Patient data - balancing access and protection

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Medical Research Council, Regulatory Support Centre

MRC Regulatory Support Centre

Support and guidance
for those conducting research
with human participants,
their tissues or data

Regulatory Support Centre

Aims

- Current UK landscape

- Challenges and opportunities around health data access for research
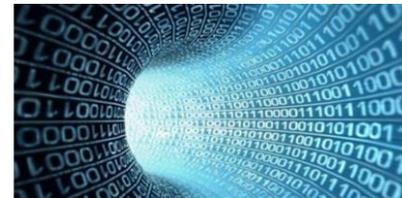
- Overview of ongoing streamlining activities

Data access approvals

Data Providers

- NHS Trusts
- NHS Digital
- Clinical Practice Research Database
- Public Health England

- Secure Anonymised Information Linkage (Wales)

- NHS Boards (Scotland)
- Information Services Division (Scotland)

Research approvals: UK-wide

Research Approvals

- NHS Ethics

- Health Research Authority

- Medicines and Healthcare products Regulatory Agency

Research approvals – England / Wales

- Confidentiality Advisory Group

Research approvals – Scotland

- Caldicott Guardian

- Public Benefit and Privacy Panel

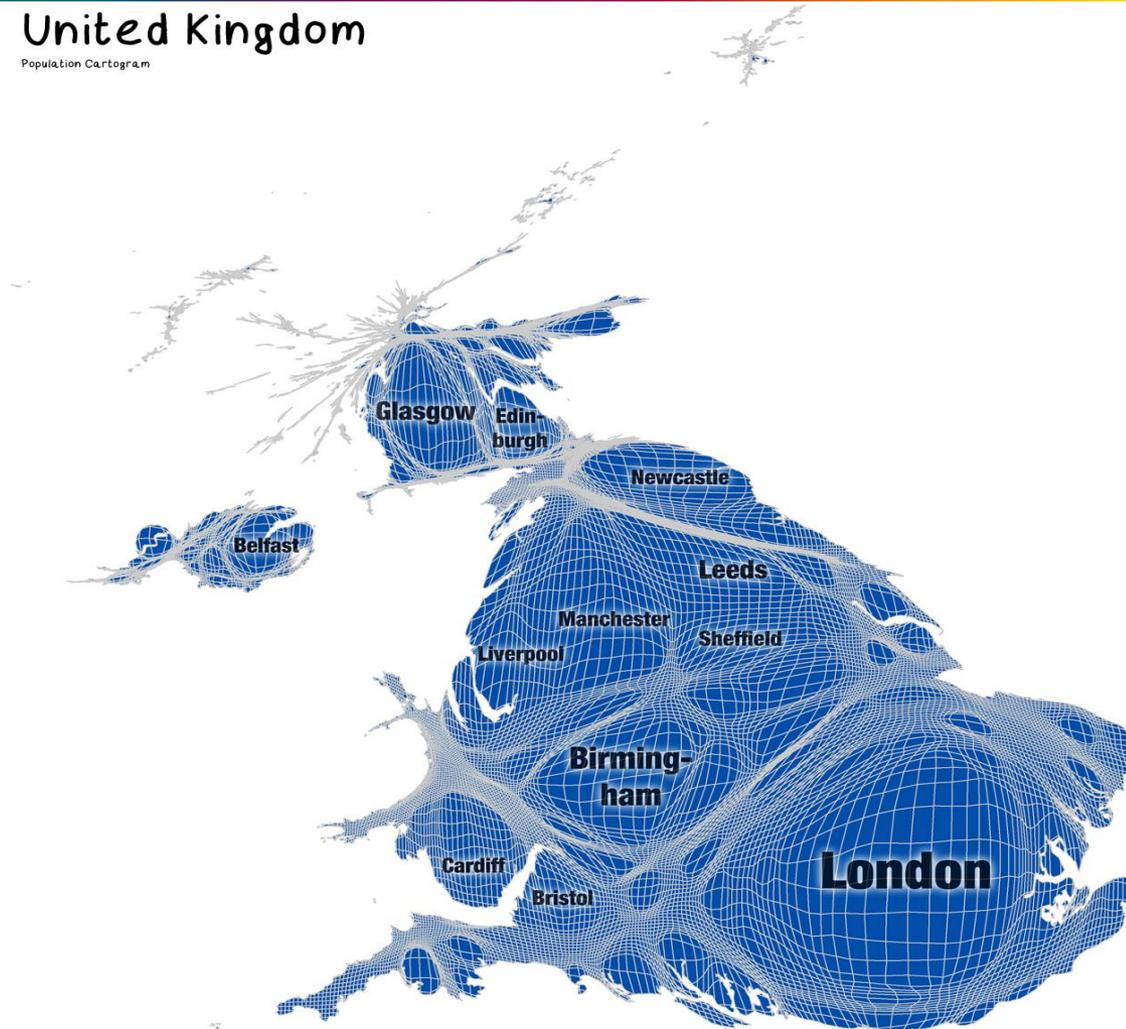# Research approvals – Northern Ireland

- Common Law

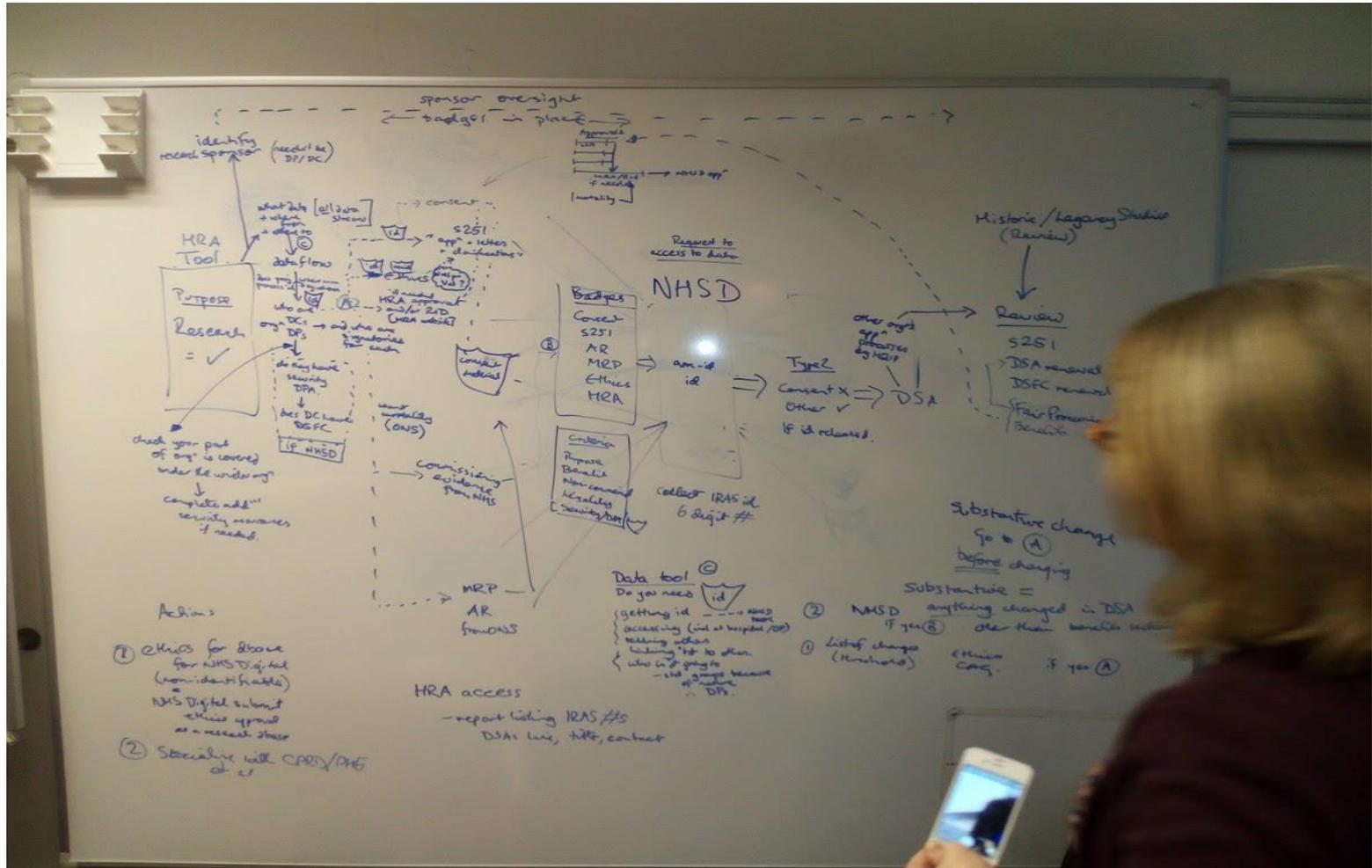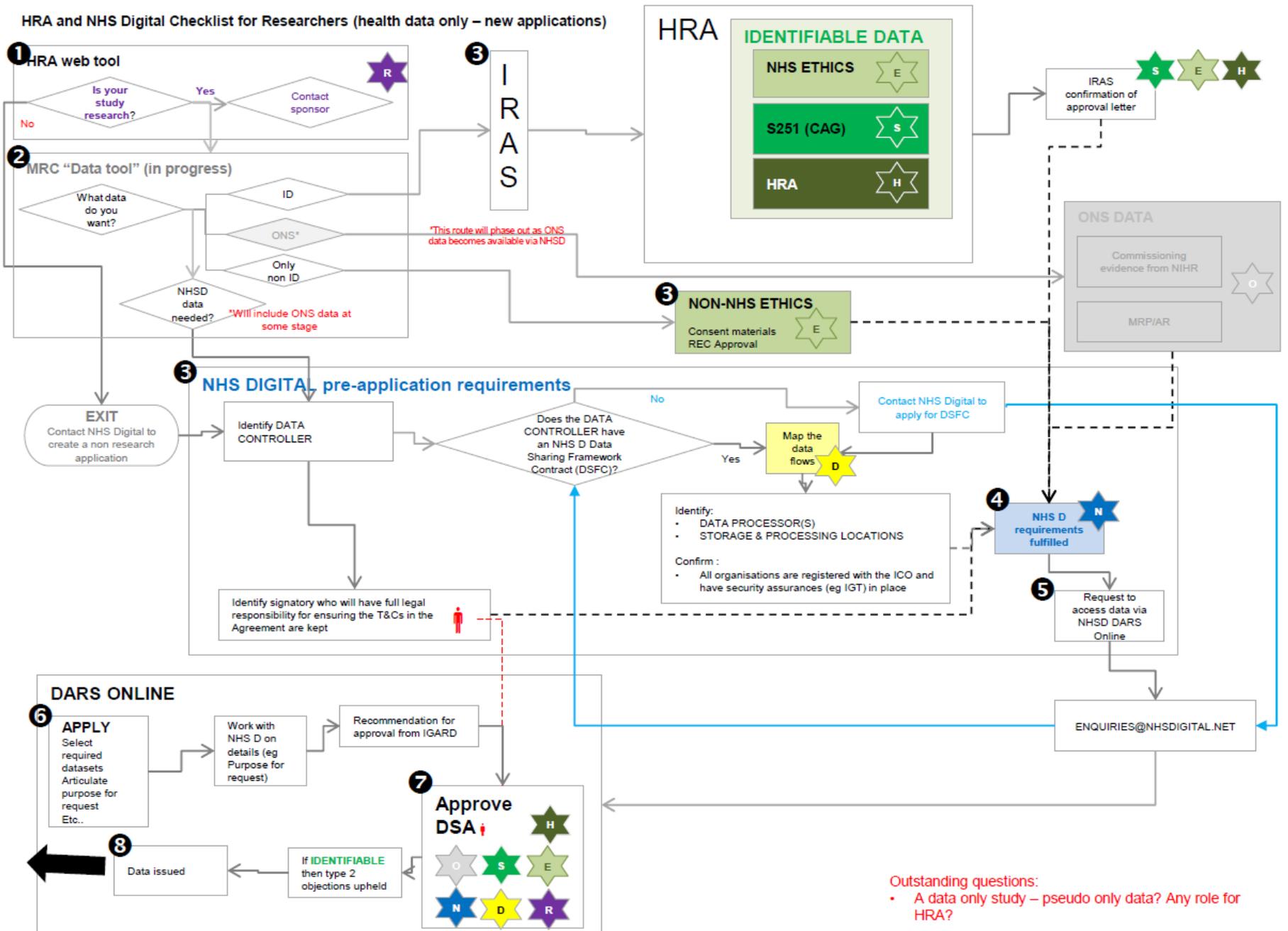# UK by Population Density

United Kingdom
Population Cartogram

Glasgow Edin-
burgh
Newcastle
Belfast
Leeds
Manchester
Sheffield
Liverpool
Birming-
ham
Cardiff
Bristol
London

Complicated

HRA and NHS Digital Checklist for Researchers (health data only – new applications)

❶ HRA web tool

Is your study research? → Yes → Contact sponsor **R**

No

❷ MRC "Data tool" (in progress)

What data do you want? → ID / ONS* / Only non ID

*This route will phase out as ONS data becomes available via NHSD

NHSD data needed?

*Will include ONS data at some stage

❸ IRAS

HRA

IDENTIFIABLE DATA

NHS ETHICS **E**

S251 (CAG) **S**

HRA **H**

IRAS confirmation of approval letter **S** **E** **H**

❸ NON-NHS ETHICS

Consent materials REC Approval **E**

ONS DATA

Commissioning evidence from NIHR **O**

MRP/AR

EXIT
Contact NHS Digital to create a non research application

❸ NHS DIGITAL pre-application requirements

Identify DATA CONTROLLER → Does the DATA CONTROLLER have an NHS D Data Sharing Framework Contract (DSFC)?

No → Contact NHS Digital to apply for DSFC

Yes → Map the data flows **D**

Identify:
- DATA PROCESSOR(S)
- STORAGE & PROCESSING LOCATIONS

Confirm:
- All organisations are registered with the ICO and have security assurances (eg IGT) in place

❹ NHS D requirements fulfilled **N**

❺ Request to access data via NHSD DARS Online

Identify signatory who will have full legal responsibility for ensuring the T&Cs in the Agreement are kept

DARS ONLINE

❻ APPLY
Select required datasets Articulate purpose for request Etc..

Work with NHS D on details (eg Purpose for request)

Recommendation for approval from IGARD

ENQUIRIES@NHSDIGITAL.NET

❼ Approve DSA **H** **O** **S** **E** **N** **D** **R**

❽ Data issued ← If IDENTIFIABLE then type 2 objections upheld

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Outstanding questions:
- A data only study – pseudo only data? Any role for HRA?

Challenges

For researchers

One research project leads to multiple applications to different organisations

Difficult to navigate the system

Understanding what is possible

Challenges

For research approvers / data providers

Legal / Policy constraints

Understanding researchers

Getting messages out to researchers

What are we doing?

Research approvers / data providers

- Understanding language

- Understanding and streamlining approval processes

- Building relationships and trust

Researchers / Research Organisations

- Transparency in what is required to access data

For support and guidance with:

- Consent, ethics and governance;

- Confidentiality, data protection and data access;

- Translational research (e.g. medicines, devices, in vitro diagnostics, cell and gene therapies etc.)

- Human tissue; and more.

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