2009 Web Seminar Series

Writing Site Specific Standard Operating Procedures (SOPs)

Instructors:

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Introduction

- This is a one-hour seminar providing a process, tools and guidelines for writing site-specific SOPs that facilitate process documentation and consistency
- An investment in your sanity

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Training Outline

- Topic 1: SOP value and purpose
- Topic 2: Recommended sections and content guidelines
- Topic 3: Protocol and site specific process breakdown
- Topic 4: Process risk identification and mitigation

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Site Specific Standard Operating Procedures

- A document for service of care
- Every protocol has a manual of operations
- Every site develops site specific SOPs
  - Institutional Standards
  - IRB Standards

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JOHNNY HAWKINS
"That's interesting – what exactly do you mean by 'thump'?"

In Simple Terms

- Prepare a step-by-step guide
- Someone could step in for you
- Guide to keep study processes going
- KISS (Keep it simple sweetheart)

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SOP Value and Purpose

- Standardizing procedures
- Training new staff members
- Process standardization
- Facilitates quality
- Manage work processes
- Minimizes miscommunication
- Identify vulnerable components
  - Present opportunity to protect

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Recommended Sections and Content Guidelines

- Cover Page
- Table of Contents
- Core Sections
  - Introduction
  - Purpose
  - Scope
  - Definitions/Abbreviations
  - References
  - Process Detail Description
- Write in a concise, step-by-step, easy-to-read- format
- SOPs should be written with sufficient detail so that someone with limited experience with or knowledge of the procedure, but with a basic understanding, can successfully reproduce the procedure when unsupervised.

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SOP#17	CTN-0032 Participant Payment (We-Pay) Procedures	Date Approved:
Approved By:	Origination Date: 9/19/08 Date Revised:	Page 1 of 2

I. **Rationale:**

The AMS CTP is a participating site in the CTN-0032 clinical trial. This is a site-specific supplement to the protocol regarding the procedures for handling Participant reimbursement procedures by using "We Pay" MasterCard Debit/Cash Cards.

II. **Procedure:**

The heart of the WePay payment system is the Card. These are MasterCard-branded pre-paid debit cards, issued by Citizens Bank. Payments are made by assigning monetary value to a Card, and transferring ownership of the Card to the Subject. Cards owned by a Subject may be reloaded – that is, subsequent payments may be added to a WePay Card already owned by that person.

1. Management, Storage, and transfer of Cards

   1.1 The Node Coordinator (NC) will obtain in person, the requested blank/unloaded cards from the Grants Office. When the NC has the cards in possession (ownership) she will then log onto UPMC We Pay System website, https://wepay.upmc.edu, and assign WePay Debit Cards by number to Study Coordinator (SC).

   1.2 The SC will enter We Pay System Website and accept Debit Cards that have been assigned. When the debit cards are accepted by the SC, they are in possession (ownership) of the SC and are the responsibility of the SC until they are assigned to the subject.

2. The WE Pay Debit Cards will be in the locked file cabinet in the MC's office at all times.

   1. Participants will be assigned a debit card during the first screening visit. They will then be in possession of the subject and they will be responsible for them at that time.
   2. Participants will bring their assigned WePay card with them to each subsequent visit. Subsequent payments will be loaded onto the same card received at screening visit.

3. Participant Reimbursement

3.1 Participants are reimbursed for their transportation, inconvenience, and time for non-treatment assessment visits CTN 0032 participants can receive a maximum amount of $140 for research visit attendance.

3.1.1 Participants will receive:

3.1.1.1 $5 for completing Screening

3.1.1.2. $35 for completing baseline assessment

3.1.1.3. $40 for one-month follow-up visit

3.1.1.4. $50 for six-month follow-up visit

3.1.1.5. $5 for calling to update locator information prior to 1-month visit and $5 for calling to update locator information prior to 6-month visit

3.2 The participant will be reimbursed at the end of visit after all research assessments have been completed.

3.3 Receipt for Payment will be printed at the end of each transaction. They will be asked to sign the receipt to confirm the amount received.

4.3.2.1 One study number receipt will be kept in study binder and the second receipt will be kept in separate We-Pay binder both located in locked file cabinet in specified 0032 study drawer. The signed copy will be kept in the participants PHI binder.

3.4 All incentives will be documented in the Participant Incentive Log, located in the participant research record in room 942.

4. Reconciling and ordering a new batch of WePay Cards

4.1 The NCDE Coordinator will order a new batch of cards from the WPIC Office of Grants and Contracts located on the Fifth Floor of the Parkvale Building on Meyran Ave. when we have only 3 cards left.

4.2 Lost or stolen cards will be discontinued on the WePay website. Follow the screen in the Lost/transfer card menu for click by click instructions.

4.3 A new card can be assigned to the participant if previous card has been lost or stolen. Return to # 1 in SOP (management, storage and transfer of Cards) for instructions

5. WPIC Office of Grants and Contracts Contact for Questions;

5.1 **Sonia Wallace 412- 248-8899 Rich Berneburg 412- 248-8828**

Protocol and Site Specific Process Breakdown

- Gather tools and paperwork needed for operation
  - Routine events
    - Urine screens
  - Risk events
    - Suicidal thoughts
- Watch operation being performed
- Role-play and brainstorm for content
  - Brings things to light
  - Consider timing each task
- Record the operation sequentially
  - Direct observation is best
  - Flow Process Charts

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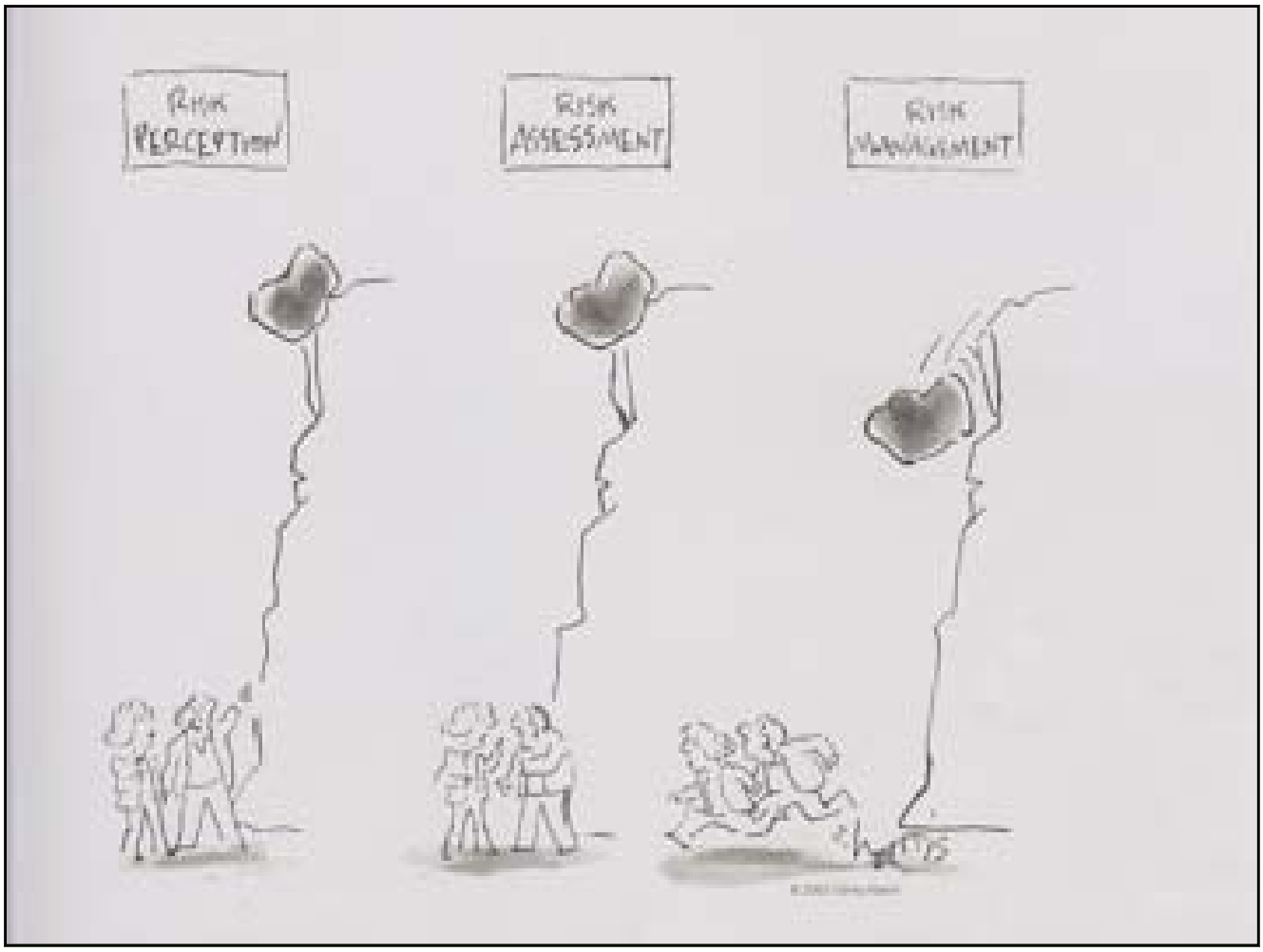
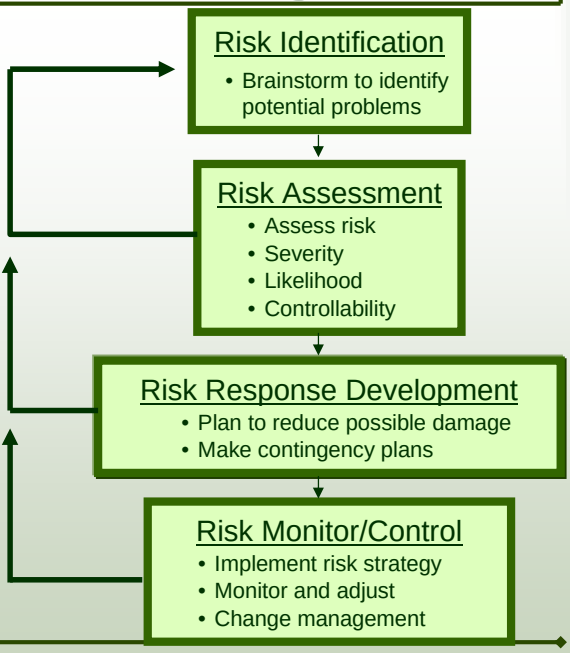

RISK PERCEPTION
RISK ASSESSMENT
RISK MANAGEMENT

Process Risk Identification and Mitigation

- Risk Management Process
  - Risk identification
    - Identify project, product and risks level
  - Risk Assessment/Analysis
    - Assess likelihood and consequences
  - Risk Planning
    - Develop plans to avoid or minimise risk impact
  - Risk Monitoring/Controlling
    - Monitor and adjust plans



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DISASTER
WAITING
TO HAPPEN
ROOM
searchlDumban1936

Revealing & Planning for Vulnerable Operations

- Generate list of possible risks
- Goal = Find potential problems before they happen
  - Break into task areas
  - Brainstorm
  - Past experience
- Focus on events that could create unwanted outcome

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Revealing & Planning for Vulnerable Operations

Events	Outcomes	Mitigation	Trigger	Responsible Person
Participant couldn't provide Urine Sample	Missed labs	Have drink available Prompt for sample collection	Conversation	greeter
Participant missed study window	Missed data	Schedule earliest day possible Reminder calls	No show	RA/RC
Snow storm	Clinic closed transportation	Reschedule	Weather report	RA/RC
Suicidal thought	Patient safety risk	Doctor for safety assessment / referral	Conversation	RA/RC/MD

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Questions

Handouts & Resources

- Handouts
  - SOP template
  - Flowchart template
- Resources online
  - Guidance for Preparing Standard Operating Procedures
    - http://epa.gov/quality/qs-docs/g6-final.pdf
  - Process mapping A Guide for Health Service Staff
    - http://www.health.vic.gov.au/qualitycouncil/downloads/process_mapping.pdf

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Upcoming Webinar

This concludes our presentation today. Thank you for joining.

- Ethical Principles in Clinical Research
  - 11/19/09

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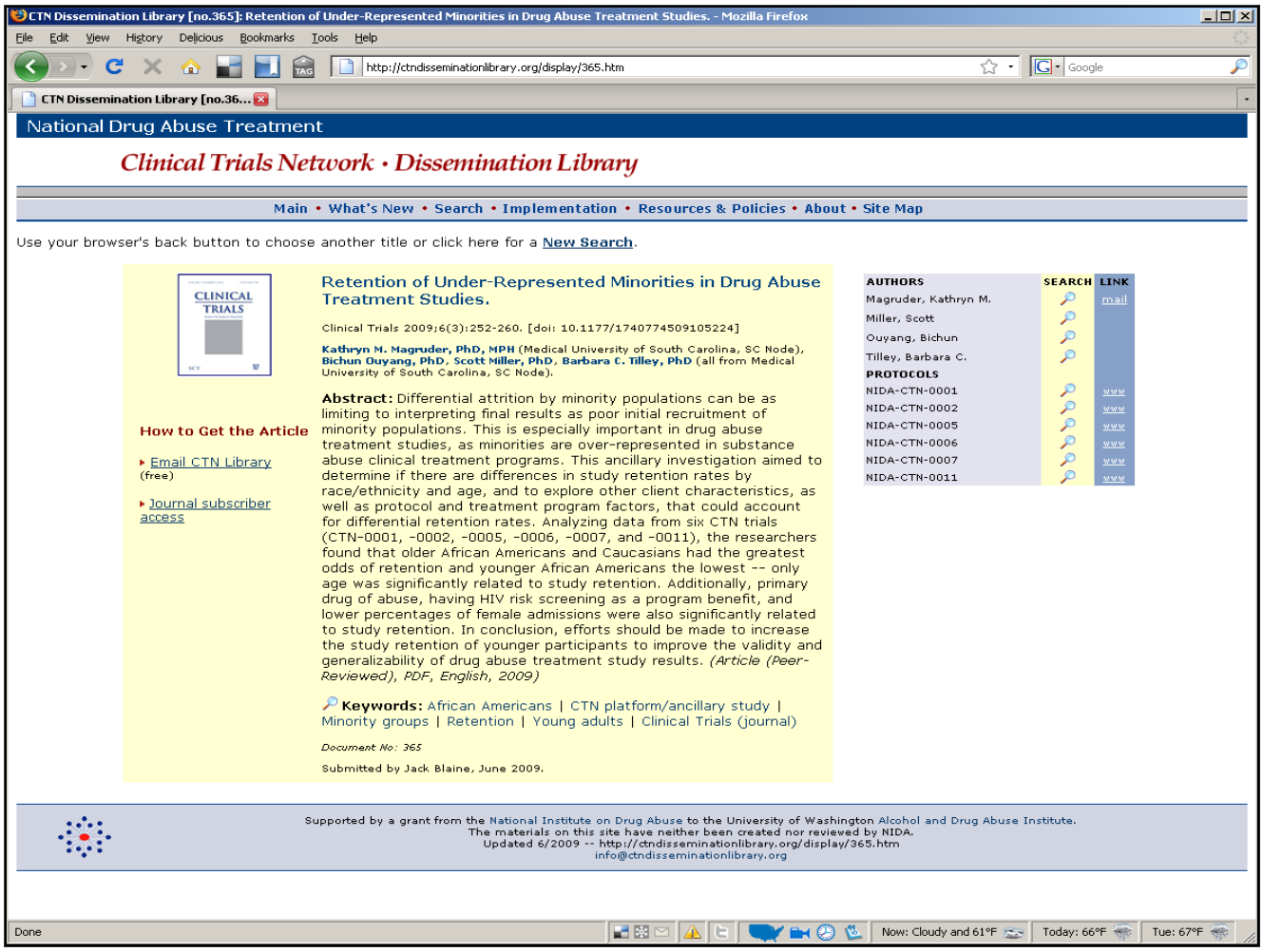
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Clinical Trials 2009;6(3):252-260. [doi: 10.1177/1740774509105224]
Kathryn M. Magruder, PhD, MPH (Medical University of South Carolina, SC Node), Bichun Ouyang, PhD, Scott Miller, PhD, Barbara C. Tilley, PhD (all from Medical University of South Carolina, SC Node).
Abstract: Differential attrition by minority populations can be as limiting to interpreting final results as poor initial recruitment of minority populations. This is especially important in drug abuse treatment studies, as minorities are over-represented in substance abuse clinical treatment programs. This ancillary investigation aimed to determine if there are differences in study retention rates by race/ethnicity and age, and to explore other client characteristics, as well as protocol and treatment program factors, that could account for differential retention rates. Analyzing data from six CTN trials (CTN-0001, -0002, -0005, -0006, -0007, and -0011), the researchers found that older African Americans and Caucasians had the greatest odds of retention and younger African Americans the lowest -- only age was significantly related to study retention. Additionally, primary drug of abuse, having HIV risk screening as a program benefit, and lower percentages of female admissions were also significantly related to study retention. In conclusion, efforts should be made to increase the study retention of younger participants to improve the validity and generalizability of drug abuse treatment study results. (Article (Peer-Reviewed), PDF, English, 2009)
Keywords: African Americans | CTN platform/ancillary study | Minority groups | Retention | Young adults | Clinical Trials (journal)
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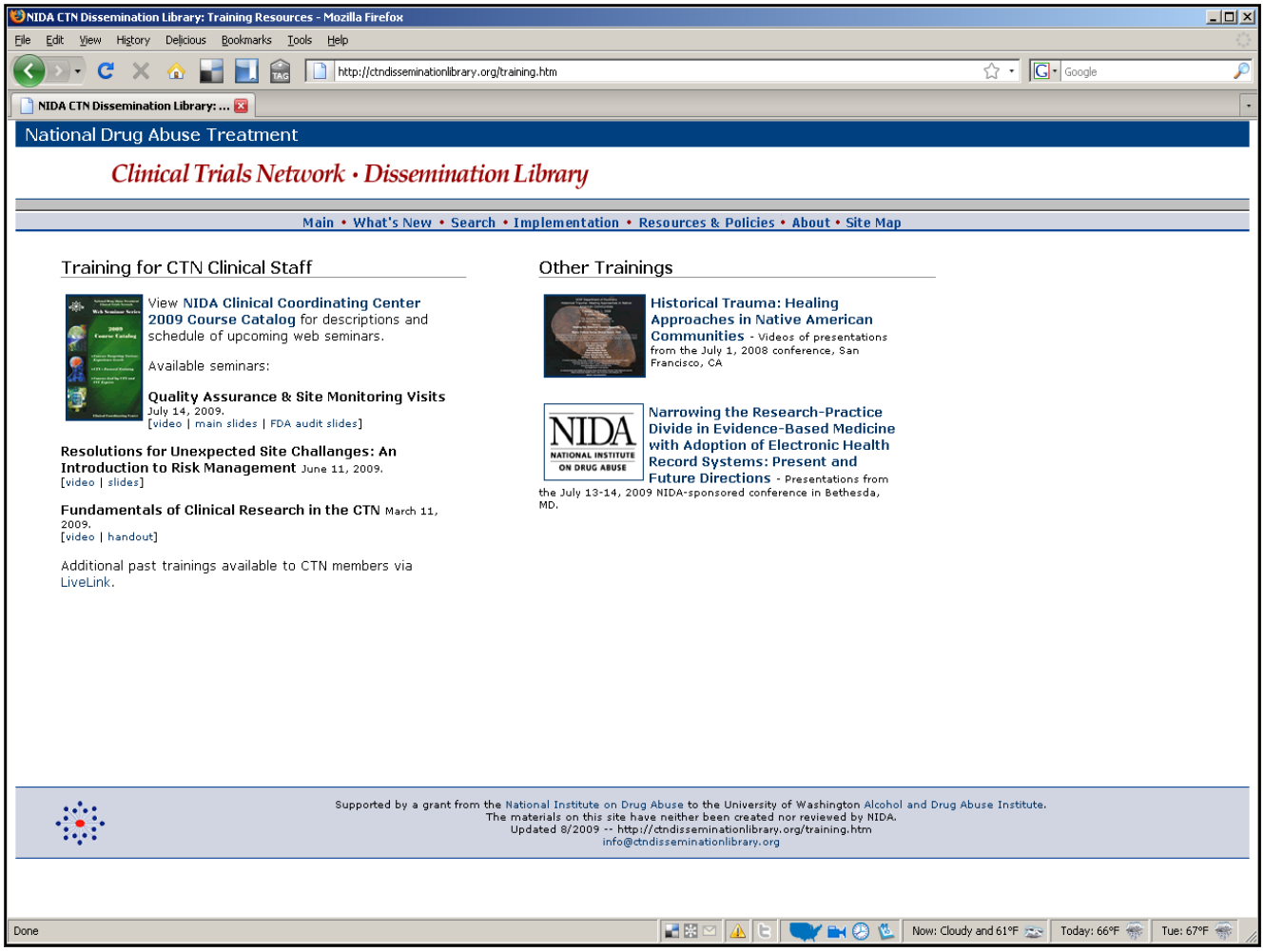
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