# How to do Research

# **Cliona Kirwan**

### **Rigorous evidence is needed**

mortality is low

thus

evidence-based medicine

# Turn your idea into a research question

- ID an area of interest or problem
- Brainstorm
- Share
- Browse
- Tolerate uncertainty
- Formulate a question
- Focused
- Feasible
- Thought-provoking
- Contribute new information

#### **Review the literature**

Pubmed Reviews Citations

Assess current knowledge Check it is novel /adding to knowledge Build the case

# **Refine research question**

Identify variables Specify population Clarify what / how tested

Туре	Example
QUANTITATIVE	To test a research hypothesis
Correlative	Does grade correlate with tumour size
Comparative	Is AAA commoner in patients with scleroderma vs no scleroderma
Experimental	Does anal fissure heal quicker with diltiazem or with no intervention
QUALITATIVE	Understand personal meanings / interpretations

#### topic / focus

research problem

statement of purpose

research question

hypothesis

aims

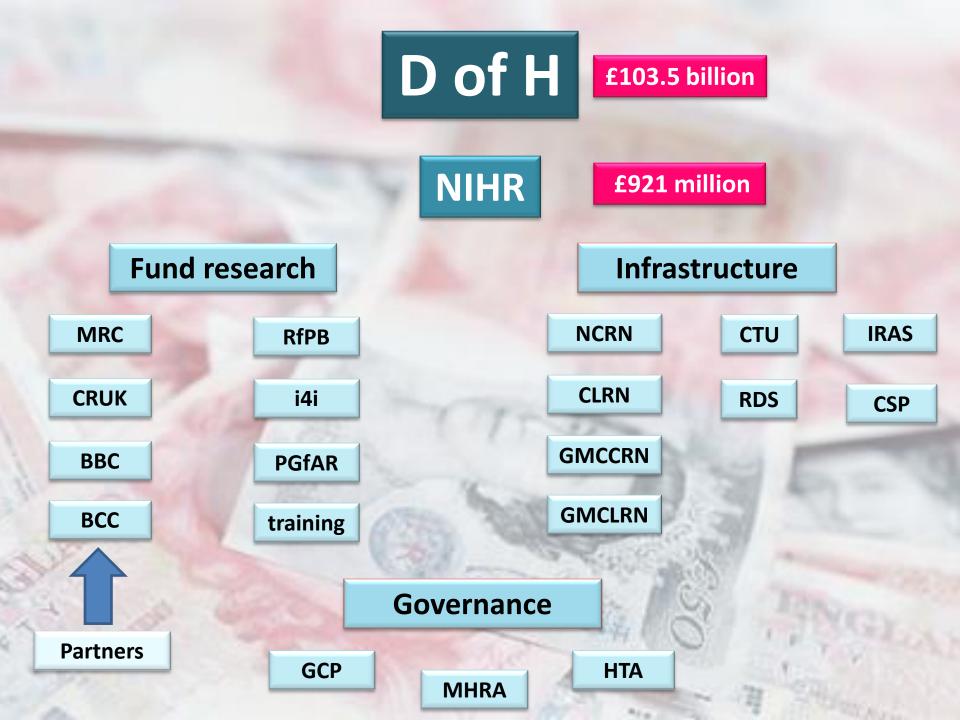
#### **Design study and develop methods**

- Endpoints
- Prospective / retrospective
- Observational / interventional
- RCT / cohort / case-controlled
- Inclusion / exclusion
- Patient pathway
- Participant involvement
- Statistical help
- Power calculation

### Writing your research proposal

- For funding
- For ethics
- For other researchers
- Ongoing guidance
- Documentary evidence

- Iterative
- Peer review
- NIHR RDS



# **Study Protocol**

- Research team
- Title
- **Research** question ٠
- Background to research question ٠
- Plan of investigation -Study design ٠
- - -Population
  - -Inclusion / exclusion
- Outcome measures
- Data collection
- Follow-up ٠
- **Planned analysis** •
- Power calculation •
- Anticipated recruitment rates ٠
- **Ethics**
- Timetable ٠
- Anticipated benefits ٠

# Funding

No costs Soft money – department / hospital Non-commercial grant **Commercial funding** NIHR RfPD i4i HTA NIHR partner Academy of Medical Sciences Alcohol Research UK\* Association for International Cancer Research Bowel Disease Research Foundation Breakthrough Breast Cancer **British Thyroid Foundation Diabetes UK** NHS Blood and Transplant Pancreatic Cancer Research Fund Royal College of Surgeons of England

# **PIS + Consent**

- use templates
- use consumers
- simple english
- beware scary words
- think long-term

- refusal / withdrawal
- pathway
- risks
- benefits
- confidentiality
- harm
- complaints

# **Obtain ethical and Trust approval**

			IRAS
HOME   MY PROJECTS   MY CONTACTS   MY DOCUMENTS	MY ACCOUNT E-LEARNING HELP CONTACT U	\$ LOGOUT	INTEGRATED RESEARCH APPLICATION SYSTEM
avigation Page (Get to this page from anywhere in your project by cliv	cking on 'Navigate')		
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roject Forms (Select the relevant form to get menus for ubmission, amendments etc)	SECTION Part A: Core study information	QUESTION RANGE	
IHS REC Form	Administrative details	Pro1. Title-A1 A2 A3 A4-A5	
IHS/HSC R&D Form (project information)	Overview of the research	<u>A6</u>	
ite-specific Forms (Create forms for each site from the REC or	Purpose and design of the research	A7 A8-A9 A10-A13 A14 14	
HS R&D Form above)	Risks and ethical issues	A15 A16 A17	
. NHS/HSC R&D Form (SSI) - [Miss Cliona Kirwan (The Christie IHS Foundation Tr)] / NotTransferred	Research procedures, risks and benefits	A18         A19         A20         A21-A22         A23         A24           A25-A26                 A24	
. NHS/HSC R&D Form (SSI) - [Miss Cliona Kirwan (University lospital of South M)] / NotTransferred	Recruitment and informed consent	A27         A28-A30         A31         A32         A33         A34           A35         C <thc< th=""> <thc< th=""></thc<></thc<>	
	Confidentiality	A36-A38 A39 A40-A42 A43-A45 A46-A49	

# **NCRN** adoption

UK Clinical Research Network : Portfolio Database

Welcome to the UK Clinical Research Network Study Portfolio

NB: The information displayed below does not replace the protocol. The latest protocol version should always be consulted before making clinical decisions.

CHAMPion	ISRCTN EudraCT		
Is systemic or tissue coagulation a prognostic marker in cancer?	MREC N°	09/H1011/47 8685	
Topic Cancer Portfolio Eligibility Automatically eligible	WHO ID		

#### Research Summary

Prospective clinical cohort study investigating durtion and significance of hypercoagulable response to surgery, correlated with tumour molecular phenotype and outcome. Pre ans post-operative plasma markers of clotting cascade activation, platelet activation, fibronolytic activity and activation of coagulation will be compared to tissue expression of equivalent markers, development of clinical VTE, tumour clinicopathological prognostic factors, and survival in patients undergoing elective abdominal and breast cancer surgery. Patients undergoing non-cancer surgery (matched for age, sex and type of surgery to the cancer patients) will provide baseline response to surgery.

Study Type	Observational	Current Status	Open
Design Type	Cohort study	Closure Date	04/08/2012
Disease(s)	All	Global Sample Size	610
Phase	N/A	Global Recruitment to Date	47%

UKCRN

#### User Guide

# **R&D** requirements

- Multicentre studies SSI
  - team CVs
- MHRA approval
- Evidence of GCP for research team
- CRFs
- Honorary research contracts
- Ethics approval
- Funding confirmation

# **Collect and collate the data**

- MTA
- HTA
- data protection
- missing data

Analysis, interpretation and impact

Statistical advice

Impact for study population Impact for wider population

Maximise - start small

Publish - salami or high impact - use research reporting guideline REMARK CONSORT

McShane Lmet al. (2005b) Reporting recommendations for tumour MARKer prognostic studies (REMARK). Br J Cancer 93: 387–391

www.consort.org