



Ethics and governance in drugs research

Dr Anne Whittaker, Associate Professor,
NMAHP Research Unit, University of Stirling

Anne.Whittaker@stir.ac.uk

UNIVERSITY of
STIRLING



Principles

- **UK Policy Framework for Health and Social Care Research**
- Legislation/legal requirements/SOPs
- Patient & public involvement (PPI)
- Scientific rationale for study
- Robust design/methods
- Dissemination/impact
- Data archiving

Key issues to address

- **Safety & welfare of participants**
- Recruitment process
- Written informed consent
- Confidentiality/anonymity/privacy
- Risks & how to mitigate them
- Data management and data protection (GDPR)
- Sensitive topics/sensitive data
- Duty of care – intervention research

Research populations & contexts

- Prisoners/prison
 - Children/Young People
 - Vulnerable adults
 - Mental illness/Cognitive impairment
 - Pregnant women
-
- Capacity to consent
 - Risky environments
 - Ethnography/Participatory methods

Ethical approval process

- University ethics committee approval
- NHS Research Ethics Committee (REC) review – IRAS application
- NHS Health Research Authority (HRA)
- Supporting documentation – Study Protocol, PIS, Consent form, other study materials
- Sponsor for research (indemnity/insurance)
- Recommend attending REC meeting!
- Substantial amendments...

NHS R&D approval process

- Site management approval to conduct study with NHS patients and staff
- Caldicott Guardian approval
- Finance - NHS support & research costs
- Research Passport / Letter of Access
- Safe Haven (secure platform)
- Approved devices
- Clinical Trials Unit
- Adverse Events

References/websites

UK Policy Framework for Health and Social Care Research

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

NHS Health Research Authority (HRA) <https://www.hra.nhs.uk/>

NHS Research Ethics Committee (REC) review

<https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/>

Other publications about good research practice: ADASS/SSRG resource pack for social care, [ESRC Framework for Research Ethics](#), the principles of ICH GCP, RESPECT Code of Practice, UUK Concordat to support research integrity, [WMA Declaration of Helsinki](#).

Thank you for listening

Research scenarios...

1. Ethnographic research with homeless injecting drug users
2. Parenting intervention research with drug-using mothers and their preschool aged children
3. Experiences of family members who have lost someone due to a drug overdose
4. Blood borne virus testing in prison
5. Clinical trial of methadone vs subutex in pregnant women
6. Young people's use of new psychoactive substances