** Research Team Training
- **SOP 04** Research Study Protocol Feasibility and Site Selection
- **SOP 05** Research Study Initiation/Activation
- **SOP 06** Informed Consent Forms
- **SOP 07** Research Ethics Board: Submissions and Ongoing Communications
- **SOP 08** Informed Consent Process
- **SOP 09** Subject Recruitment and Screening
- **SOP 10** Management of Investigational Products
- **SOP 11** Management of Biological Specimens
- **SOP 12** Adverse Event Reporting in Research Studies
- **SOP 13** Study Monitoring and Communication
- **SOP 14** Research Study Data Management
- **SOP 15** Investigator Study Files and Essential Documents
- **SOP 16** Research Study Close Out
- **SOP 17** Audits and Inspections
- **SOP 18** Clinical Trial Application
- **SOP 19** Confidentiality and Privacy

# VCHRI SOP Committee Responsibilities

- Develop new and review existing SOPs;
- Draft revisions to SOPs;
- Remain current on clinical trial regulations and guidelines, research practice, or institutional policies;
- Schedule and conduct a review of every SOP, at least once every two years, or sooner, if there are changes to regulations, guidelines, etc.; and
- Ensure that SOPs are created or updated, as needed to reflect any changes to regulations, guidelines, research practice, or institutional policies.

# Accessing the VCHRI SOPs

- VCHRI SOPs posted on the CTA Intranet site.
  - Click on the “Standard Operating Procedures” Drop Down Menu.
  - Enter Login and Password
- Tools:
  - Tools are checklists and logs that accompany SOPs.
  - N2 has provided a core set.
  - If the VCHRI community has any tools they would like to share, please send them and we will post.

# General Information

- SOPs contain minimal text copied from regulations and explanations of why procedures are done.
- Information belongs in policies, not procedures.
  - SOPs are designed to reflect '*how*' a procedure is done, not '*why*' it is done.
  - The '*why*' component is part of the training process.
  - Study team members need to understand the '*why*' concepts in order to be deemed suitably trained to perform these procedures.
- Reference list of regulations at the end of the procedure highlights applicable '*why*' documents.
- Tools not subject to audits.
  - Related to an SOP but not a formal attachment.
- An Acronyms and Terminology list is available to facilitate SOP reading.

# Using the VCHRI SOPs

- Approval of each SOP is confirmed by the dated signatures of:
  - Vice President Research, VCH
  - Regional Manager, Clinical Trials Administration, VCH
- Authorized versions are posted on the CTA Intranet.
- Implementation of the SOP is confirmed by posting the SOP on the VCHRI CTA intranet.
- VCH research community notified via email (i.e., Clinical Trials Communicator).
- VCHRI research site accesses the SOPs by logging onto the VCHRI CTA intranet.
- SOPs printed by research site.
- Site Research Manager/Director may sign off.

# Using the VCHRI SOPs

- What if our Department already has SOPs?
  - The VCHRI SOPs are at this point not “mandatory”.
  - Offered as a resource.
  - Benefit of using the VCHRI SOPs: you do not have to maintain them/write them.

# Using the VCHRI SOPs

- How do we know when an SOP is no longer active?
  - VCHRI will review and amend as necessary all SOPs **bi-annually**.
    - The N2 SOPs have been reviewed and revised annually.
    - VCHRI will review the revised N2 SOPs prior to rolling them out to the VCHRI research community.
  - The VCHRI SOPs will be rolled out with the current effective date.
  - VCHRI Research Community will receive updates and information related to the SOPs through the “Clinical Trials Communicator”.

# Using the VCHRI SOPs

- **What is the difference between Revision History “Summary of Changes” (Section 7.0 of each SOP) and “Revision Summary?”**
  - In the back of each SOP there is a brief history called “Revision History” to document what was changed.
  - The “Revision Summary” is a separate document that goes with the SOP and expands on the “Revision History” to explain where exactly the changes are, what it states and why the change was made.
  - This was done to make it easier for you to be educated on the SOP and the changes.

# Using the VCHRI SOPs

- Can the sponsor of my study review and take the SOPs?
  - Every sponsor is encouraged to review the SOPs. This needs to occur onsite as the SOPs cannot be distributed outside the organization.
  - If you receive feedback/comments from a Sponsor related to the SOPs, please forward it.

# Using the VCHRI SOPs

- What do I do if the set of SOPs does not have the SOP I need?
  - Any VCHRI research personnel may identify the need for new or revised SOPs, based on findings from a scheduled SOP review, audit, or changes to regulations, guidelines, research practice, or institutional policies.
  - Email Stephania –
    - VCHRI SOP Committee will be informed, as well as the N2 SOP Committee.
    - If new SOPs are deemed necessary by the N2 SOP committee they will be developed in a timely fashion. (immediately if a regulatory change; with the annual review if not urgent).
  - The VCHRI SOP Committee will write the original SOP following the standard format, or amends (if possible) the previously approved SOP, according to this procedure.

# Using the VCHRI SOPs

- What happens to the old version on an SOP?
  - Old versions of the SOPs are retired in an archive folder on the VCHRI CTA Intranet and will remain there in case you require access to them.

# Using the VCHRI SOPs

- Can I make copies of the SOPs?
  - You can make copies of the SOPs provided you do not distribute them outside your organization.
  - Please ensure you are aware of the date to ensure you are working with the version that you need.

# Using the VCHRI SOPs

- Can I share the SOPs with others in my institution, outside my therapeutic areas?
  - If your institution is a member of N2, the SOPs can be made available to all hospital staff.
  - Please ask them to contact VCHRI.

# Using the VCHRI SOPs

- Where can we send comments on the SOP content?
  - Comments and questions should be directed to Stephania Manusha.
  - The VCHRI SOP committee will review all comments as part of the bi-annual review process.

# VCHRI SOP Education

- Fall 2010
  - Lunch n Learns
    - Facilitated discussion
    - Focused on one VCHRI SOP

VCHRI Research Education Program 2010-2011

<http://www.vchri.ca/s/Workshops.asp>