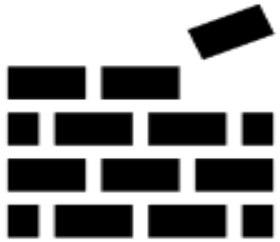
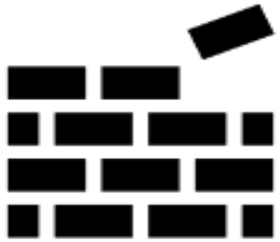


The Informed Consent Decisions & Choices (ICDC) Tool

- Mapping decisions and choices for participants and trial designers at every stage

Relton & Amstutz

Who gives Information	**What**
HCP	RQ & rationale
HC organisation - GP practice, hospital	Data collection/ use of data
Research organisation	Random selection to group
Trained non-HCP	Intervention
Government	Control (no exp intervention)
Media	Tests, Blood samples etc
Who gives Consent	**How**
Patient	F2F
Member of the public	Verbal
Research participant	Written
Group e.g. cluster guardian	Electronic: Written + signature/ thumbprint
Proxy - parent, carer	Phone
	Video
When	
Entry into system/ institution	**Where**
At risk of disease	Clinical setting
Disease onset/ diagnosis	Emergency treatment
Treatment onset	Non healthcare setting
Treatment failure	Other
Before randomisation	
After randomisation	
Before baseline data collection	
After baseline data collection	



EXAMPLE

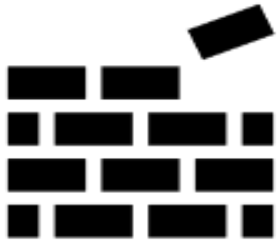
Standard approach to informed consent

One single stage

STANDARD APPROACH

WHAT	WHEN	WHO
1. Contact by research team	Before	baseline data collection
2. Use of routinely collected and/or observational data	Before	random allocation
3. Provide additional data	Before	experimental tx delivery
4. Additional tests		
5. Receive experimental treatment		
6. Random allocation		

Target population



EXAMPLE 

Staged & tailored approach to informed consent - Hospital setting

STAGE 1 of 2

WHAT	WHEN		WHO (Tailored)
1. Contact	Before	baseline data collection	Pancreatic cancer patients at Dutch cancer centres
2. Use of routinely collected and/or observational data	Before	random allocation	
3. Provide additional data	Before	experimental treatment delivery	
6. Future randomisation			
7. SOC w/o further notice (control group only)			

Cohort: The Dutch Pancreatic Cancer Project (PACAP)

Daamen et al

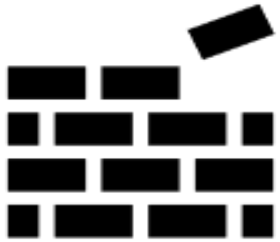
STAGE 2 of 2

WHAT	WHEN	WHO (Tailored)
1. Contact	Before / After: baseline data collection	Pancreatic cancer patients at Dutch cancer centres
2. Use of routinely collected and/or observational data	Before / After: random allocation	Already consented to 1
3. Provide additional data		Already consented to 2
5. Receive experimental treatment	Before: experimental treatment delivery	Already consented to 3
6. Future randomisation		Already consented to 6
7. SOC w/o further notice (control group only)		Already consented to 7

Cohort: The Dutch Pancreatic Cancer Project (PACAP)

RCT: Recurrent Disease Detection After Resection of Pancreatic Adenocarcinoma Using a Standardized Surveillance Strategy

Daamen et al



EXAMPLE

Staged & tailored approach to informed consent
- Community setting

STAGE 1 of 3

WHAT	WHEN		WHO (Tailored)
1. Contact	Before	baseline data collection	General/HC system members
2. Use of routinely collected and/or observational data	Before	random allocation	
	Before	experimental treatment delivery	

8. Other: information *'to look at the benefit of health treatments'*

Cohort recruitment: South Yorkshire Cohort (Yorkshire Health Study)

STAGE 2 of 3

WHAT	WHEN		WHO (Tailored)
1. Contact	Before	baseline data collection	General/HC system members
2. Use of routinely collected and/or observational data	Before	random allocation	People with depression/anxiety
	Before	experimental treatment delivery	Already consented to 1
			Already consented to 2

8. Other: information ‘to look at the benefit of health treatments’

Cohort recruitment: South Yorkshire Cohort (Yorkshire Health Study)

Sub-Cohort recruitment: South Yorkshire Cohort (Yorkshire Health Study)

STAGE 3 of 3

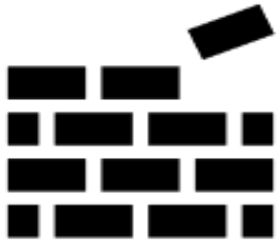
WHAT	WHEN			WHO (Tailored)
1. Contact	Before	After	baseline data collection	General/HC system members
2. Use of routinely collected and/or observational data	Before	After	random allocation	People with depression/anxiety
5. Receive experimental tx	Before		experimental tx delivery (intervention)	Already consented to 1
				Already consented to 2
				Already consented to 8

8. Other: information 'to look at the benefit of health treatments'

Cohort recruitment: South Yorkshire Cohort (Yorkshire Health Study)

Sub-Cohort recruitment: South Yorkshire Cohort (Yorkshire Health Study)

RCT: DEPSY 1st RCT within the South Yorkshire Health Study Cohort



ANOTHER EXAMPLE

Staged & tailored approach to informed consent
- Community setting

STAGE 1 of 2

WHAT	WHEN		WHO (Tailored)
	Before	baseline data collection	Proxy assent: All village chiefs in the ComBaCaL villages HOW: Oral consent
2. Use of routinely collected and/or observational data	Before	random allocation	All villagers in the ComBaCaL villages HOW: Electronic consent
3. Provide additional data			
4. Additional tests	Before	experimental treatment delivery	
6. Future randomisation			
7. SOC w/o further notice (control group only)			
8. Other: Qualitative sub-study (to be approached for additional audio-recorded interviews)			

Cohort: Community-Based Chronic Disease Care in Rural Lesotho (ComBaCaL)

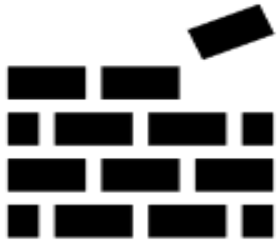
STAGE 2 of 2

WHAT	WHEN			WHO (Tailored)
2. Use of routinely collected and/or observational data	Before	After	baseline data collection	Proxy assent: All village chiefs in the ComBaCaL villages HOW: Oral consent
3. Provide additional data	Before	After	random allocation	All villagers in the ComBaCaL villages HOW: Electronic consent
4. Additional tests	Before		experimental treatment delivery	Already consented to 2
5. Receive experimental treatment				Already consented to 3
6. Future randomisation				Already consented to 4
7. SOC w/o further notice (control group only)				Already consented to 6
8. Other: Qualitative sub-study (to be approached for additional audio-recorded interviews)				Already consented to 7
				Already consented to 8

HOW: Oral consent

Cohort: Community-Based Chronic Disease Care in Rural Lesotho (ComBaCaL)

RCT: Community-based, eHealth Supported Type 2 Diabetes Care by Lay Village Health Workers in Rural Lesotho (ComBaCaL T2D)



The Informed Consent Decisions & Choices (ICDC) Tool

- For more information please contact us
- Clare Relton c.relton@qmul.ac.uk
- Alain Amstutz alain.amstutz@unibas.ch