

Ethical and Operational Issues in Preventing Co- Enrollment

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Introduction

- Areas of Co-enrollment
- Definition of Co-enrollment
- Motivations for Co-enrollment
- Prevention of Co-enrollment
- Why prevent Co-enrollment?
- Ethical issues
- Operational issues
- Solution
- South African solution?
- Conclusion
- Acknowledgements

Areas of Co-enrollment

- Schools
- Computer software sales
- Drug and alcohol abuse rehabilitation programs
- Clinical trials

Definition of Co-enrollment

“Concurrent enrollment”

“Multiple enrollment”

Co-enrollment is a situation where the participant is enrolled in more than one clinical trial at the same time, or in the same clinical trial at different sites at the same time

Motivations for Co-enrollment

- Financial
- Curiosity
- Ignorance
- Other

Prevention of Co-enrollment

- Education of community
- Reasons for participation in clinical trial
- Alert Staff
- Shared database
- Cooperation

Why Prevent Co-enrollment?

- Safety of participants
- Data integrity
- Study outcome

Ethical Issues

- Safety
- Benefit
- Consent
- Confidentiality
- Biometrics

Ethical Issues (Cont.)

- Use of information limited to preventing multiple enrollments
- Disclosure limited to:
 - ID number
 - Clinical trial
 - Study product
 - Clinical trial site

Operational Issues

- What?
- How?
- Speed
- Reliability
- Sustainability
- Cost

Solution

frmEmployee

Participant

Number	Surname	Name
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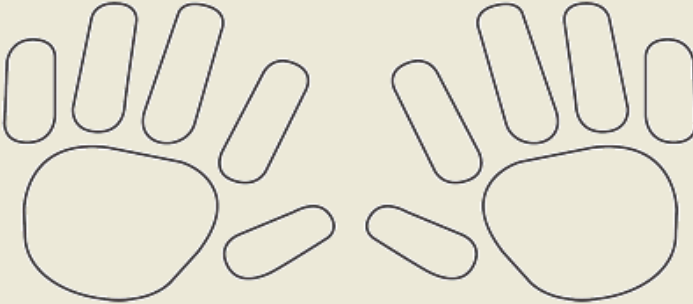
New
Update
Delete
Save
Refresh
Close

Participant Details

Name

Surname

Fingerprints



Enrolled Finger

Solution (cont.)

- Fingerprint system
- Web-based
- Secure
- Easy and quick to implement
- Low system requirements
- Bolts onto existing systems and processes
- Cost-effective
 - Once-off setup cost
 - Fixed monthly fee



Solution (cont.)

- Reliable
- Sustainable
- No hardware lockdown
- Needs minimal training



Solution (cont.)

- Redundancy & high availability:
 - Power
 - Data backup
 - Network
 - Standby server with replication

South African Solution?

- X
- Y
- Different numbering systems: ID/passport
- International solution?

Conclusion

- ❑ Co-enrollment is problematic
- ❑ Solution needed
- ❑ Cooperation among sites
- ❑ Excellent, cost-effective System required



Ngiyabonga!

Thank you!

Gracias!

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