Standard Operating Procedures (SOPs)

Dr. Marie Jackson

Definition of SOPs

A standard operating procedure is a set of step-by-step instructions compiled by an organization to help staff carry out **complex, routine operations**.

Purpose of SOPs

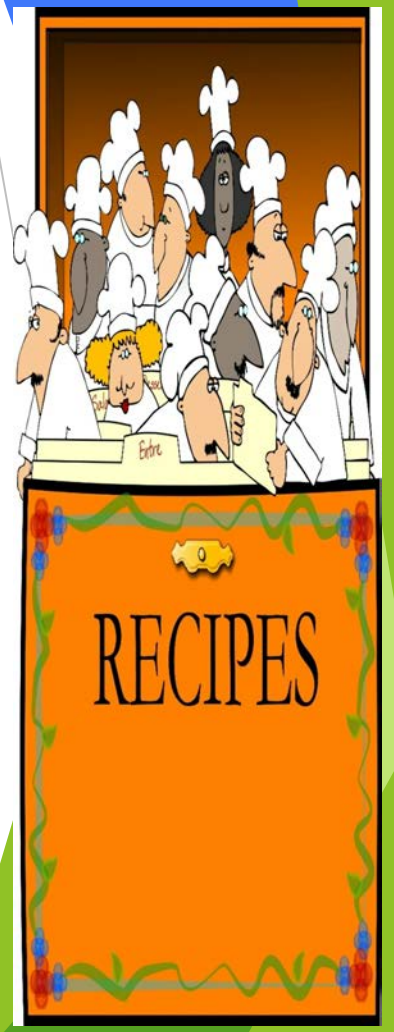
SOPs aim to achieve **efficiency, quality output** and **uniformity of performance**, while reducing miscommunication and failing to comply with industry regulations.

https://en.wikipedia.org/wiki/Standard_operating_procedure

Benefits of SOPs

- Provides the framework for a well-controlled, compliant clinical trial by ensures the integrity of the data collected
- Ensures you meet regulations
- Excellent training resource for new team members
- Offers opportunity to examine and improve processes
- Promotes accountability for team members

Think of an SOP like a recipe for clinical trials operations at your site



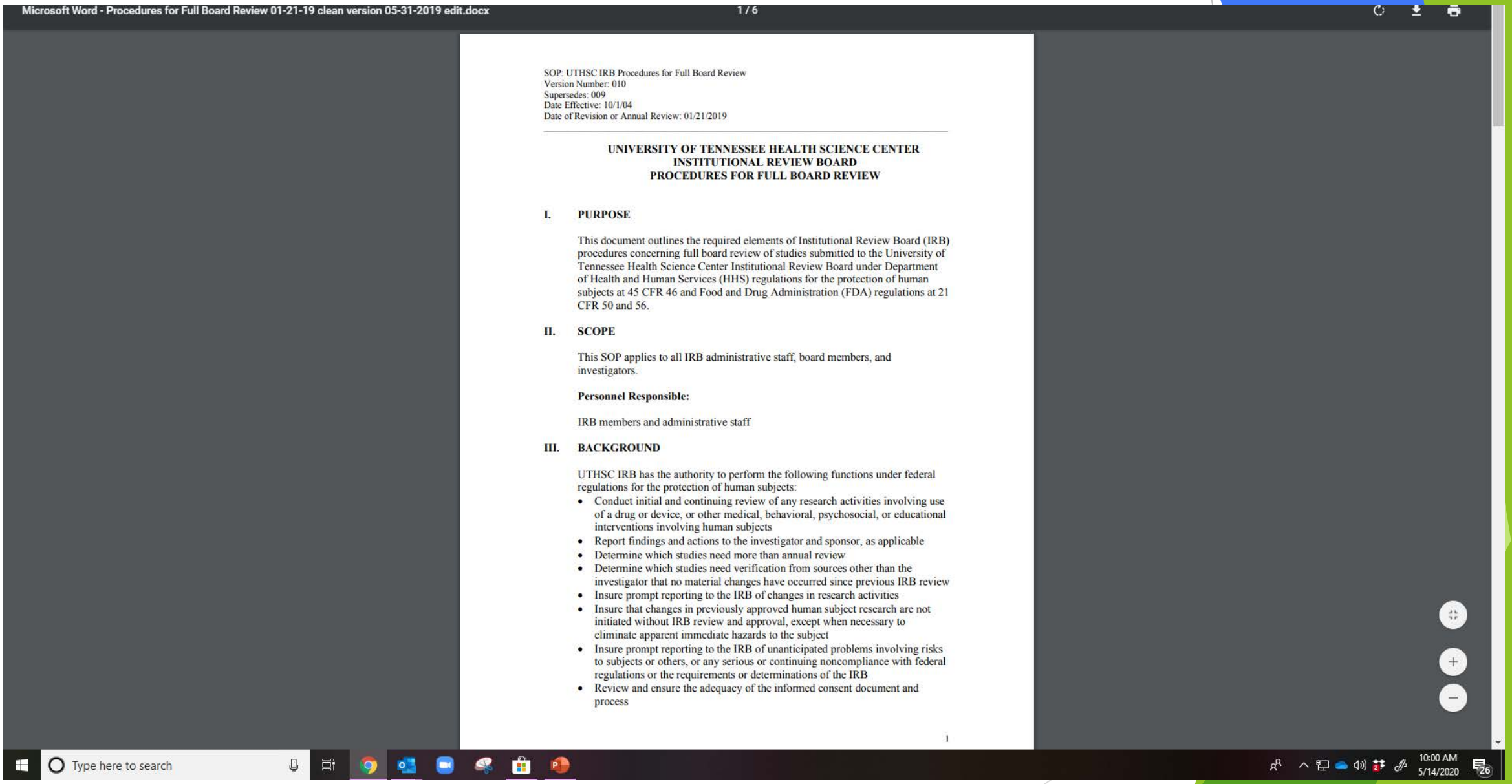
How to Begin

- Assemble teams
  - An upstream, downstream, and outside
- Set clear goals and timelines
- Gather applicable literature regarding regulations, review and record
- Create a list of procedures to be included
- Discuss the procedures/steps/any foreseeable issues
- Identify the Owner-(this is usually the most senior leader in unit)

E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)
Guidance for Industry

Create a Standard Template

Title	Section headers	Purpose	Definition	Scope/Responsible individuals
Background	Procedures	Reference to applicable guidance and regulations	Signature of approving authoritative person/date	Page numbers
	Attachments/Appendix	History of Change	Date of : • Version • Initial approval • Effective date • Revision	


Microsoft Word - Procedures for Full Board Review 01-21-19 clean version 05-31-2019 edit.docx
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SOP: UTHSC IRB Procedures for Full Board Review
Version Number: 010
Supersedes: 009
Date Effective: 10/1/04
Date of Revision or Annual Review: 01/21/2019
UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
PROCEDURES FOR FULL BOARD REVIEW
I. PURPOSE
This document outlines the required elements of Institutional Review Board (IRB) procedures concerning full board review of studies submitted to the University of Tennessee Health Science Center Institutional Review Board under Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR 46 and Food and Drug Administration (FDA) regulations at 21 CFR 50 and 56.
II. SCOPE
This SOP applies to all IRB administrative staff, board members, and investigators.
Personnel Responsible:
IRB members and administrative staff
III. BACKGROUND
UTHSC IRB has the authority to perform the following functions under federal regulations for the protection of human subjects:
• Conduct initial and continuing review of any research activities involving use of a drug or device, or other medical, behavioral, psychosocial, or educational interventions involving human subjects
• Report findings and actions to the investigator and sponsor, as applicable
• Determine which studies need more than annual review
• Determine which studies need verification from sources other than the investigator that no material changes have occurred since previous IRB review
• Insure prompt reporting to the IRB of changes in research activities
• Insure that changes in previously approved human subject research are not initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject
• Insure prompt reporting to the IRB of unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB
• Review and ensure the adequacy of the informed consent document and process
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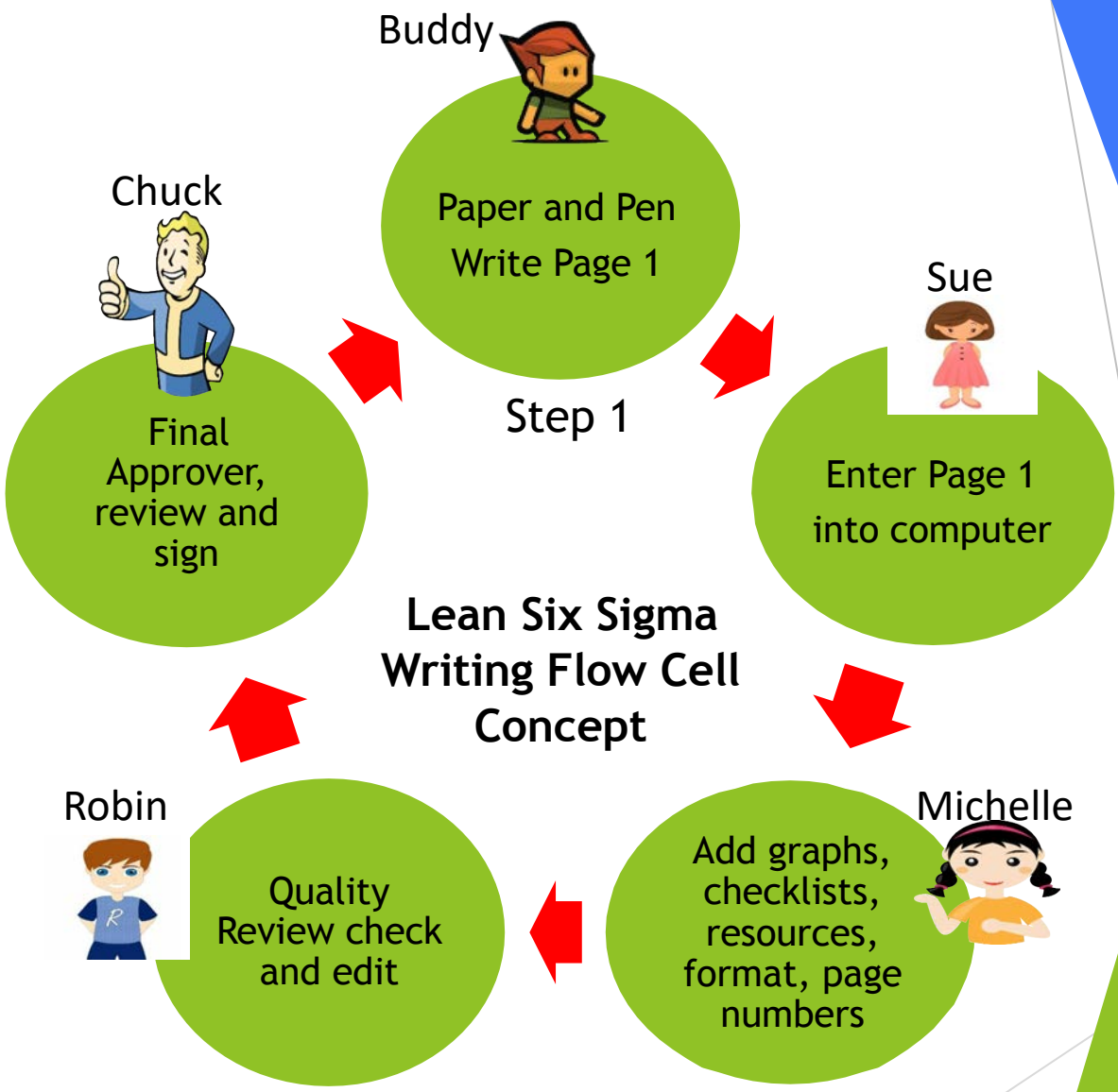
Begin Writing

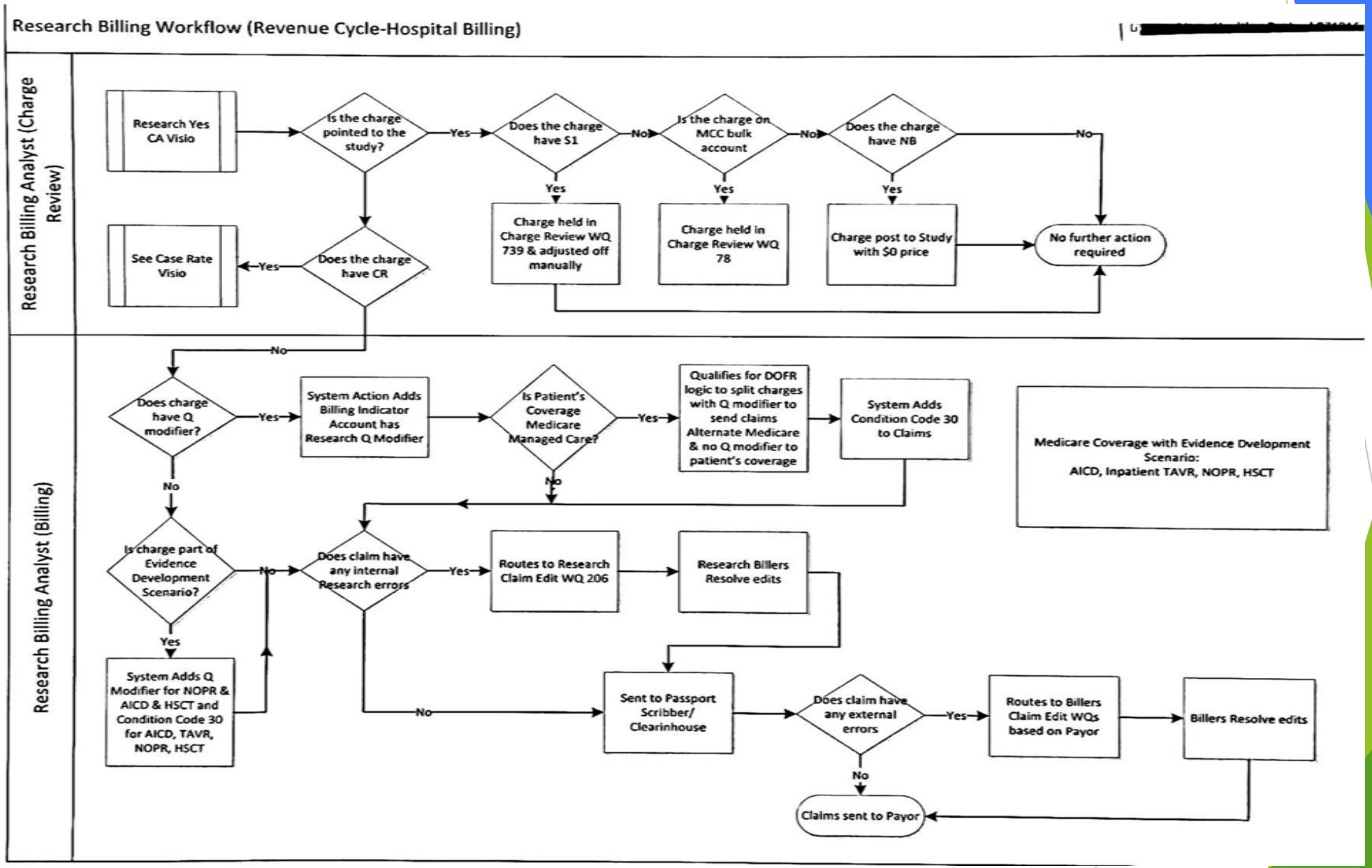
<u>WHO writes SOP?</u>

Determine the following:

- Who knows the details in the process?
- Who performs the task(s)?
- Department directors
- Quality department staff



Example of Workflow within SOP



TIPS for Creating SOPs

- First, SOP on SOP and include a glossary of terms
  - Definitions, numbering, standard format, sections, training, revision…
- Be comprised of short, concise, active sentences
- Include adequate details to clearly guide research staff to conduct a procedure
- Contain a specific aim and written in a general format that can be easily followed by a broad audience
- Demonstrate compliance with regulations and guidance
- List tasks in the correct order to be conducted

Does it Work?

- Test the SOP- does it actually work as written?

Can a team member successfully perform the process unsupervised?

Approval Process

Establish the approval process by determining who will review and make the decision to approve

- The author of the SOP will sign
- The department head that has been designated to approve the SOP will also sign the form
- A responsible party will also be assigned the task for revisions/reviews and maintain a master list of SOPs

Distribution/Training

Distribution, education and training on new departmental SOPs should be consistent

- Notify study team that there is a new SOP
- Place the signed original copy in an SOP binder/electronic folder
- Keep the paper/electronic original in a secure location

- Choose the best training approach for the SOP
  - Document the date each research staff has been appropriately trained and deemed competent to perform the SOP
  - Train new staff on all SOPs when they join the study team
  - Consistently monitor members of the study team to ensure they are following SOP procedures
  - Provide refresher training at regular intervals-annual required trainings

Train and Re-Train!

Implementation

- **After** the study team has had adequate training the SOP can be implemented
- Notify the team member the SOP is effective and should be implemented
- Document the date the SOP became effective
- Reassess the SOP process/procedures a few days after the implementation to ensure all procedures can be implemented without any errors/revisions/issues

Review of SOPs

When should a review be performed?

- At least an annually
- Regular intervals as needed to reassess applicability of procedures
- When trends of noncompliance occur
- In response to a monitoring/audit finding
- After a reporting of issues by the study teams or other involved parties

Why should reviews be performed?

- To ensure the procedures still apply
- Review to assess if any content/procedures require updating

Who should conduct the review?

- SOP owners, study team members, and approval authorities

What to Consider When Reviewing SOPs

IF IT HAS BEEN AWHILE SINCE YOU HAVE UPDATED YOUR STANDARD OPERATING PROCEDURES, HERE ARE A FEW IMPORTANT QUESTIONS TO CONSIDER:

ARE THE PURPOSE AND INSTRUCTIONS OF YOUR SOP CLEAR AND CONCISE (I.E. DO SOME OF THE INSTRUCTIONS ALLOW TOO MUCH ROOM FOR INTERPRETATION)?

IF YOU ARE SEEING NONCOMPLIANCE WITH SOPS, WHAT LANGUAGE NEEDS TO BE UPDATED OR REMOVED (I.E. PROVIDING MORE DEFINED TIMELINES FOR DELIVERABLES)?

HAVE THERE BEEN ANY POLICY CHANGES (I.E. UPDATED REGULATORY REQUIREMENTS IN A CERTAIN REGION)?

DO THE PROCEDURES WORK WELL TOGETHER, OR IS THERE DUPLICATION AMONG DIFFERENT PROCEDURES? OR MAYBE WORSE, ARE THERE CONFLICTING REQUIREMENTS?

Revising & Archiving

- Revision occurs when:
  - Deviations occur that require a procedure/SOP to be revised
  - Regulations, guidance, or policies change
- Revision process:
  - A designated member of the study team manages this process
  - Create audit trails, use track changes
- Archiving:
  - Old versions need to be archived when SOPs are updated
  - Keep all signed originals in the SOP binder/folder (electronic or paper)
  - Label superseded versions as “Archived”
  - Remove superseded versions from circulation

Master Tracking List of the SOPs

Reference	Version	Title	Associated Document(s)
SOP-QA-9	V2	Receiving Informed Consent	•Informed Consent Form •Participant Information Sheet (PIS) Guide •Study Withdrawal Form
SOP-QA-17	V1	Project Committees	
SOP-QA-19	V4	Amendments	•Amendment Log
SOP-QA-15*	V3	Drug Accountability	•Emergency Unblinding Form •IP Order Form •Temperature Monitoring Log •Drug accountability log

What SOPs are needed?

How many SOPs are we talking about?

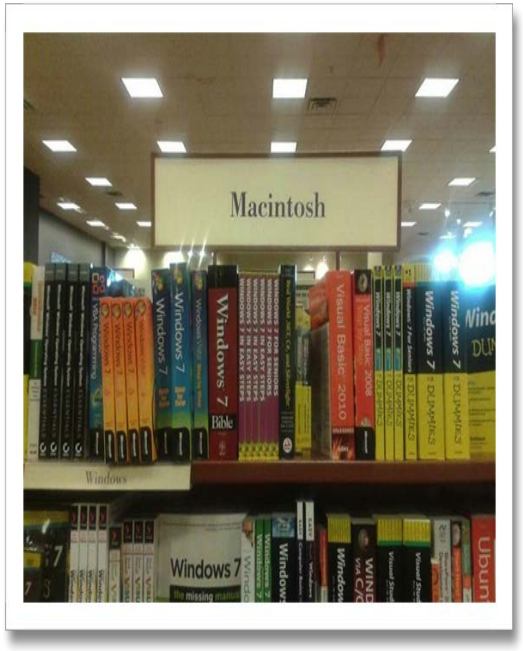
List of SOPs that Research Teams May Need to Have:

- 1. SOPs process for SOPs
- 2. Responsibilities of the Research Team
- 3. Screening, Recruitment, Enrollment, and Retention of Participants
- 4. Informed Consent Process
- 5. Essential Documents and Recordkeeping
- 6. IRB Submissions: Initial, Revision, Continuing Review, and Closure
- 7. Event Reporting (AE, PD, UP)
- 8. Clinical Research Billing and Coverage Analysis
- 9. IP Accountability, Storage, Transportation, Shipping, Destruction
- 10. Monitoring and Auditing
- 11. Study Closure
- 12. Emergency/Disasters (COVID)

Common Errors

Not updating SOPs as needed

Not documenting training



Not properly distributing

Not versioning or including an effective date

Making SOPs too detailed

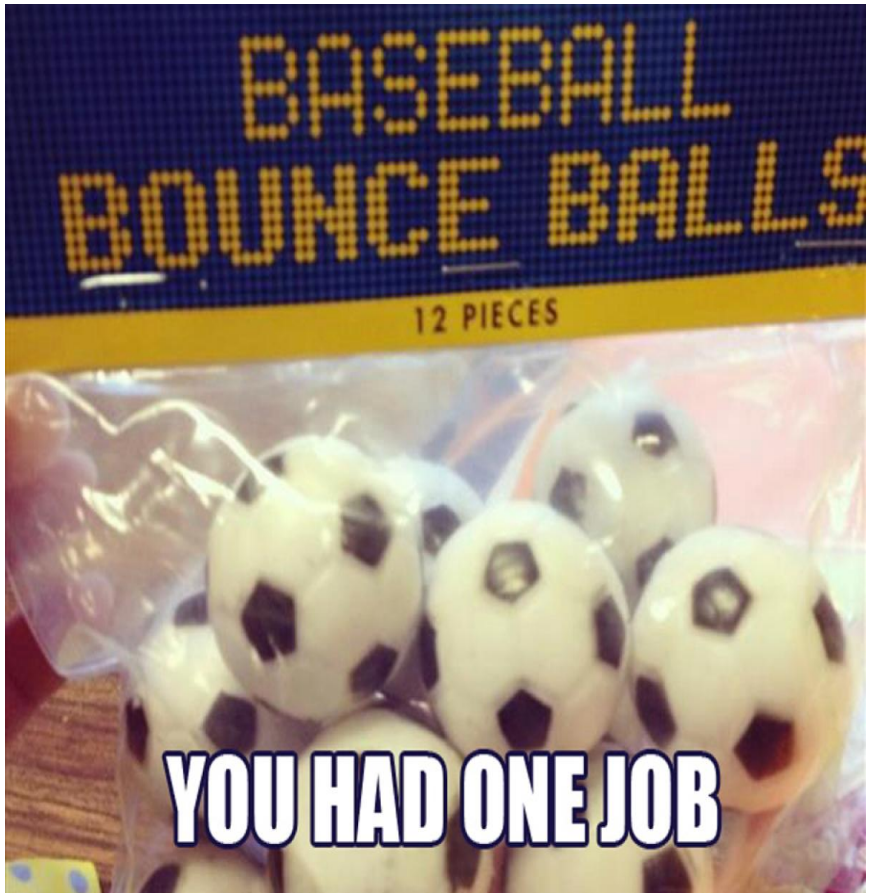
Writing the procedures

in a manner that can not be followed

Failure to train the team especially when the SOP is revised

Implementing a new SOP or a revision BEFORE training

FDA will issue a 483 if you are not following your own SOPs



“Making the simple complicated

is commonplace;

making the complicated simple,

awesomely simple,

that’s creativity”.

-Charles Mingus