

Research plan: where to get help?

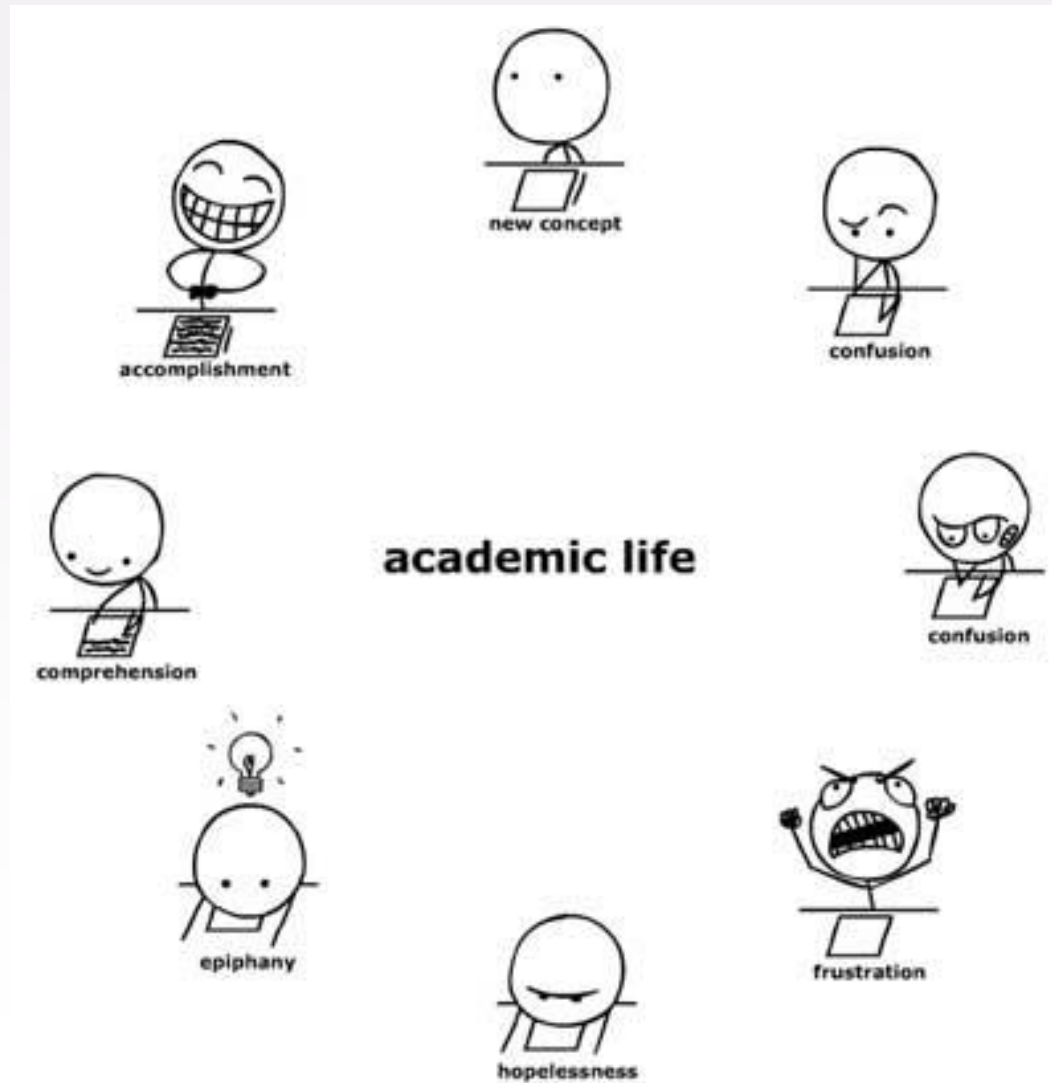
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University College London

Acknowledgement

- Some of these slides are based on slides developed for the SpRITE, EU-SpRITE and VOICE programmes (funded by Gilead, co-developed with Paddy Mallon)



Why do research?



Why do research?

- To reflect on current practice/patient management with a view to improving patient care
- To investigate initial associations seen in your patients
- To develop own skills and/or increase your chances of a new job
- To raise the department's profile or increase opportunities for more income
- To increase opportunities for collaboration
- **Because it's fun and fulfilling!**

The steps of a research project

Identify research question

Develop concept sheet

Conduct pilot study

Prepare funding application

Develop study protocol

Obtain approvals

Develop analysis plan

Conduct study

Analyse data

Disseminate findings

Topics to be covered

- Identifying a clear research question
- Selecting the right study design
- Dealing with the paperwork
- Disseminating your findings
- Getting your research funded

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What do you want to study?

- Continual evolution in the:
 - practice of medicine
 - drugs available
 - patient population
 - virus
 - disease manifestations
- Always be on the look out for gaps in knowledge
- Read around, attend conferences/meetings, talk to colleagues, monitor novel observations in your patients...
- Start by identifying a broad area that interests you and then home in on a specific research question

Identifying a clear research question

What do you want to study?

My patients are getting older – I'm interested in assessing the affect of ageing on HIV

Far too vague – what aspect of ageing are you specifically interested in?

Well some of them are taking so many drugs –that can't help their adherence to cART

Getting better – what do you mean by 'adherence'...

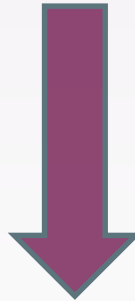
Identifying a clear research question

- Should have a clear and unambiguous research question before starting to design study
- Think carefully about the **patient population**, the **intervention/exposure** and the **outcome**
- This will allow you to make the most appropriate decisions surrounding the choice of study design, data collection method and the study size
- Question should have clinical/biological relevance

Identifying a clear research question

From this:

What is the effect of ageing on HIV?



To this:

Is there a relationship between the number of non-ARV drugs that an HIV-positive person is receiving for the treatment/prevention of co-morbidities, and his/her self-reported proportion of ARV tablets that are taken at the appropriate time?

Identifying a clear research question

- Read around – make sure your question hasn't already been answered
- Determine if you are able to answer the question:
 - Do you have the financial and laboratory resources?
 - Do you have access to the correct patient population?
 - Do you have the time?
 - Do you have the necessary skills?
- If 'no' to any or all of these, can you collaborate with people who can provide them?
 - Affiliated university researchers?
 - Statistical support?
 - Trust R&D support?
 - PhD student?

Topics to be covered

- Identifying a clear research question
- **Selecting the right study design**
- Dealing with the paperwork
- Disseminating your findings
- Getting your research funded

Selecting the right study design

Meta-analyses/systematic reviews of well-designed and conducted studies

Randomised controlled trial (RCT)

Cohort study

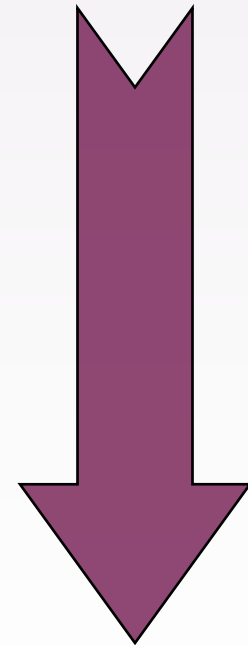
Case-control study

Cross-sectional study

Case series/case note review

'Expert' opinion

**BEST QUALITY
EVIDENCE**



**WORST QUALITY
EVIDENCE**

Selecting the right study design

- The research questions that can be addressed in any study will depend on the study design
- Whilst some designs may offer benefits in terms of costs, time and administrative effort, studies that are quick and cheap to perform will generally provide less robust evidence
- Research question **SHOULD** determine choice of study design
- In practice, lack of time and/or resources usually plays a major part in decision...

Pilot studies

- From Wikipedia...
 - ...a small scale preliminary study conducted in order to evaluate feasibility, time, cost, adverse events, and effect size (statistical variability) in an attempt to predict an appropriate sample size and improve upon the study design prior to performance of a full-scale research project
- Focus on:
 - Parameter estimates (treatment effect, SD)
 - Feasibility assessment (recruitment rates, barriers to participation, reasons for early drop-out)
 - Pre-test questionnaires
 - Assess reproducibility, etc.

Pilot studies are NOT....

- Small exploratory or descriptive studies
- An excuse to conduct an under-powered study
- A small study that can be done by a student or junior researcher without any funding

Thabane *et al.* *BMC Medical Research Methodology* 2010, **10**:1
<http://www.biomedcentral.com/1471-2288/10/1>



COMMENTARY

Open Access

A tutorial on pilot studies: the what, why and how

Lehana Thabane^{1,2*}, Jinhui Ma^{1,2}, Rong Chu^{1,2}, Ji Cheng^{1,2}, Afisi Ismaila^{1,3}, Lorena P Rios^{1,2}, Reid Robson³, Marroon Thabane^{1,4}, Lora Giangregorio⁵, Charles H Goldsmith^{1,2}

Research or audit?




National Research Ethics Service

The National Research Ethics Service (NRES) reviews research proposals to protect the rights and safety of research participants and enables ethical research which is of potential benefit to science and society.

Defining research – guidance from NRES

The purpose of this leaflet is to help you decide if a project is research, which normally requires review by a Research Ethics Committee (REC), or whether it is some other activity such as audit, service evaluation or public health surveillance.

Patients expect health professionals to undertake audit and service evaluation as part of quality assurance. These involve minimal additional risk, burden or intrusion for participants, and are regulated outside of NRES.

Research may involve greater risk, burden or intrusion for participants than standard clinical practice. It may generate conflicts of interest for the researcher, which will require review by an ethics committee. With some exceptions, research requires review by a REC.

The table in this leaflet helps to confirm if your activity is research, audit, service evaluation or public health surveillance.



Research or audit?

- **Research:**
 - **Primary aim:** to derive generalizable new knowledge – to find out what you *should* be doing
 - **Principal mode of dissemination:** research presentations and/or publications
 - **Target audience:** wider clinical or research community
- **Audit/service evaluation:**
 - **Primary aim:** to measure *standards* of care; to find out if you *are* doing planned activity and, if so, to assess whether it is working
 - Does not use intervention without a firm basis of support, allocate treatment by *protocol* or *randomisation*
 - **Principal mode of dissemination:** internal reports
 - **Target audience:** colleagues, NHS management

Audit is NOT....

- An excuse to do a study that doesn't require ethics approval

Topics to be covered

- Identifying a clear research question
- Selecting the right study design
- **Dealing with the paperwork**
- Disseminating your findings
- Getting your research funded

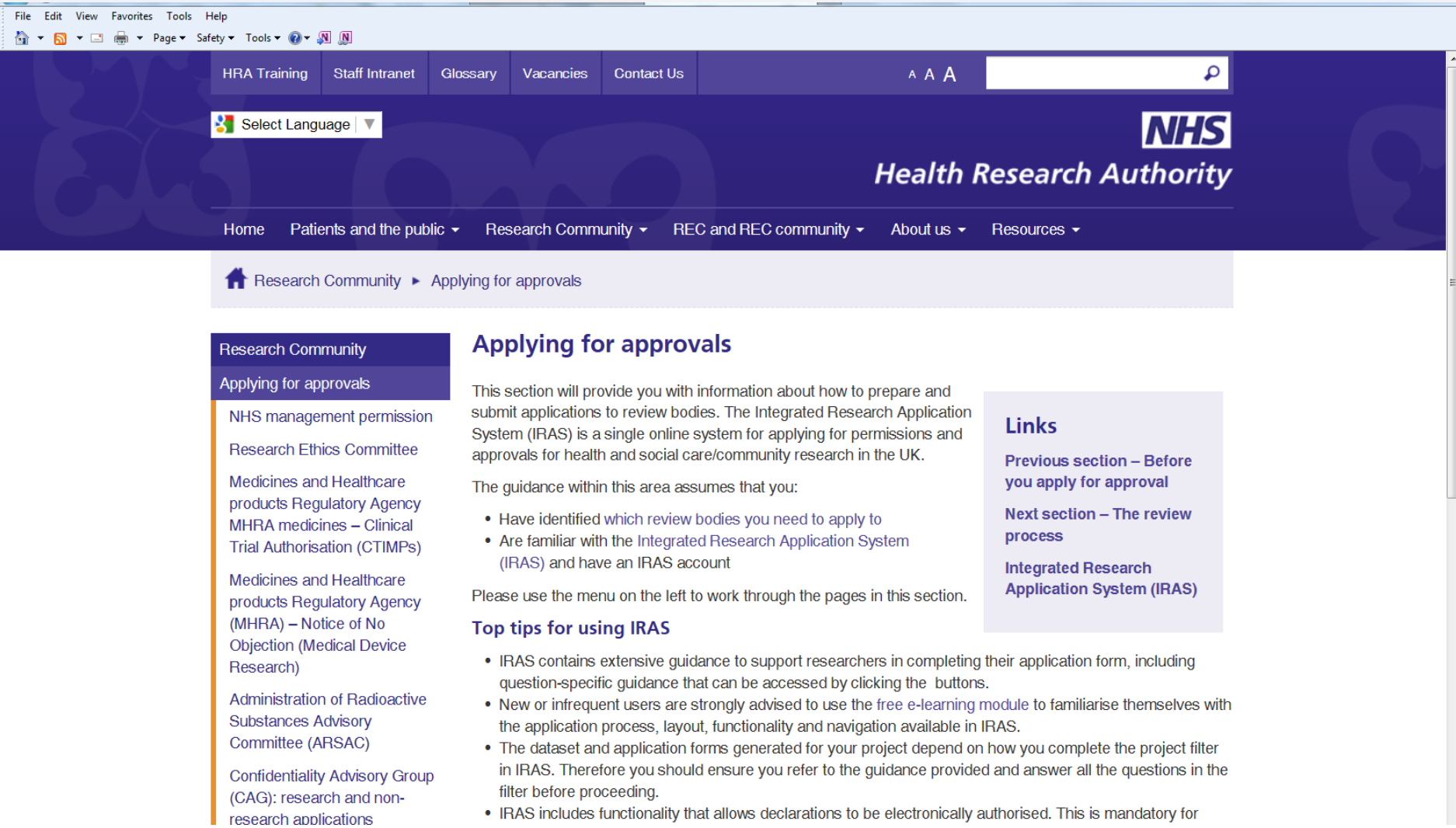
Developing a concept sheet

- Brief document that defines how you will answer your research question
- Can be used for review by all investigators/sponsors
- Flexible format to allow for modifications at an early stage
- Provides opportunity to establish feasibility
- Helps to identify major defects in study design
- Forms the basis for the study protocol or funding application

Developing a study protocol

- More detailed document which sets out the conditions under which you will conduct research
- Includes information from the concept sheet
- Used for ethics/R&D approval
- After approval, all additional changes constitute amendments:
 - Minor amendments: changes to study team, changes to assessments/fasting requirements
 - Major amendments: changes to major endpoints or length of study
- All amendments require additional ethics approval

Getting study approvals



The screenshot shows the NHS Health Research Authority website. The top navigation bar includes links for HRA Training, Staff Intranet, Glossary, Vacancies, and Contact Us. A search bar and a language selection dropdown are also present. The main navigation menu includes Home, Patients and the public, Research Community, REC and REC community, About us, and Resources. The breadcrumb trail shows the path: Home > Research Community > Applying for approvals. The left sidebar contains a list of links under the 'Research Community' heading, with 'Applying for approvals' selected. The main content area is titled 'Applying for approvals' and contains introductory text, a list of tips, and a 'Links' section.

Research Community

Applying for approvals

- NHS management permission
- Research Ethics Committee
- Medicines and Healthcare products Regulatory Agency
MHRA medicines – Clinical Trial Authorisation (CTIMPs)
- Medicines and Healthcare products Regulatory Agency (MHRA) – Notice of No Objection (Medical Device Research)
- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG): research and non-research applications

Applying for approvals

This section will provide you with information about how to prepare and submit applications to review bodies. The Integrated Research Application System (IRAS) is a single online system for applying for permissions and approvals for health and social care/community research in the UK.

The guidance within this area assumes that you:

- Have identified which review bodies you need to apply to
- Are familiar with the Integrated Research Application System (IRAS) and have an IRAS account

Please use the menu on the left to work through the pages in this section.

Top tips for using IRAS

- IRAS contains extensive guidance to support researchers in completing their application form, including question-specific guidance that can be accessed by clicking the buttons.
- New or infrequent users are strongly advised to use the [free e-learning module](#) to familiarise themselves with the application process, layout, functionality and navigation available in IRAS.
- The dataset and application forms generated for your project depend on how you complete the project filter in IRAS. Therefore you should ensure you refer to the guidance provided and answer all the questions in the filter before proceeding.
- IRAS includes functionality that allows declarations to be electronically authorised. This is mandatory for

Links

[Previous section – Before you apply for approval](#)

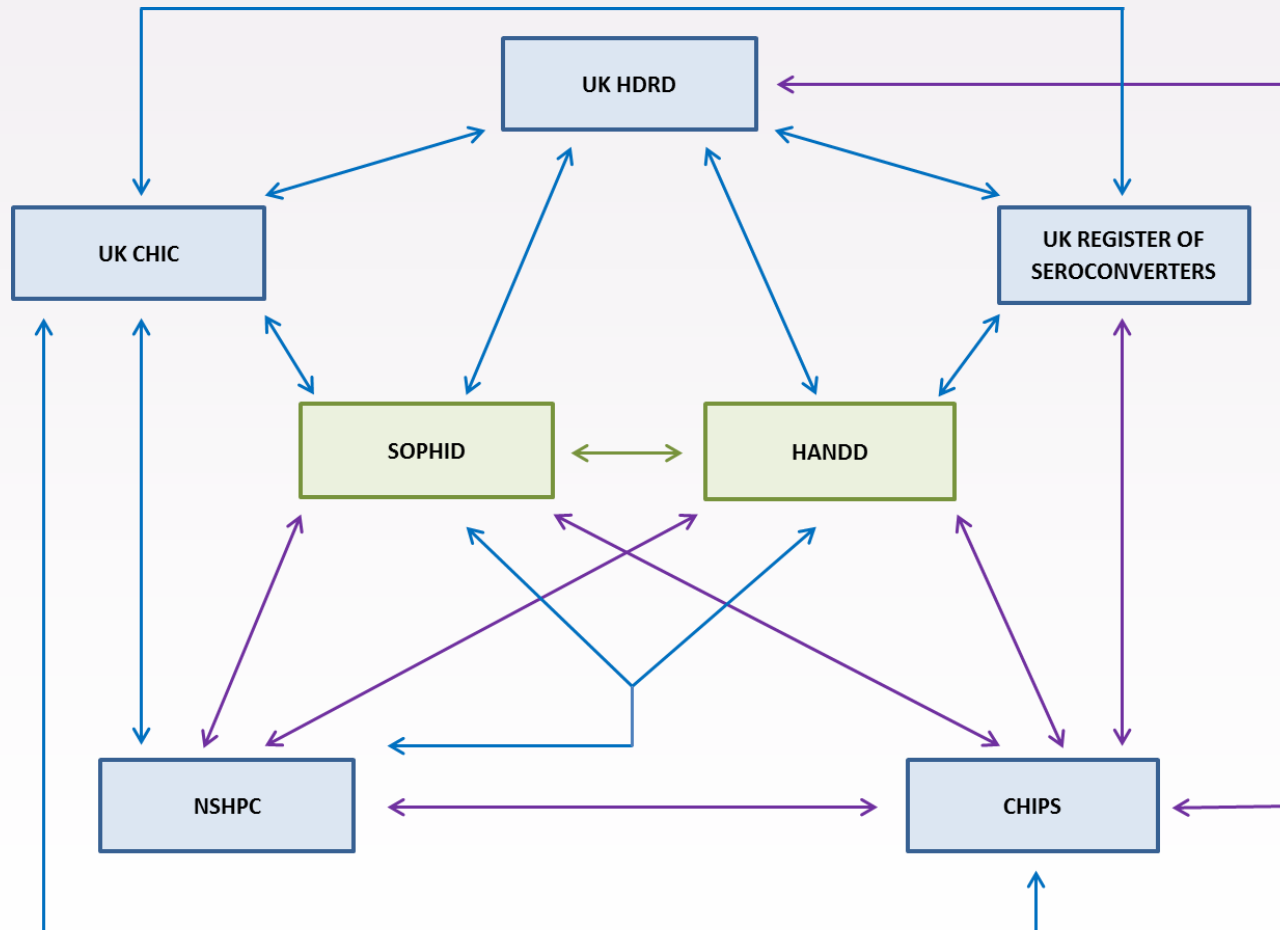
[Next section – The review process](#)

[Integrated Research Application System \(IRAS\)](#)

Maximising existing resources

- Don't try to re-invent the wheel – if someone has already collected data, can you use that information?
- Explore opportunities for direct linkage with surveillance and public health databases (e.g. mortality records)
- Linkage with local laboratory services
- Linkage with Pharmacy/drug dispensing databases
- Linkage with disease-specific registers (e.g. cancer registries)

Maximising existing resources



↔ Adult Data

↔ Paediatric Data

Collaborating with others

- Can be effective way to maximise research outputs
- Be pro-active in searching for opportunities to collaborate
- Develop your own protocol for sharing data
- Ensure that you (and collaborators) have necessary approvals in place to allow for data sharing
- Ensure confidentiality
- Develop clear policy for authorship and any acknowledgements/credits

Topics to be covered

- Identifying a clear research question
- Selecting the right study design
- Dealing with the paperwork
- **Disseminating your findings**
- Getting your research funded

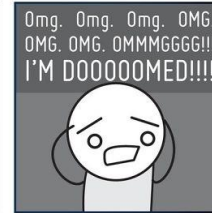
Writing papers

Writing papers

- A FIELD GUIDE TO - PROCRASTINATORS



The Cleaner



The Panicker



The List Maker



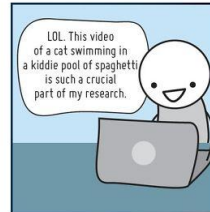
The Napper



The Sidetracker



The Social Sharer



The Internet Researcher



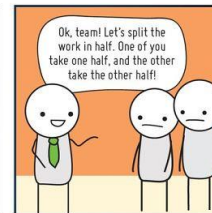
The Snacker



The Gamer



The Watcher



The Delegator



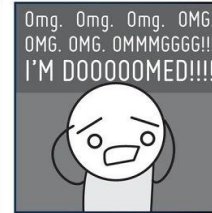
The Perpetuator

Writing papers

- A FIELD GUIDE TO - PROCRASTINATORS



The Cleaner



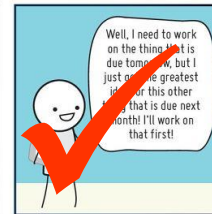
The Panicker



The List Maker



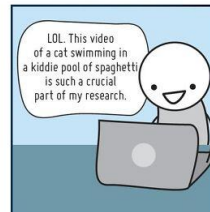
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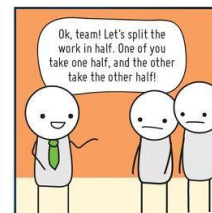
The Snacker



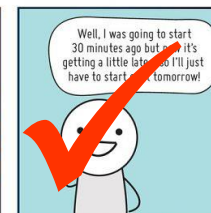
The Gamer



The Watcher



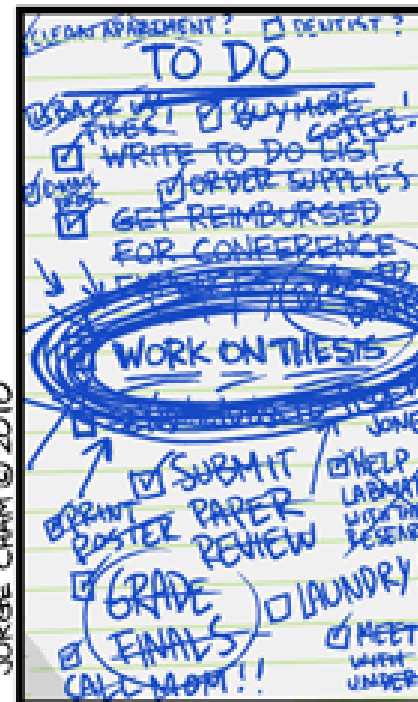
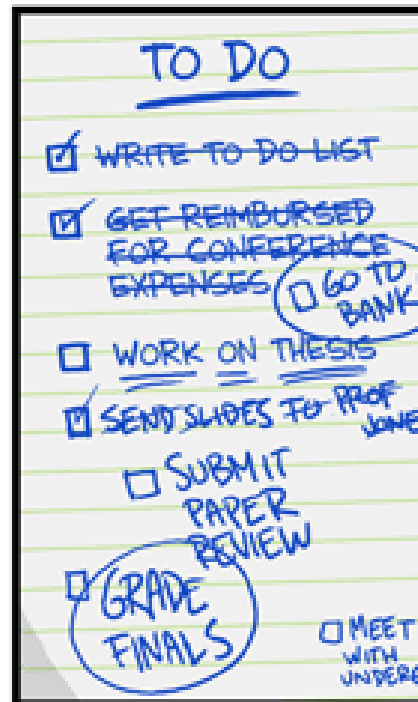
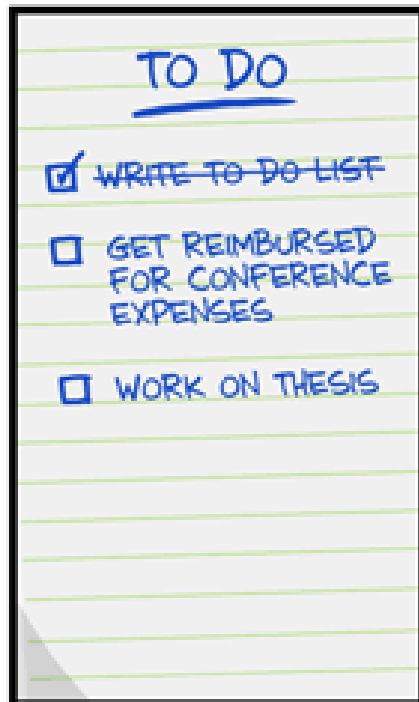
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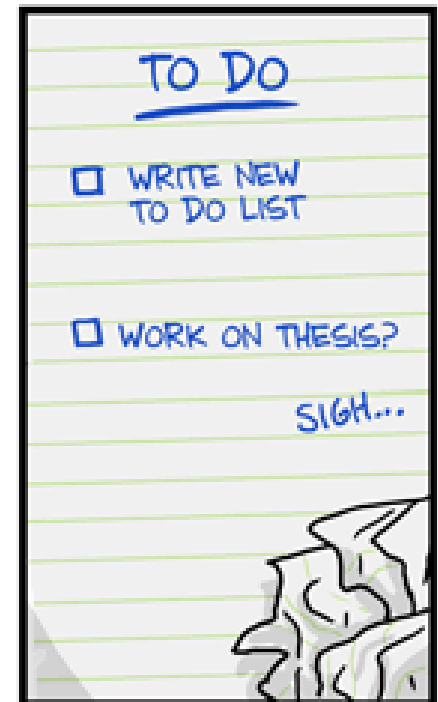
The Perpetuator

Writing papers

YOUR "TO DO" LIST



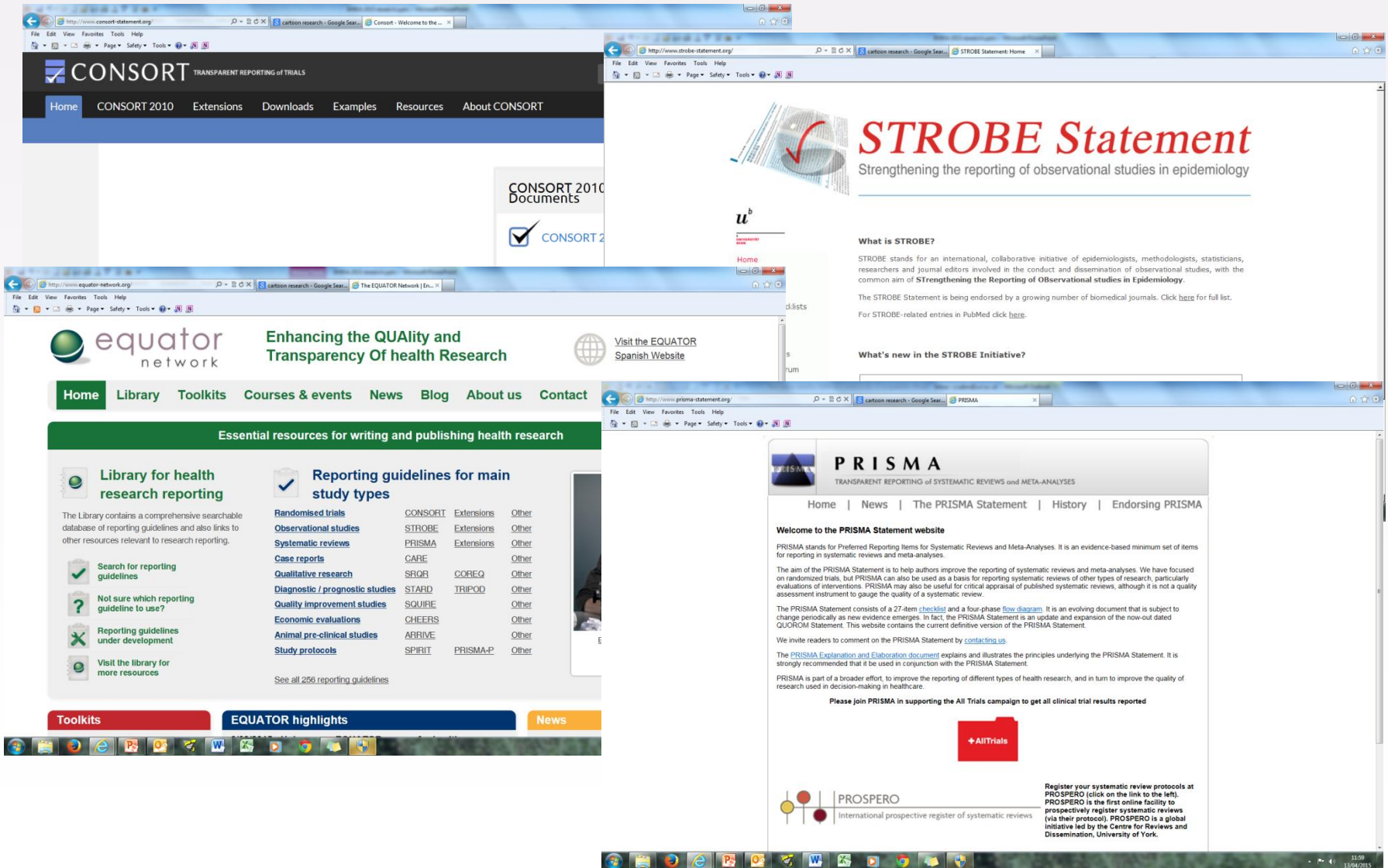
JORGE CHAM © 2010



Initial experiences

- Your first paper will...
 - be dreadful
 - take months to write
 - be far too long (aim for <3000 words)
 - be rejected (probably on several occasions)
- You will take the referee's comments personally!
- You will try to work out who the referees are...
- You will be very precious about what you have written
- But it's all good for the soul!

Writing papers



The screenshot displays a desktop environment with four browser windows open, each showing a different reporting guideline website. The desktop taskbar at the bottom shows various application icons and the system clock indicating 11:09 on 13/04/2015.

CONSORT Statement
 CONSORT 2010 Documents
 CONSORT 2010

STROBE Statement
 Strengthening the reporting of observational studies in epidemiology
 What is STROBE?
 STROBE stands for an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of **STrengthening the Reporting of Observational studies in Epidemiology**.
 The STROBE Statement is being endorsed by a growing number of biomedical journals. Click [here](#) for full list.
 For STROBE-related entries in PubMed click [here](#).
 What's new in the STROBE Initiative?

equator network
 Enhancing the QUALity and Transparency Of health Research
 Visit the EQUATOR Spanish Website
 Home | Library | Toolkits | Courses & events | News | Blog | About us | Contact
 Essential resources for writing and publishing health research
 Library for health research reporting
 Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions	Other
Observational studies	STROBE	Extensions	Other
Systematic reviews	PRISMA	Extensions	Other
Case reports	CARE		Other
Qualitative research	SRQR	COREQ	Other
Diagnostic / prognostic studies	STARD	TRIPOD	Other
Quality improvement studies	SQUIRE		Other
Economic evaluations	CHEERS		Other
Animal pre-clinical studies	ARRIVE		Other
Study protocols	SPIRIT	PRISMA-P	Other

 See all 256 reporting guidelines

PRISMA
 TRANSPARENT REPORTING OF SYSTEMATIC REVIEWS and META-ANALYSES
 Home | News | The PRISMA Statement | History | Endorsing PRISMA
 Welcome to the PRISMA Statement website
 PRISMA stands for Preferred Reporting Items for Systematic Reviews and Meta-Analyses. It is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses.
 The aim of the PRISMA Statement is to help authors improve the reporting of systematic reviews and meta-analyses. We have focused on randomized trials, but PRISMA can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions. PRISMA may also be useful for critical appraisal of published systematic reviews, although it is not a quality assessment instrument to gauge the quality of a systematic review.
 The PRISMA Statement consists of a 27-item [checklist](#) and a four-phase [flow diagram](#). It is an evolving document that is subject to change periodically as new evidence emerges. In fact, the PRISMA Statement is an update and expansion of the now-outdated QUOROM Statement. This website contains the current definitive version of the PRISMA Statement.
 We invite readers to comment on the PRISMA Statement by [contacting us](#).
 The [PRISMA Explanation and Elaboration document](#) explains and illustrates the principles underlying the PRISMA Statement. It is strongly recommended that it be used in conjunction with the PRISMA Statement.
 PRISMA is part of a broader effort, to improve the reporting of different types of health research, and in turn to improve the quality of research used in decision-making in healthcare.
 Please join PRISMA in supporting the All Trials campaign to get all clinical trial results reported
 +AllTrials
 Register your systematic review protocols at PROSPERO (click on the link to the left). PROSPERO is the first online facility to prospectively register systematic reviews (via their protocols). PROSPERO is a global initiative led by the Centre for Reviews and Dissemination, University of York.
 PROSPERO
 International prospective register of systematic reviews

Writing papers

- Abstract: use conference abstract as a template
- Introduction: identify the gap in knowledge, sell its importance, end with aim and/or hypothesis
- Methods: use protocol as template, describe population, recruitment, assessments, statistical methods
- Results: demographics, primary, secondary and any sensitivity analyses
- Discussion: concisely state principal finding(s) and place in context of other work, discuss results in wider context; speculate on potential mechanisms; discuss limitations

Other ways to disseminate your findings

- Publications/posters/oral presentations – expected but may not reach all relevant audiences



Other ways to disseminate your findings

- Publications/posters/oral presentations – expected but may not reach all relevant audiences



Other ways to disseminate your findings

- Publications/posters/oral presentations – expected but may not reach all relevant audiences



Other ways to disseminate your findings

- How will you ensure that your research findings can be translated into clinical care?
- Who are the key stakeholders in your research?
 - Patient community
 - Academics
 - Clinicians
 - Other healthcare professionals
 - Funders/commissioners
 - Public health professionals
 - Global health leaders
- What are your plans for engaging with each of them outside of the normal academic route?

Other ways to disseminate your findings

- How will you get your research findings out to the HIV community and other audiences (e.g. hospital managers, funders, etc.)
 - Websites (how do people 'find' your website)
 - Study reports
 - Social media
 - Mass media
 - School education



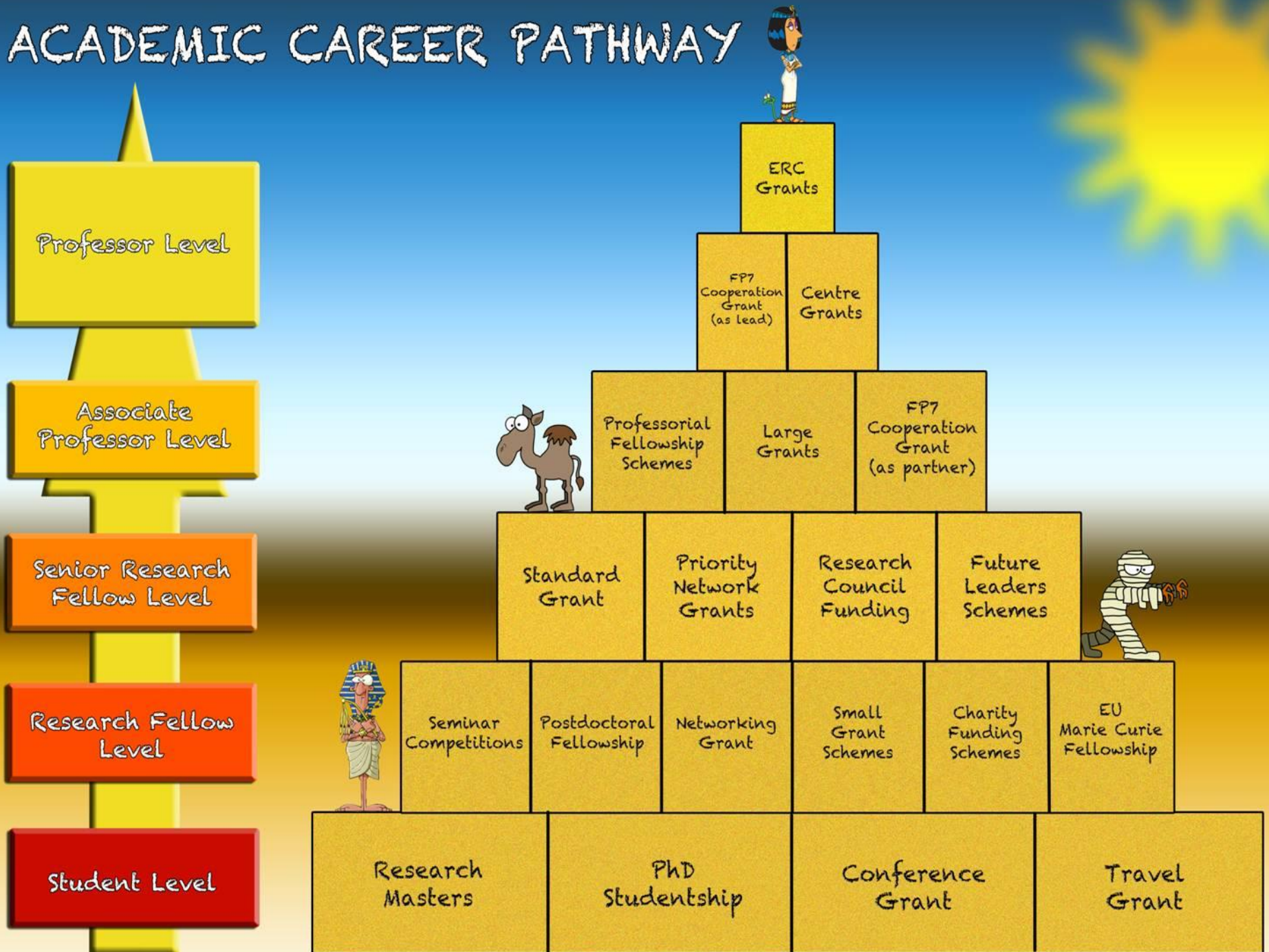
Topics to be covered

- Identifying a clear research question
- Selecting the right study design
- Dealing with the paperwork
- Disseminating your findings
- **Getting your research funded**

Getting your research funded



ACADEMIC CAREER PATHWAY



Getting your research funded

- Research Councils (www.rcuk.ac.uk)
- National Institute for Health Research (NIHR)
- Wellcome Trust
- European Union
- Charities/BHIVA
- Academic institutions
- NHS Trusts/CLRN funding
- Pharmaceutical companies

Pharmaceutical company/charity funding

- Useful sources of funding for new researchers and/or small projects – may help in development of CV (to give a good track record)
- Often limited in terms of budget
- Charities may not pay ‘full economic costs’ or overheads; often viewed negatively by universities
- In contrast, universities may charge high rate of overheads for grants from pharmaceutical industry

BHIVA Research Awards

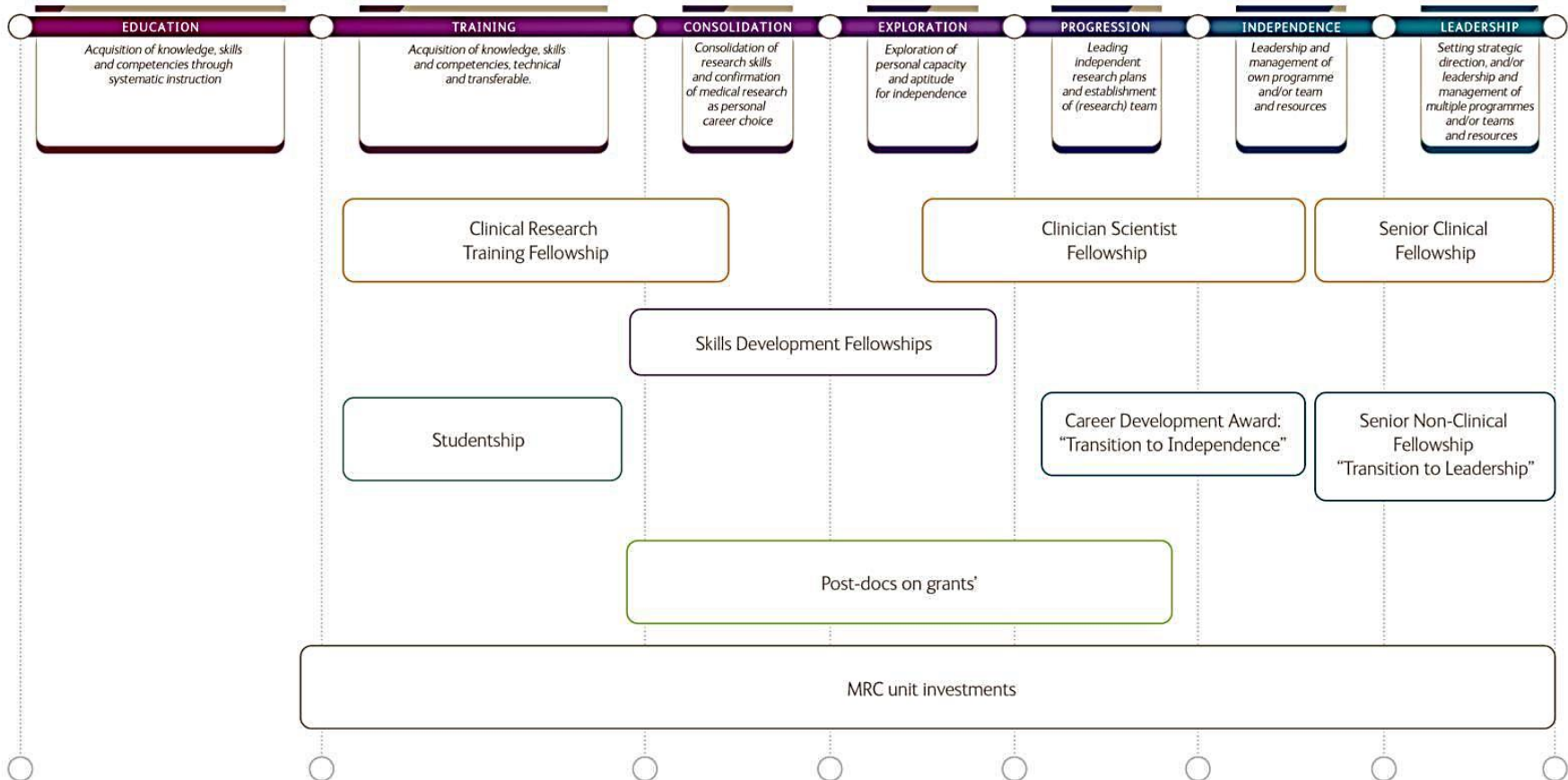
- Competitive scheme, open to all BHIVA members
- Research projects that impact on the improvement of clinical care and management of PLWH in the UK
- Awards of £10K/project; one bigger award (£30K) in 2015
- Applications considered on merit and relevance to BHIVA objectives
- Applications from persons not yet independent researchers or who do not hold an established academic or clinical post are particularly welcomed

MRC

- Promote research into all areas of medical and related sciences with aims of improving the health and quality of life of UK public, and contributing to wealth of the nation
- Response mode (project/programme) grants
- Strategic initiatives and calls for proposals in specific areas
- Fellowships

MRC

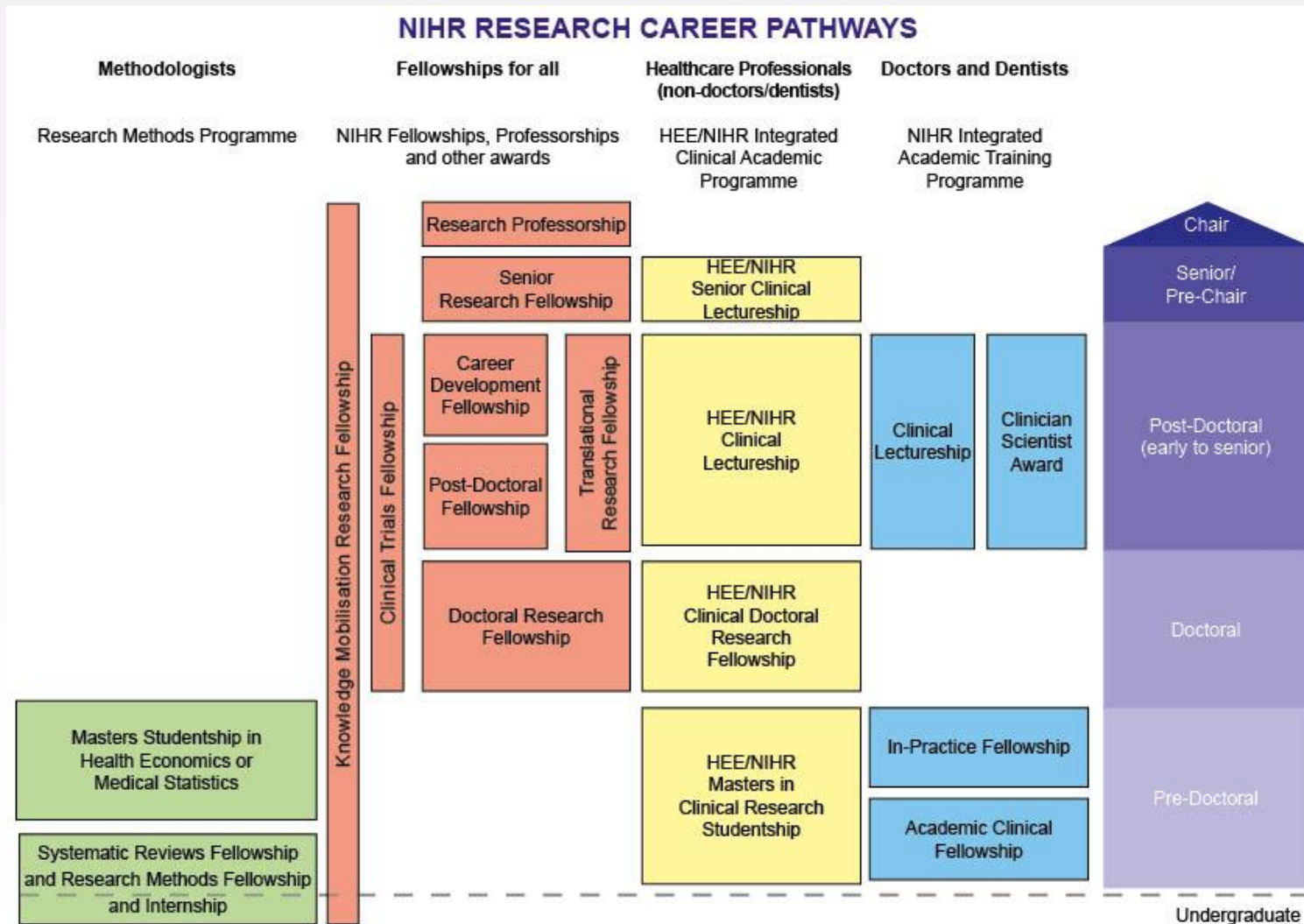
Fellowship schemes



NIHR

- NHS, social care and public health research to support decision making by professionals, policy makers, patients and carers
- Commissioned research and themed calls on specific – calls on specific topics
- Researcher-led research
- Commissioned research and themed calls on specific topics (e.g. Antimicrobial Resistance)
- Training and career development awards

NIHR – training and career development



Steps to becoming an investigator

1. Build up your CV: publications, presentations
2. Develop a broad area of expertise
3. Develop a track record
4. Co-applicant on research grants
5. Seek 'soft' money
 - Scholarships, institutional grants, pharmaceutical funding
6. Fellowship or new investigator grants
7. Project grants/large pharma awards
 - Demonstrate ability to supervise (MD / PhD)
 - Develop collaborations / establish research team
8. Programme grants

Preparing a grant application

- Read the guidance notes carefully
- Is this funding call really suited to me, at my stage of career?
- Start working on the application as far in advance as is humanly possible (not the night before)
- Think about the panel and who will review the application – pitch the application accordingly
- Allow time for institutional sign-off

Why do grants get rejected?

- Not clear how research will add to what is going on internationally or will lead to health benefits
- Unfocused, over-ambitious project
- Unlikely to answer question
- Inappropriately costed (under- OR over-costed)/doesn't represent good value for money
- Methodology not sufficiently detailed
- Lack of preliminary data/appropriate experience
- Lack of good track record/publication record

Final words

- Research IS fun and fulfilling!
- There are well established processes you can follow that will save you time and effort
- Collaborations can be extremely productive, enjoyable and can lead you in unexpected directions
- Engage with your local R&D offices – they are there to support you
- Good luck!