



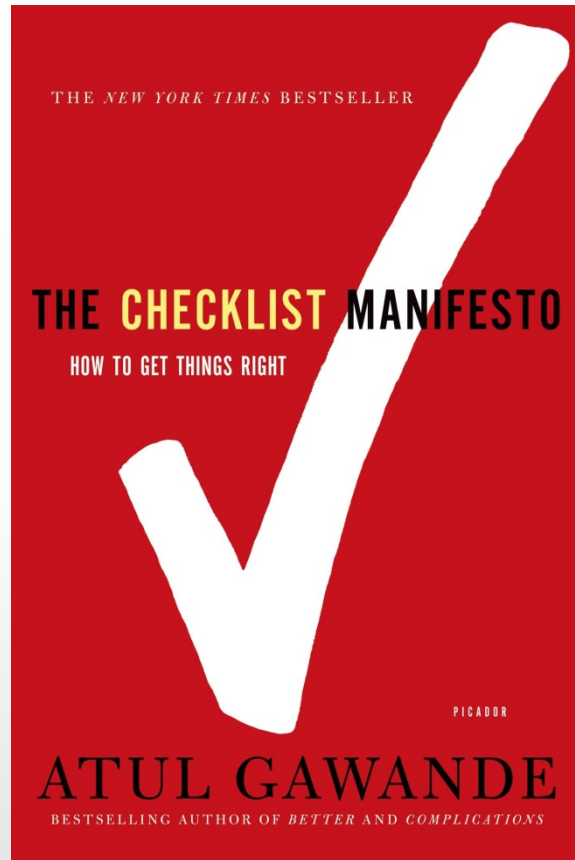
Stephanie Robins M.Sc.
Coordonnatrice de recherche en
Reproduction et la santé mentale
Hôpital général juif de Montréal
13 Juin, 2019



Réseau de recherche en interventions
en sciences infirmières du Québec

Quebec Network on Nursing
Intervention Research

Inspiration



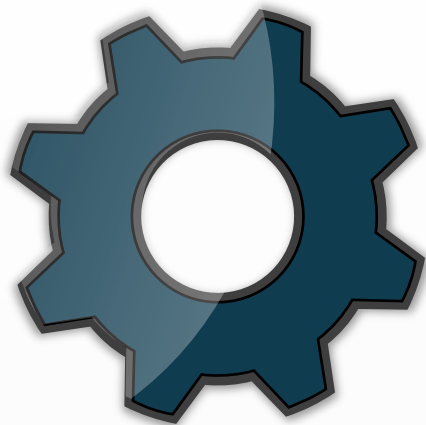
Using tools to 'get things right'

- Also, do the right things
- In our context – obtain trustworthy and **useful** data



A research study: moving parts, and moving targets





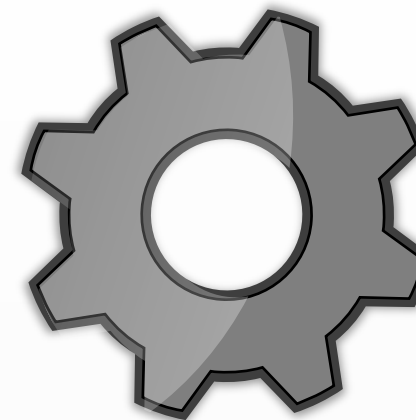
1 : Your Team

- Communicating
- SOPs
- Scripts, training
- Hiring



2: Participants

- Approach
- Tracking
- Follow up



3: Data

- Scoring & Data dictionary
- EDC, storage
- Methods



Communicating:



1 : Your Team

❖ **Communicating**

SOPs

Scripts, training

Hiring



Communicating:



- ✓ Cloud based, digital workspace and data organization platform
- ✓ Centralize discussions and work, and eliminate e-mail
- ✓ Allows for real time conversations among many users
- ✓ free, standard, premium



1 : Your Team

❖ Communicating

SOPs
Scripts, training
Hiring



1 Channels



2 Direct Messaging



RRISIQ Present... Stephanie Robins

Threads

Channels

- # general
- # journalclub
- # labmeetings
- # nicu-paper
- # random
- # gravens2018

+ Add a channel

Direct Messages

- Slackbot
- Stephanie Robins (you)
- john
- Miss. RUA Slacker

+ Invite people

Apps

+ Install Google Drive

#journalclub

☆ | 👤 - | 🔒 0 | ✎ Add a topic

Today

john 2:08 PM
joined #journalclub along with Stephanie Robins.

Stephanie Robins 2:15 PM
PDF

Kimel.pdf
1 MB PDF

Psychoneuroendocrinology
journal homepage: www.elsevier.com/locate/psyneuen
Oxytocin receptor DNA methylation in postpartum depression
Mary Kimmel^{1,2}, Makena Clive³, Fiona Gergen⁴, Jerry Cnirivann⁵, Tori Brown⁶, Olivia Cox⁷, Matthias W. Beckmann⁸, Johannes Kornhuber⁹, Peter A. Fasching¹⁰, Lauren M. Osborne¹¹, Elisabeth Binder¹², Jennifer L. Payne¹³, Zachary Kaminsky¹⁴

Miss. RUA Slacker 9:42 PM
joined #journalclub.

I am just about to arrive- sorry, running three minutes behind schedule.
Please start journal club!

bold _italics_ ~strike~ `code` ""preformatted"" >quote



Based on 1,168 responses. ± 2.81 margin of error with 95% confidence (July 2015)

Has Slack made finding information easier for you?

62.4% Yes

12.2% I don't know

25.4% No

Based on 461 responses. ± 4.53 margin of error with 95% confidence (July 2015)

Do you think Slack has improved the culture of your team?

79.0% Yes

10.4% I don't know

10.6% No

Based on 461 responses. ± 4.53 margin of error with 95% confidence (July 2015)

Has using Slack helped you feel more connected to your team?

88.6% Yes

2.7% I don't know

8.7% No

Based on 1,411 responses. $\pm 2.61\%$ at 95% confidence. (March 2016)

Slack's mission is to make your working life simpler, more pleasant, and more productive. Are we succeeding in that mission for you?

86.9% Yes

8.3% I don't know

4.8% No

Based on 1,411 responses. $\pm 2.61\%$ at 95% confidence. (March 2016)

All images from Slack, https://a.slack-edge.com/7b00/img/survey/slack_survey_results.pdf



See also a succinct and clear librarian's evaluation (2018) of Slack:

Johnson H. A. (2018). Slack. *Journal of the Medical Library Association : JMLA*, 106(1), 148–151.
doi:10.5195/jmla.2018.315
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5764588/>



1 : Your Team

Communicating

❖ **SOPs**

Scripts, training

Hiring



The main SOP: The Data Collection Protocol

A document that outlines all phases of preparing for and collecting data

- ✓ All recruiting staff are given a copy of this document
- ✓ All staff must agree they have read it
- ✓ One copy of this document lives on a Slack channel or other accessible network, or is printed and stays in the lab.



1 : Your Team

Communicating

❖ **SOPs**

Scripts, training

Hiring



A small caveat- we are slowly transitioning to digital





SOPs: The Data Collection Protocol

1) Preparation items before recruitment

- ✓ Consent forms, ensure Wi-Fi is working, or your data device is charged
- ✓ Call participants to confirm interviews

2) Resources

- ✓ Contact information of your own team
- ✓ Name of investigators
- ✓ List of important resource people at each site, including phone numbers, address

3) The Rules of engagement

- ✓ Inclusion criteria (this is its own checklist)
- ✓ Procedure for approach
- ✓ Scripts

4) Processes

- ✓ How to unlock tablets & computers; electronic data capture sign ins , screen shots
- ✓ What to do with all forms, which ones matter
- ✓ Unexpected situations (coordinator emergency contact, SAE)



1 : Your Team

Communicating
SOPs

❖ **Scripts, training**
Hiring



Training: verbal and non verbal communication

Scripts

- ✓ Write scripts of what you want to say to participants. You will think of things you did not when you imagined speaking to them.

Practicing recruitment

- ✓ Role play with staff and students



1 : Your Team

Communicating
SOPs

❖ **Scripts, training**
Hiring

Scripts: the verbal

Intro

Hello, my name is Stephanie, I am working in collaboration with the doctors and nurses of this clinic and a researcher Dr. Nancy Feeley.

Gauge Saturation

Have you heard about our study? Not yet? Then would now be a good time to discuss our study underway in the (unit, clinic) to see if you would be interested in participating?

Eligibility

If no- document if try later, or refusal

If yes- 'Great, as a first step, lets see if you qualify'

The sell

Coercion versus
Informed consent

Describe study, why their contribution is valuable

In this study, we wanted to understand the needs of(fill).....

The ask


Would you be interested in participating? Do you want some time to think about it?




Train for recruitment- the non verbal


Articles

The Role of Nonverbal Communication Behaviors in Clinical Trial and Research Study Recruitment

Susan E. Morgan , Aurora Occa, Ashton Mouton & JoNell Potter

Pages 461-469 | Published online: 17 Jun 2016

Download citation  <https://doi.org/10.1080/10410236.2016.1140266>

 Check for updates

 Full Article

 Figures & data

 References

 Citations

 Metrics

 Reprints & Permissions

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ABSTRACT

Few studies have examined the communication behaviors of those who recruit for clinical trials and research studies, particularly of nonmedical professionals who often do the bulk of recruiting. This focus-group study of 63 recruiters analyzes the ways in which nonverbal communication behaviors support the process of recruitment, using the lens of communication accommodation theory. Results indicate that recruiters first “read” potential study participants’ nonverbal communication for clues about their state of mind, then use nonverbal communication to achieve a sense of convergence. Specific nonverbal communication behaviors were discussed by recruiters, including smiling, variations in the use of voice, adjusting body position, the appropriate use of physical touch, the management of eye contact, and the effect of clothing and physical appearance. Implications for recruitment practice are discussed.

Same authors:
<http://dx.doi.org/10.5772/intechopen.70192>



1 : Your Team

Communicating
SOPs
Scripts, training
❖ **Hiring**



Hiring

From within your team

- ✓ Volunteers
- ✓ Referrals from other researchers

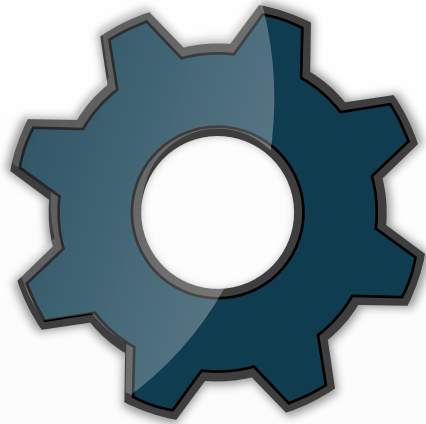
Career and Placement Services

- ✓ Free service



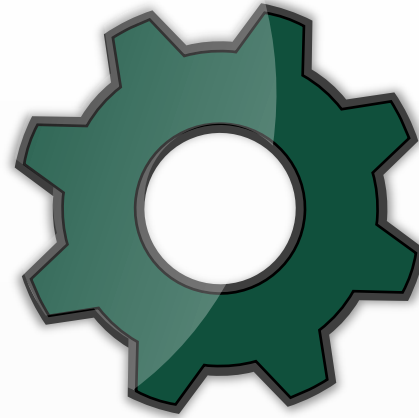
Hiring

McGill	U de M	UQAM	CONCORDIA
https://www.mcgill.ca/caps/employers/hire	http://www.cesar.umontreal.ca/emploi/employeur/index.htm	https://vie-etudiante.uqam.ca/employeur/nouvelles-et-ressources.html	https://excel.concordia.ca/employers/login-page.htm



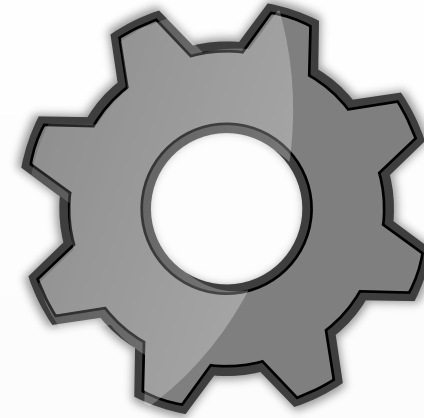
1 : Your Team

- ✓ Communicating
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- ✓ Hiring



2: Participants

- Approach
- Tracking
- Follow up



3: Data

- Scoring & Data dictionary
- EDC, storage
- Methods



Recruitment: the approach

Assessing eligibility example (Large studies)

Approached Tracking Sheet

Instructions: Use a **new** tracking sheet *every* day while recruiting. Use this form to keep track of *every* person you approach in the clinic. Keep track of both people you approach who agree to go through the eligibility triage, and those who indicate they don't want to participate even before knowing whether they are eligible.

Recruiter: _____ Date (YY_MM_DD) _____ SITE: _____

#	Sex		Agreed to eligibility triage?		If yes, Ineligible (I), Refused (R), Missed (M), Consent (C)	If no, reason for refusal If yes, write participant ID (e.g., busy, not interested)
	M	F	Yes	No		
1						
2					I	
3						



2: Participants

❖ Approach

Tracking
Follow up



Recruitment: approached (potential) participants

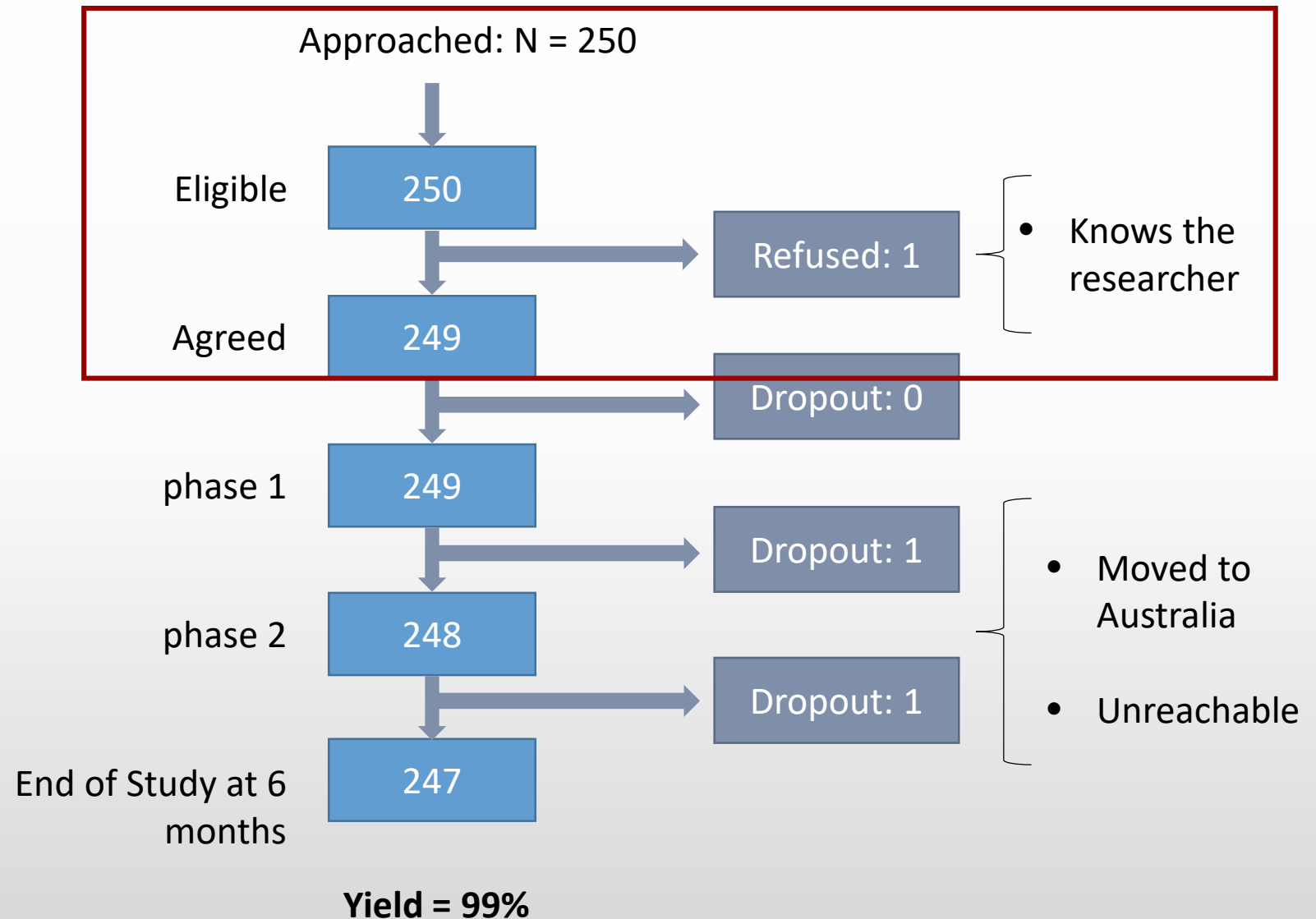
- ✓ Yes
- ✓ No (declined study)
- ✓ Thinking about it





Recruitment: approached

Consort Diagram (THE DREAM)





2: Participants

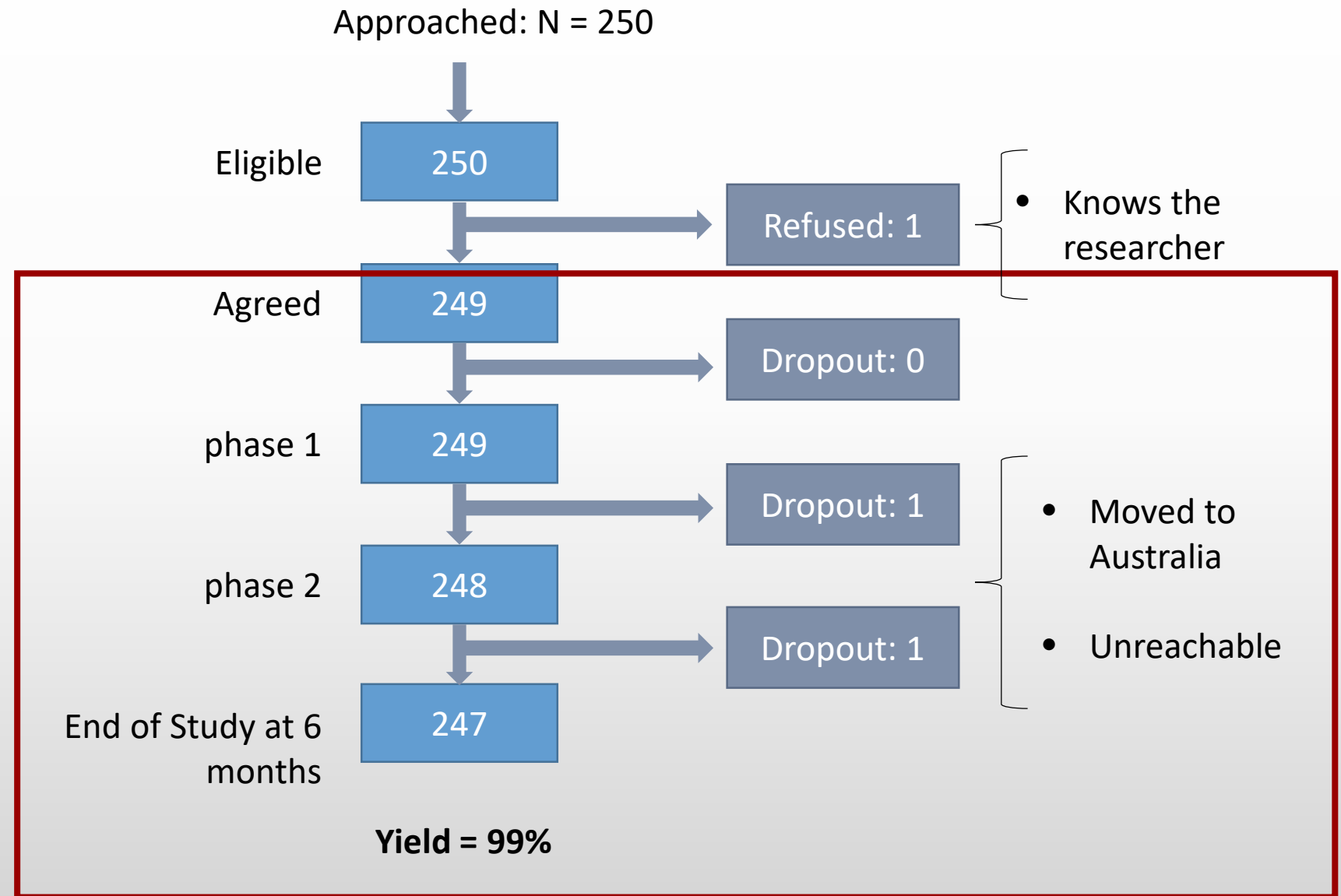
Approach

❖ **Tracking**

Follow up



Participants- tracking through study



2: Participants

Approach
❖ Tracking
Follow up



Participants- tracking through study

ID	Date Recruited	Questionnaire package phase 1	Due to be discharged	2-4 weeks between Q1 and 2?	Questionnaire package phase 2	Discharged	Notes
1001-SR	2019-02-05	2019-02-05	2019-03-01	Yes	2019-03-01	2019-06-11	Discharged much later than expected. Check if still qualifies for follow up portion at 6 months
1002-RU	2019-02-06	2019-02-07	2019-04-01	Yes	2019-04-01	2019-04-02	
1003-AB	2019-02-15	2019-02-15	?	No		2019-02-17	
1004-CD	2019-02-15	2019-02-15	2019-03-07	Yes			



2: Participants

Approach

Tracking

❖ **Follow up**



Participants: tracking at or past end of study



2: Participants

Approach

Tracking

❖ **Follow up**



Following up:

- I authorize a person delegated by the doctor in charge of this research study to communicate with me directly to ask if I am interested in participating in other research:

Yes ☐

No ☐

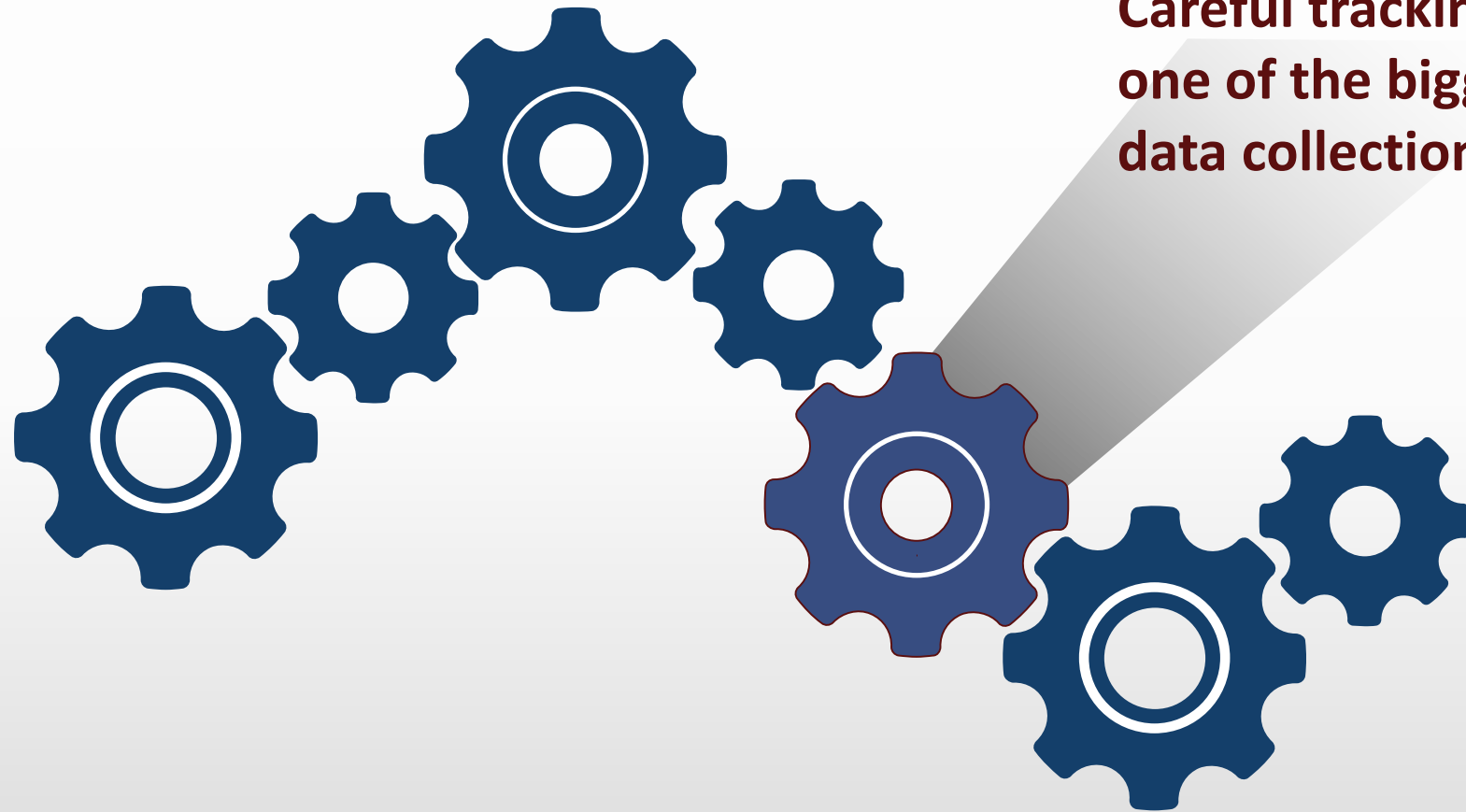
Name of participant

Signature

Date



Tracking

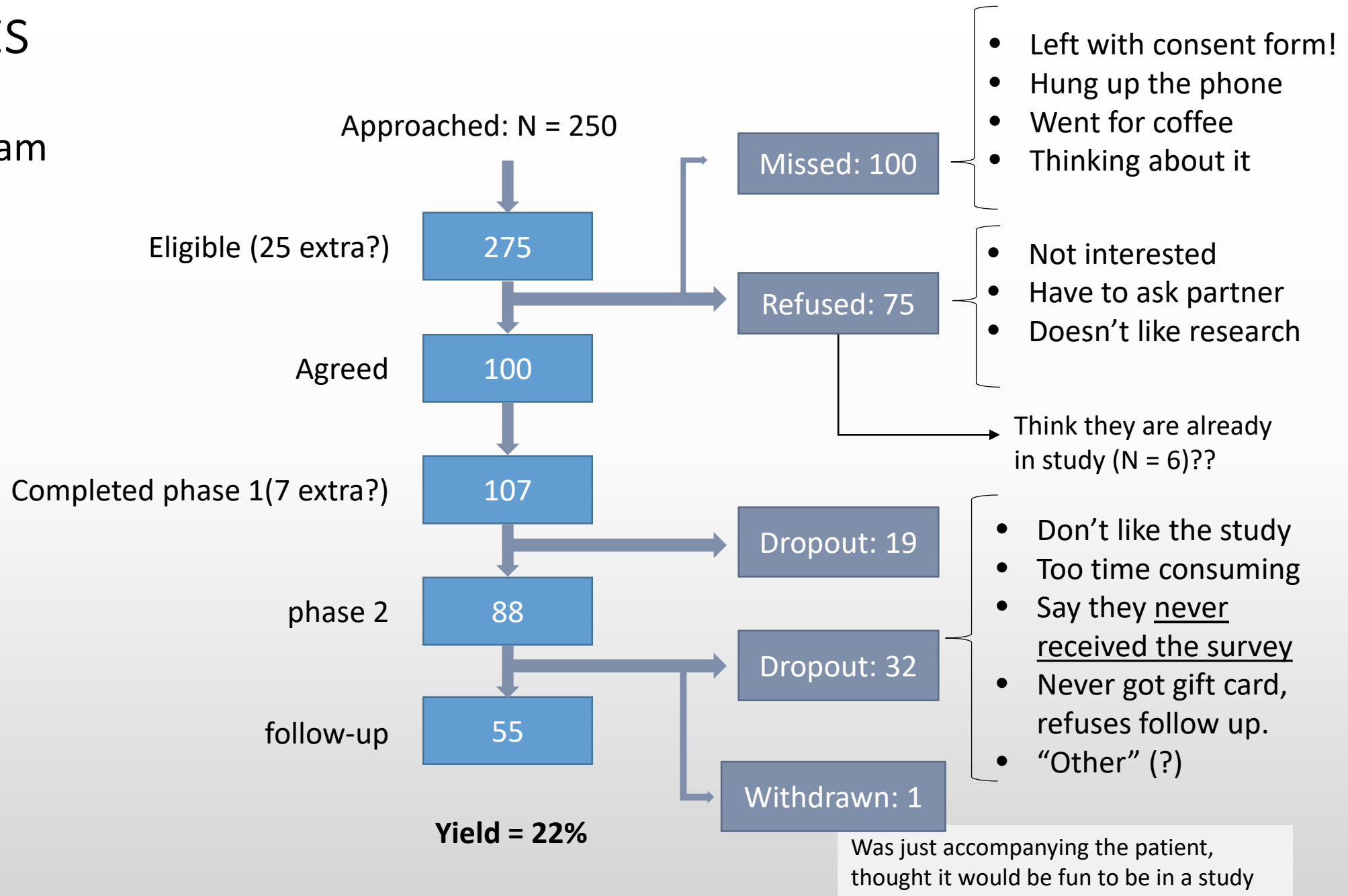


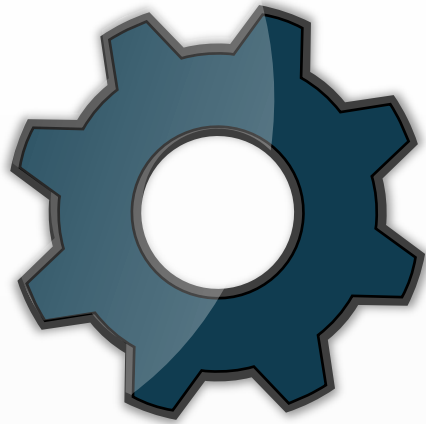
**Careful tracking is perhaps
one of the biggest
data collection concerns**

Participants

Consort Diagram

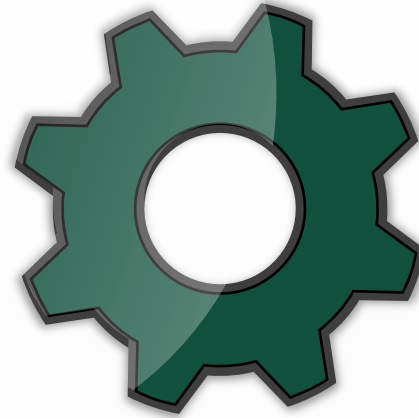
THE (semi) REALITY





1 : Your Team

- ✓ Communicating
- ✓ SOPs
- ✓ Scripts, training
- ✓ Hiring



2: Participants

- ✓ Approach
- ✓ Tracking
- ✓ Follow up



3: Data

- Scoring & Data dictionary
- EDC, storage
- Methods



Scoring



3: Data

- ❖ **Scoring & Data dictionary**
- EDC- Storage Methods





Scoring Manual

Reference document, created in house

- 1) A table of contents
- 2) A table with an overview if you have many measures at many different time points

3) Each **measure** :

- ✓ Official Name
- ✓ Construct being measured
- ✓ Range of scores
- ✓ Clinical Cut-offs
- ✓ Description of the measure
- ✓ Scoring of all items
- ✓ Calculation of sum scores and subscales
- ✓ References for reliability and validity
- ✓ Populations it is used in





Data: 'What's the score?'

ID	EPDS 1	EPDS 2	EPDS 3	EPDS 4	EPDS 5	EPDS 6	EPDS 7	EPDS 8	EPDS 9	EPDS10	EPDS TOTAL
1001-SR	1	0	1	2	2	0	3	1	3	0	
1002-UR	0	0	0	1	1	1	1				
1003-AB	2	2	1	1	0	0	0	0	1	1	
1004-CD	1	0	0	0	0	0	1	1	1	0	
1005-EF	3	3	1	1	2	3	1	2	3	3	
1006-EG	3	3	0	0	0	0	1	2	2	0	



Scoring Manual

A common measure of depression: EPDS

Use these scores to create Database

Calculate the reliability of your own sample to compare

We recently added a new section to our scoring manual- similar populations to our own

Edinburgh Postnatal Depression Scale (EPDS)

NAME of MEASURE: Edinburgh Postnatal Depression Scale (EPDS)

CONSTRUCT MEASURED: Maternal Depression

SCORES OBTAINED: Not at risk or at risk for depression (Dichotomous outcome)

THEORETICAL RANGE: 0-30

INTERPRETATION / CUT-OFF: Respondents who score 12 and above are classified as at risk for a depressive disorder. If used as a community screener, 10 and above is used.

Higher Scores = Greater Symptoms

MEANINGFUL CLINICAL CHANGE: Score would change from above the cut-point to below the cut-point, or the reverse

DESCRIPTION OF MEASURE:

- This 10-item scale designed to screen for postpartum depression in community samples has also been used in follow up studies up to 4 years postpartum.

SCORING:

- The items are rated on a scale from 0 to 3, and refer to symptoms experienced in the past 7 days. (Response schemes vary by question)
- Items 3, 5-10 are reverse scored.
- Sum scores for the 10 items to generate a total score
- Total score of 12 or higher are in clinical range = at risk for depression, referred for help.

RELIABILITY:

- The split-half reliability of the scale is 0.88, and the standardized alpha coefficient is 0.87.

VALIDITY:

- In validation studies, using a cut score of 12, the EPDS was found to have a sensitivity of 68% to 95%, and a specificity of 78% to 96%, when compared to a diagnosis of major depression made by psychiatric interview.

Cox, J.L., Chapman, G., Murray, D., & Jones, P. (2003). Validation of the Edinburgh Postnatal Depression Scale (EPDS) in non-postnatal women. *Journal of Affective Disorders*, 39, 185-189. Cox, J.L., J.M. Holden, and R. Sagovsky, *Detection of postnatal depression: development of the 10-item Edinburgh Postnatal Depression Scale*. *The British Journal of Psychiatry*, 1987.150: p. 782-786.



Data: ‘What’s the score?’

ID	EPDS 1	EPDS 2	EPDS 3_R	EPDS 4	EPDS 5	EPDS 6	EPDS 7	EPDS 8	EPDS 9	EPDS10	EPDS TOTAL
1001-SR	1	0	1	2	2	0	3	1	3	0	13
1002-UR	0	0	0	1	1	1	1				.
1003-AB	2	2	1	1	0	0	0	0	1	1	8
1004-CD	1	0	0	0	0	0	1	1	1	0	4
1005-EF	3	3	1	1	2	3	1	2	3	3	22
1006-EG	3	3	0	0	0	0	1	2	2	0	11



Adjunct to scoring manual: data dictionary

	A	B	C	D	E	F	G
1	Time points	Description	Notes				
2	T1	Prenatal 1 (12-14 weeks gestation)	All participants' demographic data will be here.				
3	T2	Prenatal 2 (32-34 weeks gestation)	Only the Quebec community sample have data here				
4	Abbreviations	Meaning	Notes				
5	EPDS	Edinburg Postnatal Depression Scale	Measure of depression				
6	CWS	Cambridge Worry scale	Measure of worry				
7	SCL	Somatization Subscale of the Symptoms Checklist-90-R	Measure of somatic symptoms				
8	GAD	General anxiety disorder	Measure of anxiety				
9	ANRQ	Antenatal risk questionnaire	Measure of psychosocial risk				
10	AVP	Circulating Vasopressin	name of gene regions				
11							
What things mean			EPDS	GAD-7			



Data Dictionary

GAD	General anxiety disorder	Measure of anxiety
pp2_gad1	PP2 GAD- anxious, nervous on edge	Score 0-3 (0= not at all, 1= several days, 2= mopre than half the days, 3= nearly every day)
pp2_gad2	PP2 GAD-not being able to control worry	Score 0-3 (0= not at all, 1= several days, 2= mopre than half the days, 3= nearly every day)
pp2_gad3	PP2 GAD-worrying about different things	Score 0-3 (0= not at all, 1= several days, 2= mopre than half the days, 3= nearly every day)
pp2_gad4	PP2 GAD-having trouble relaxing	Score 0-3 (0= not at all, 1= several days, 2= mopre than half the days, 3= nearly every day)
pp2_gad5	PP2 GAD-Being restless	Score 0-3 (0= not at all, 1= several days, 2= mopre than half the days, 3= nearly every day)
pp2_gad6	PP2 GAD-Easily annoyed	Score 0-3 (0= not at all, 1= several days, 2= mopre than half the days, 3= nearly every day)
pp2_gad7	PP2 GAD-Feeling something awful might happer	Score 0-3 (0= not at all, 1= several days, 2= mopre than half the days, 3= nearly every day)
pp2_gadtotal	PP2 GAD Total score	number

What things mean

GAD-7

EPDS

+

Scoring

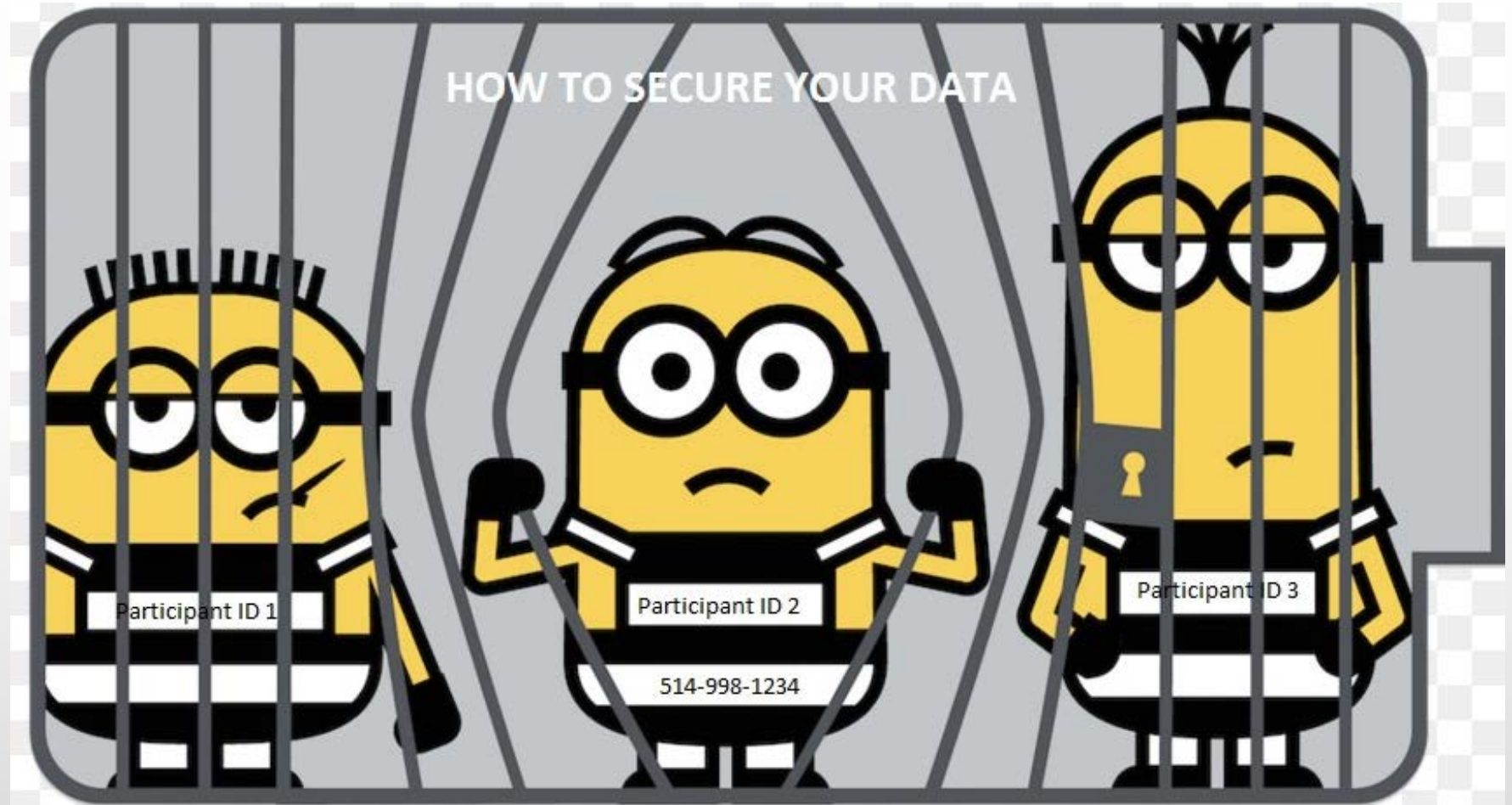


3: Data

Scoring & Data
dictionary

❖ **EDC- Storage**
Methods

Electronic Data Capture and Storage



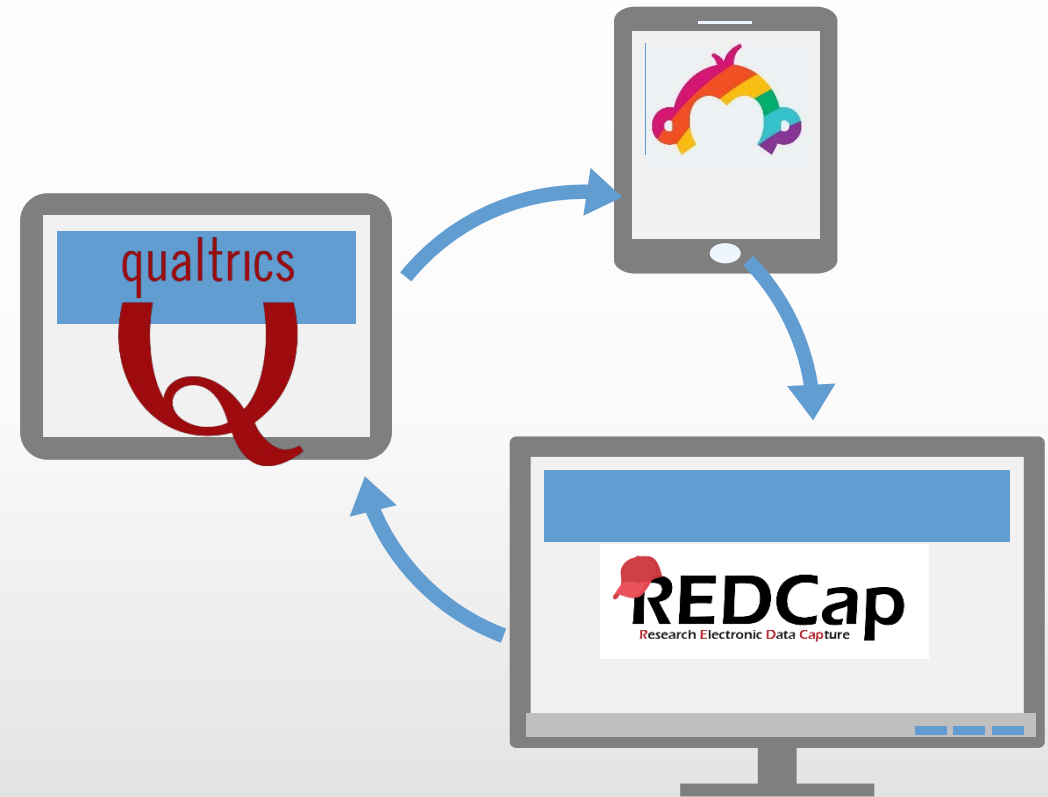
3: Data

Scoring &
Data dictionary
❖ **EDC- Storage
Methods**



Electronic Data Capture

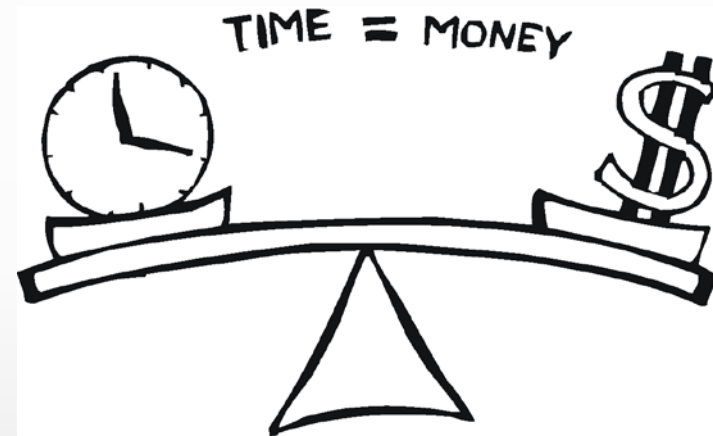
- Growing Tendency to EDC
- Send surveys, capture data
- Speed
- Access to data
- Accuracy
- Database export





EDC: challenges

- 1) Learning how to navigate the system, invest money and time
- 2) Your participants need to be EDC comfortable
- 3) Your REB is going to have LOTS of technical questions for you, especially about the security of your data.





Security: locked up, backed up

SAFE DATA STORAGE

Password protected file

Password protected computer (work)

Network drive at your institution*

Network institution servers backup at remote sites with firewalls and anti-virus

Hard drive in office password protected

Mobile apps produced for research

Paper in a locked cabinet, in office



Security: locked up, backed up

SAFE DATA STORAGE	RISKY DATA STORAGE
Password protected file	Hard drive of personal computer at home
Password protected computer (work)	USB key outside of office
Network drive at your institution*	Some cloud servers*
Network institution servers backup at remote sites with firewalls and anti-virus	Google Calendar, forms
Hard drive in office password protected	Slack*
Mobile apps produced for research	
Paper in a locked cabinet, in office	*= may be ok, the jury is out

Scoring



3: Data

Scoring & Data
dictionary

EDC- Storage

❖ **Methods**



Master Methods

I've learned two important lessons in life. I can't recall the first one, but the second one is that I need to start writing stuff down.





Thank you for your attention!

srobins@jgh.mcgill.ca



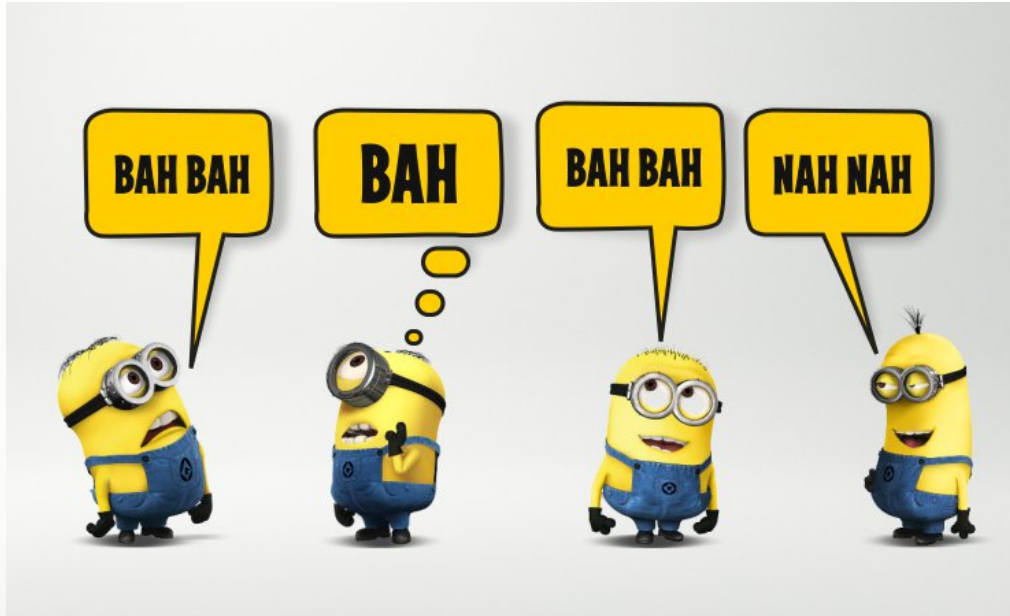
Communication: Slack certifications

The image is a screenshot of the Slack website, specifically the 'Compliance certifications and regulations' section. The page is in French. At the top, there is a navigation bar with the Slack logo, links for 'Pourquoi choisir Slack?', 'Solutions', 'Ressources', 'Tarifs', and 'Your Workspaces'. Below the navigation bar, the main heading reads 'Réalisez tous vos projets avec Slack'. Underneath, a subheading states 'En alignant les compétences et les processus dans votre équipe, Slack décuple la qualité du travail.' There is a form for 'E-mail professionnel' and a button labeled 'FAITES UN ESSAI GRATUIT'. Below this, a link says 'Utilisez-vous déjà Slack ? Connectez-vous'. The bottom of the main section features the text 'La collaboration à portée de main'. To the right, there is a section titled 'Compliance certifications and regulations' which lists various certifications and regulations in a grid format. Each entry includes a logo, the name of the certification, a brief description, and a link to download the certificate or report.

Compliance certifications and regulations			
 FedRAMP (Li-SaaS) Federal Risk and Authorization Management Program View certificate →	 NIST 800-171 Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations	 SOC 2 (Type II) Trust Services Principles	 SOC 3 Service Organization Controls Download the report ↓
 ISO/IEC 27001 Information Security Management System (ISMS) Download the certificate ↓	 ISO/IEC 27017 Security Controls for the Provision and Use of Cloud Services Download the certificate ↓	 ISO/IEC 27018 Protection of Personally Identifiable Information (PII) Download the certificate ↓	 HIPAA Health Insurance Portability and Accountability Act Request our Requirements for HIPAA Entities
 EU/US Privacy Shield Swiss/US Privacy Shield Data Privacy Practices	 CSA Cloud Security Alliance		

And more Bloopers next slide

Scoring Bananamannual



Banana Ripeness Scale

NAME of MEASURE: Banana Ripeness Scale (BRS)

CONSTRUCT MEASURED: The ripeness of bananas

SCORES OBTAINED: The extent to which a minion perceives the ripeness of a banana

THEORETICAL RANGE: Raw Scores from 1-4

INTERPRETATION / CUT-OFF:

- This measure has no validated cut offs nor meaningful clinical change
- A greater score indicates a riper banana.

DESCRIPTION OF MEASURE:

- This 4-item scale is designed to measure perceived ripeness of bananas

SCORING:

- The four items ask respondents to appraise the ripeness
- Each item is rated on a Likert-type scale from 0 ("not ripe") to 4 ("banana bread ready").
- To obtain the total score: Reverse score items 2 and 3, and then sum across all four items.

RELIABILITY:

- Gru et al. demonstrated test-retest reliability in a sample of Canadian bananas.

VALIDITY:

- According to Gru et al. (2019), the BRS has demonstrated strong criterion validity measured against banana chlorophyll content.

REFERENCES : Gru, F. (2019). Evaluating the psychometric properties of the Banana Ripeness Scale. Journal of Minion Health, 385-396.