

**Faculty of Health and Wellbeing  
PhD students' workshops 2016/2017**

**Ethics approval and research governance:  
when, why and how?**

**Procedures for Seeking and Gaining Approval  
in the Faculty**

**Wednesday 09 November 2016**

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# Outline

- ◆ Requirement
- ◆ Purpose
- ◆ History
- ◆ Helsinki
- ◆ Informed consent
- ◆ National Research Ethics Service (NRES)
- ◆ Research governance
- ◆ Research Ethics Committees (REC)
- ◆ Human Tissue Authority
- ◆ SHU Procedures
- ◆ Applications

Requirement: when

**Whenever humans are participants**

Purpose: why

**Protection for participants and  
researchers**

# History: why

- ◆ Second World War
- ◆ Nuremburg war trials



# History: why

- ◆ Second World War
- ◆ Nuremburg war trials
- ◆ Doctors



# History

- ◆ Freezing experiments
- ◆ Professor Ernst Holzlöhner
- ◆ Dr Sigmund Rascher



# History: personal links

- ◆ Otto Jakubovic PhD
- ◆ Holocaust Memorial Day,  
January 27
- ◆ Liberation of Auschwitz-  
Birkenau by Soviet  
Forces in 1945



# History: personal links

- ◆ William Edward Winter DFM
- ◆ RAF number: 1685355
- ◆ Bomber Command, 106 (CVI) squadron
- ◆ Flight sergeant
- ◆ Wireless operator
- ◆ 31 missions (October 1944-April 1945)
- ◆ Otto Jacobovic



# History: why

- ◆ Tuskegee
- ◆ Second World War
- ◆ Nuremburg Code (Dr Leo Alexander)
- ◆ United Nations Declaration of Human Rights
- ◆ LD 50's
- ◆ Helsinki (1964) (<http://www.wma.net/e/approvedhelsinki.html>)
- ◆ Beecher and Pappworth
- ◆ Bristol, Alder Hey, North Staffs
- ◆ Human Tissue Act 2004
- ◆ Fraud
- ◆ Hwang Woo-Suk 2006

# Helsinki: why

- ◆ 1964
- ◆ 1975 Tokyo
- ◆ 1983 Venice
- ◆ 1996 Somerset West
- ◆ 2000 Edinburgh
- ◆ 2002 Washington (para 29)

## Informed Consent: why Participant Information Sheet (PIS)

1. Purpose
2. Procedures, including risks
3. Benefits
4. Questions
5. Withdrawal and refusal
6. Without prejudice
7. Complaints
8. Signature

# Informed Consent: why Informed Consent Form (ICF)

INFORMED CONSENT FORM	
<b>TITLE OF PROJECT:</b>	
<b>The participant should complete the whole of this sheet himself/herself</b>	
Have you read the Participant Information Sheet?	YES/NO
Have you had an opportunity to ask questions and discuss this study?	YES/NO
Have you received satisfactory answers to all of your questions?	YES/NO
Have you received enough information about the study?	YES/NO
To whom have you spoken? ..... Do you understand that you are free to withdraw from the study: at any time without having to give a reason for withdrawing and without affecting your future medical care	YES/NO
Have you had sufficient time to consider the nature of this project?	YES/NO
Do you agree to take part in this study?	YES/NO
Signed ..... Date .....	
(NAME IN BLOCK LETTERS).....	
Signature of Parent / Guardian in the case of a minor .....	

## National Research Ethics Service (NRES)

- ◆ The overseeing body for all NHS-related work
- ◆ The template for all other ethics committees
- ◆ Research governance

## Research Ethics Committees

- ◆ NHS-type work
- ◆ Higher risk
- ◆ Age
- ◆ Drug trials
- ◆ Disease
- ◆ Independent Scientific Review

# Human Tissue Authority

- ◆ Regulatory body for the Human Tissue Act 2004
- ◆ Predominantly but not exclusively pathology
- ◆ Tissue
- ◆ Storage
- ◆ Gene expression . . .



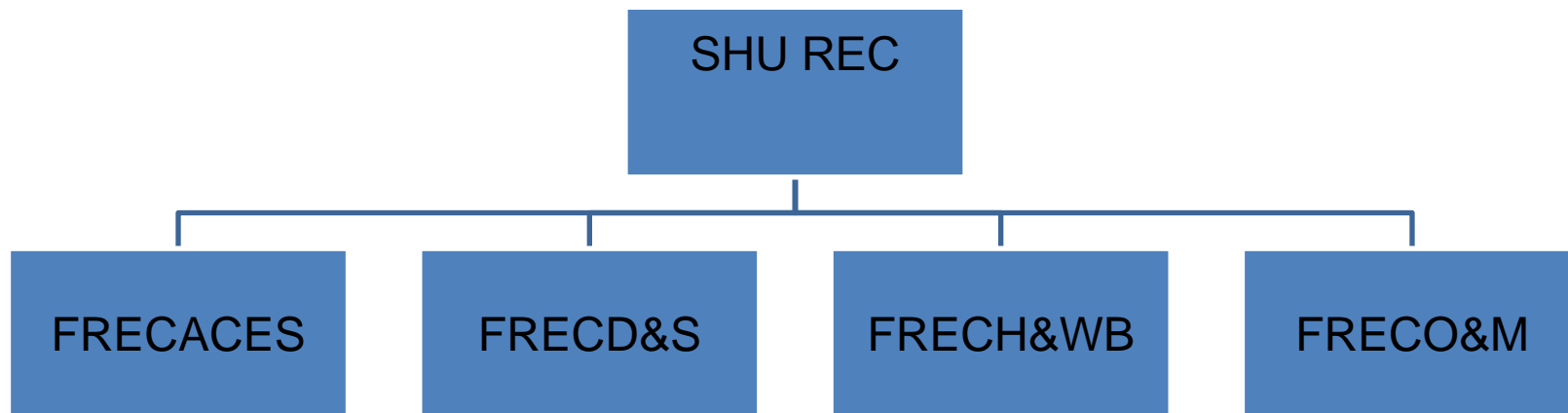
# SHU Procedures: how

## ◆ University-wide

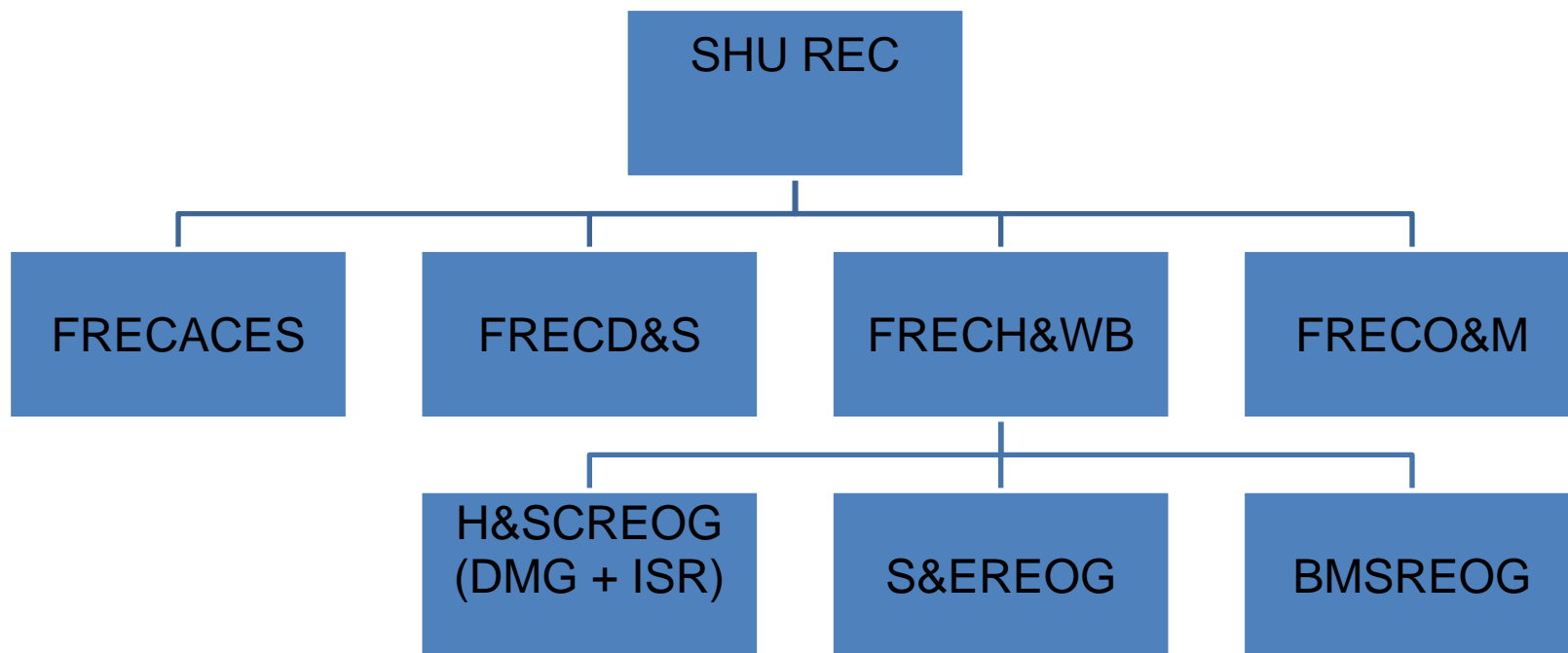
<http://www.shu.ac.uk/research/ethics/approval.html>

- Humans
- Scientific practice
- Sources of funding

# SHU Procedures



# SHU Procedures



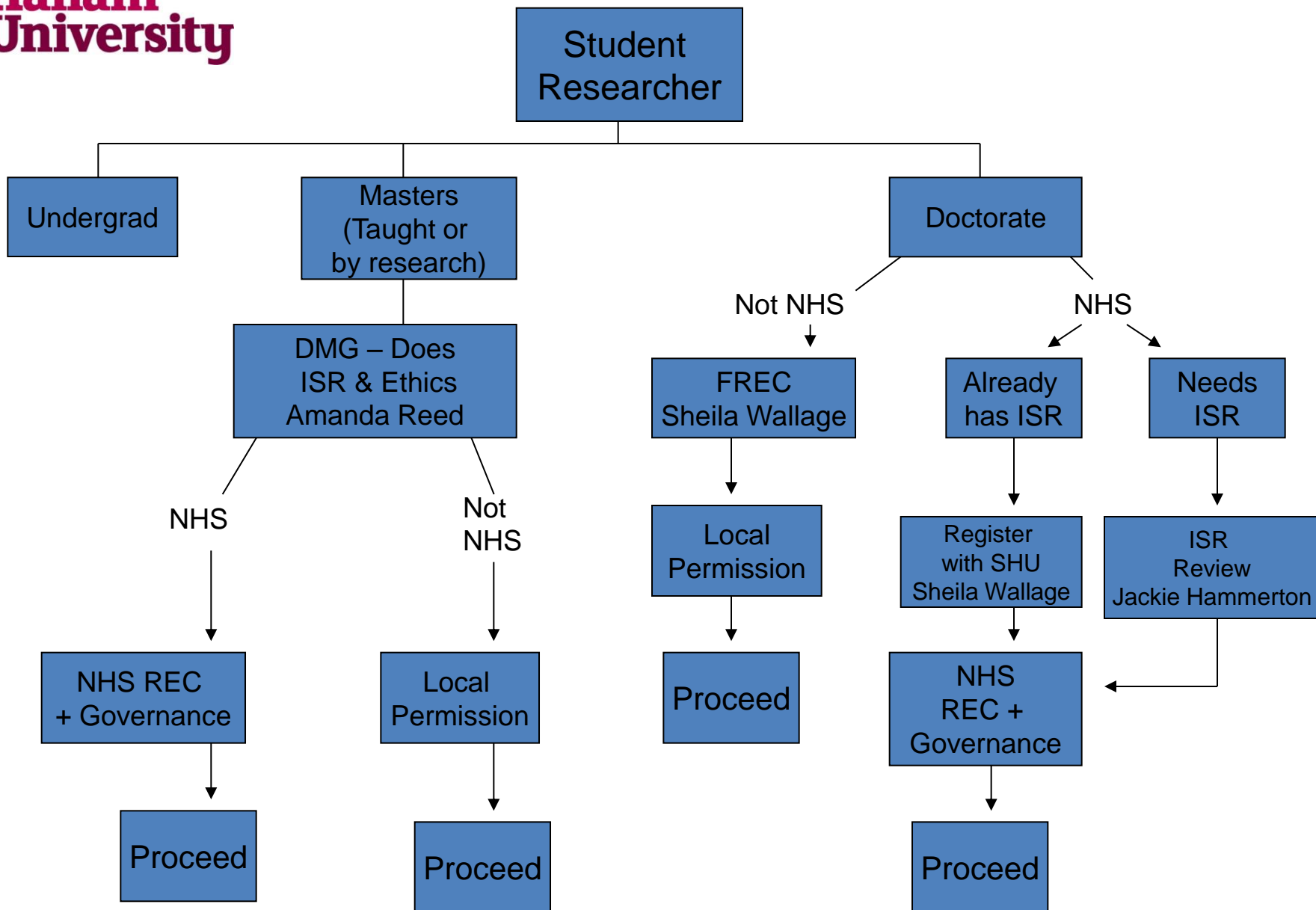
# The challenge

# The challenge

1,500 projects per year

- ◆ Undergraduate
- ◆ Taught and research masters
- ◆ Taught and research PhD's
- ◆ Staff
- ◆ NHS and non-NHS
- ◆ Sponsorship
- ◆ Statutory requirements
- ◆ Protection (participants and researchers)
- ◆ Indemnity

# HSC Research Process



# SHU Procedures

- ◆ Faculty of Health and Wellbeing
  - Composition of the Committee
  - Documentation
  - Administration
  - Applications
  - 1,500
- ◆ <http://www.shu.ac.uk/research/ethics/approval.html>

# SHU Procedures

- ◆ Contents of an ethics application:
  - Outline and question
  - Sampling
  - Outcome measures and predictors
  - Analytical techniques
  - CRB
  - Collaborations
  - IC form and PIS
  - Risk assessments
  - Sponsorship
  - Site file/project file



# SHU Procedures

- ◆ Signing off
  - Major procedures
  - Minor procedures