NHS HE Information Governance Working Group

Notes of Initial Meeting on 29th August 2013
Held at Centre Point, New Oxford St, London

Present:

Kirsty Benn-Harris (KBH)	NIHR CRN Coordinating Centre
Stuart Bloom (SBl)	Mott MacDonald
Andrew Burnham (AB)	University of Leicester
Will Crocombe (WC)	University of Leeds
Michael Hollis (MH)	Institute of Cancer Research
Vanessa Kaliapermall (VK)	HSCIC
Bridget Kenyon (BK, Chair)	UCL
Sarah Lawson (SL)	NPEU, University of Oxford
Lucy Lucas (LL)	HSCIC
Janet Messer (JM)	Health Research Authority
Shane Murphy (SH)	UCL
Malcolm Teague (MT)	Janet
Hawys Williams (HW)	Arthritis UK
Apologies:	
Athanasios Anastasiou (AA)	University of Plymouth
John Brent (JB)	HSCIC
Sally Bridges (SBr)	Health Education Kent Surrey Sussex
Paul Newton (PN)	HSCIC
Trevor Peacock (TP)	UCL
Christopher Walker (CW)	University of Leeds (train failure on way to meeting)
Alyson Williams (AW)	University of Manchester

Welcome & Introductions

1 BK welcomed everyone and thanked them for volunteering for this working group. Everyone introduced themselves.

Current HSCIC position and plans regarding the IGT and related issues

2 VK explained that the IG teams from the previous IG Policy team at the Department of Health and the IG team at the previous NHS Information Centre have been combined to form a small team at the new Health and Social Care Information Centre (HSCIC). There has been a reduction in numbers so the HSCIC IG team are currently limited on what they can take on. Nevertheless they are pleased to be at this meeting to work with Research and Education representatives. In terms of capacity there are discussions with NHS England and it is hoped that more IG work will be commissioned from them, with a resultant increase in resources.

3 There are two other main relevant work streams already established:

a. S251 request review with the aim of simplifying the process, looking at the application process itself and how the IGT fits in. This is being done by the HRA related Confidentiality Advisory Group and VK can advise on recommendations emerging from this group.
b. Annual review of the IGT, both in terms of the functionality of the IGT website etc but also the content of the requirements.

4 Any suggestions for changes made by the Working Group would have to go through three stages of approval in the following order:

a. IGT editorial group made up of HSCIC IG group people, DH IG policy and standards leads with possibly some input from NHS England Area Teams.
b. Board with NHS England for IG, looking at requirements from a healthcare perspective
c. Health and Social Care Information Standards Board whose job it is to review, scrutinise and track proposed changes, against the evidence provided.

5 The review of the IGT takes in to account annual consolidated feedback from the Exeter Helpdesk. There will then be a look at national developments e.g. this year the Caldicott 2 report and the IG Best Practice report expected later in the year. Also the developments related to the Public Services Network (PSN) and its code of connection. VK can advise the Working Group as these things emerge.

6 A formal change request process is being introduced for future IGT changes (LL to send through when it is available). There is a push to streamline the IGT process and so proposals to increase the complexity are unlikely to be supported without a significant business case. In general VK advised:

Difficult to add or change:

- Views
- Requirements (which all tend to emanate from the Acute view which is the most comprehensive)
- Requirement description headers (as these cross many views)
- Attainment levels

Areas which could be added or improved more easily:

- Guidance material e.g. additions specific to research and education
- Shared resources in the "Knowledge Base" e.g. research and education relevant example policies

Where new statements are needed then would look to the Working Group to draft these.

7 VK passed over to LL, the Project Manager of IGT releases, to go through key timescales. LL reported:

- Version 11.2 is underway at the moment for expected release at the end of October. A part year release is unusual but it focuses on mainly minor technical changes e.g. adjusting typos, some functionality for internal use, enhancements to the reporting tool).
- Version 12 has a release date of June 2014. Working back from this means:
    - **Firm proposals on changes to the requirements or guidance are needed in January 2014**
    - Firm proposals for technical enhancements to the website are needed by December 2013, to give time for the small group (2-3) web developers to build them in to the system.

Questions and Discussion

8 SL said that in her role of trying to help other University of Oxford research groups with the IGT, she is finding that there is often a delay getting to the IGT in the first place i.e. being allocated an organisation code and getting through the first application form. 6 months to a year was the typical range and it had taken one group 18 months.

9 VK said it was first of all important to understand the levels of support available:

- Exeter Helpdesk – 1st line, what is in the system
- 2nd line – can do their best if there is an Organisation Data Service (ODS) number
- 3rd line – the central HSCIC team for more complex queries

With it still being relatively early days with research and education groups then probably the 3rd line support is needed. WC asked how to trigger access to the 3rd line support? SL said she would like to provide guidance to the Oxford groups on what questions to ask. On further discussion it was agreed that in the first instance the Working Group would review the application form (to be provided by VK) and feed in comments on issues.

Action 1.1: Working Group to review the IGT application form and feed comments back to BK or MT.

10 VK also reported that a structure was emerging for the organisation codes, and this is going to be clarified and improved in the future so that the right information is captured at the start. The approach is for instance for a particular research group or study:

Stem code/1st part of code	- University code (many already allocated)	e.g. EE90001
2nd part of code	- Medical School/School of Health or similar	e.g. MSH
3rd part of code	- Research Project or Team, or similar	e.g. RPT

So with the examples, the code finally issued could be EE90001-MSH-RPT

11 AB commented that as Universities or Faculties do not necessarily oversee applications from individual research groups, then sometimes the researcher getting in touch will not

have a clue about this. SL wondered whether a crib sheet for HSCIC on how Universities typically operate might help. VK said that in some instances it is known that a University is active in trying to coordinate an approach e.g. UCL is working with JB and PN. It was agreed that the Working Group could generate a list of University coordinating contacts on IGT where they exist so that if a new enquiry comes in from a University they can be linked to that contact for support as well.

Action 1.2: A list of University coordinating contacts on IGT will be created as a point of reference for HSCIC and any new University applicants. - MT

12 WC said that at his CTU in Leeds there are many projects – can you do the IGT once? VK said yes as long as the same arrangements and principles apply e.g. person responsible for IG, training, policies (on IG, security, records management etc.) and IT infrastructure. WC asked whether it mattered who employed those involved. VK said the important thing is that they come within the same accountability framework e.g. if some staff employed by others, accountability for IG has to be agreed. MH said that the ICR uses honorary contracts for this issue.

13 Another question was which category to pick, particularly between Secondary Use Organisation and Hosted Secondary Use Team/Project? VK responded that the general rule was:

University &/or University Faculty - Secondary Use Organisation
Research Team or Project - Hosted Secondary Use Team/Project

From an HSCIC point of view the bigger the better but the Working Group felt that typically groups could not wait for a University or higher level approach as many research groups operate relatively independently. However a higher level approach is encouraged and tends to emerge as more groups show interest.

14 BK said that she had been discussing with VK a University/Faculty facilitation approach being adopted at UCL. UCL/Faculty of Life and Medical Sciences are creating a technical solution with associated services such as training that individual research groups can then opt in to using. The idea, supported by VK, is that this core element can be assessed through the IGT and this can then be quoted as a given by an individual research group that makes use of it. For instance it could cover 20% or more of the research groups's IGT submission. SM added that in any IGT submission improvement plan they have been looking to see which elements can be covered by the Life and Medical Sciences Faculty opt in service, and which to the individual group or study. This has led to the IGT for some individual schools obtaining approval within 4 week.

Terms of Reference

15 The draft terms of reference were reviewed. A number of changes were suggested for a revised draft including:

i. Clarification of the scope – should be research and education whether in Higher Education, Pharma, Commercial Research Organisations, Charities etc.
ii. Wording to reflect the areas where the IGT can be most likely changed i.e. preferably no new view.
iii. Explicit task to develop a clearer understanding of ISO 27001/2 and the IGT through the explicit mapping of the requirements.
iv. Change in emphasis on data transfer mechanism review
v. Include the IGT Knowledge Base and the HRA website as other key communication channels
vi. Adding a role for general encouragement for clinical research and education groups to embrace the IGT as a "one-stop shop" for assurance that good practice is adopted. Currently there is a culture that the IGT is only relevant if it has to be done for a s251 request and we need to move beyond that.

Action 1.3: Develop a mapping between ISO 27001/2 requirements and the IGT – BK, and SBI offered to help.

Action 1.4: Review existing guidance around use of safe havens in relation to secure transfer of patient data between the NHS and research and education organisations. - MT

16 It was noted that the other main user type for the Hosted Secondary Team/Project view was Public Health departments within Local Authorities. It will be necessary to review any proposed changes in light of an impact to this group but VK thought it best for the Working Group to consider this as a second stage after the initial review of requirements from the research and education perspective.

17 BK raised a particular issue that had emerged already at UCL. A principal investigator (PI) in becoming a user of the IGT for his or her project or department is encouraged to report any incidents through the IGT website and these go to the Information Commissioner's Office (ICO). However the formal responsibility for any breach lies with the relevant Data Protection Officer ("the PI reports the incident and the DPO is sent to prison"). The issue is that the DPO is out of the loop which is a concern. VK said that a filter is being developed so that only those with a sufficiently high impact level to be of interest to the ICO are sent through to them. There is also a proposal to add a tick box for the Senior Responsible Owner to sign off an incident report, but that is not in the next release (v11.2). This may be included for IG Toolkit V12 release.

Action 1.5: VK will raise the issue of the potential DPO bypass in incident reporting with the ICO and NHS England and report back.

Action 1.6: The Working Group will include in its output guidance on local formal notifications to the DPO as at least a stop gap measure.

SL volunteered to collate any guidance and exemplar material that could be shared across the community e.g. in the IGT Knowledge Base

Action 1.7: Requests will be made for resources that IGT applicants are willing to share to the wider community – SL

Action 1.8: Feedback on frequently found issues reported to HSCIC to be shared - VK

Feedback from Individual Groups

18 UCL – BK reported that a lot of work is being done at the moment on a Faculty approach with template policies, procedures and guidelines as well as the creation of a technical environment that aims to be a "safe haven" once that is fully defined. UCL research groups can opt in to use this facility. The research group retains the responsibility for making the IGT submission. So far there are a few pilots on board, trying to keep the numbers manageable to start with, and it is still early days.

19 University of Leicester – AB said he was involved in this through the BRISSKit project which has registered for the IGT. AB has previous experience of the IGT from a Mental Health NHS Trust. One of the challenges with BRISSKit is that it involves a team of people most of whom are external to the University and another is that the project involves the creation of software which is not yet using patient identifiable data but may do in the future. There have been some recent changes with the BRISSkit project and the host University at Leicester so the next main thing is to reclarify the objective and who is responsible for achieving it.

20 Mott MacDonald – SB is working with third data processors and is glad the scope is beyond Universities alone. SB believes that there should be a stronger focus on data quality in the secondary use related IGT views. KBH added that she thought the data quality requirement (400) was a bit unwieldy and seemed to be a mishmash of requirements. It was agreed that this needs to be looked at particularly, as part of the requirements review.

21 ICR – MH said it was an interesting time trying to get the research groups on board with the IGT, when many think they don't have to. He is helping those teams that are moving on with this now. A particular question was whether it matters if the various components of a requirement exist in different places rather than within one document such as an IG policy? VK responded that in principle it doesn't matter as long as the requirements are covered appropriately.

22 Arthritis UK – HW said as Research Governance Office she is interested in the IGT in two main ways:

- how it applies to a major project using NHS data for arthritis research – INBANK

- in terms of funding other research groups there is a concern that too much of that research effort and time might be invested on the IGT process.

The sort of issues perceived so far:

- When trying to find out how relevant the IGT is for the INBANK project then didn't know really how to ask that.
- how prescriptive are the requirements, and the evidence to support the assessment
- accountability
- When based in a massive organisation like a University, knowing what has been done and by whom already (working in silos).

23 CTU, University of Leeds – WC said that he has registered for an organisation number and will be working on the IGT over the next 6-9 months as new projects are coming up that will require it.

24 NPEU, University of Oxford – Following the achievement of the IGT by the National Perinatal Epidemiology Unit (NPEU) at Oxford, SL now has a coordinating role at Oxford to help other groups with the IGT. Gradually other groups and the wider University are realising the importance of the IGT when working with the NHS. Trying to help with "top down" activities as well as coordinate "bottom up". One objective is to refine the process from a University point of view. Almost all of the groups have most if not all of what is needed but they don't necessarily recognise this as the vocabulary is different and a slightly different way of looking at it is required. SL would like to help the Exeter Helpdesk as well.

25 SL said there is much emphasis on training but the online training module seemed to need N3 access. VK said that there was a sister "IG training tool" that in theory any IGT User can use and it doesn't need N3 access. You have to register for this. However VK noted that because of capacity issues priority is currently being given to NHS users. The PowerPoint presentation can be used. KBH said that at the NIHR CRN they had found that a lot of the HSCIC training package was not applicable to researchers. They had created their own e-learning package and are willing to share this with others. KBH also noted that the e-learning package does not have to receive DH/HSCIC approval any longer, as long as the published criteria are met.

Action 1.9: The NIHR CRN IGT training package will be made available to others - KBH

26 NIHR CRN – Further to the training package as above, KBH said the barriers were similar to those described by SL for Oxford. Further to that some requirements aren't relevant e.g. the Caldicott Guardian requirement. The CRN is looking to support the local CRNs through the process so having more tailored guidance and exemplar material would be very helpful. UCL's approach of a generic core facility/set of policies plus local group input also sounded useful.

27 SL asked about the review process as she would like to provide some guidance on this to the Oxford groups e.g. NPEU responded whether they had policies or not whereas another group that had also achieved the IGT had uploaded all their policies to the IGT system. VK said it was not necessary to upload everything, they reserve the right to request access to key policies e.g. IG Policy, IT Security Policy. Either these can be uploaded if requested or access given to a server where they are already held. VK did say that if policies etc are uploaded to the IGT system then this is done via https: and they are on a secure server. There is an access policy on the site so they are not available for all to see.

28 WC asked what are the safeguards to the required policies and procedures actually existing and being used. It was agreed that many of the questions/requirements overlap and a group would soon get in to difficulties if it did not submit the consistent truth. However MH said the push in the NHS was for internal audit to check IGT submissions and WC suggested that as the MHRA already audit for instance Clinical Trial Units then they might audit the IGT for research groups. JM said it was early days for this but she would take that back to the MHRA.

Action 1.10: Raise the idea that the MHRA might include the IGT in their audits of CTU's etc. – JM

Timescales & Future Meetings

29 BK suggested:

- Teleconference in mid-September
- Teleconference in mid-October
- Physical meeting at the end of October
- The October meetings subject to the potential for an update IG Workshop aimed wider that the Working Group itself e.g. to review the IGT requirements in focused break-out streams.

Action 1.11: Arrange follow-up meetings and workshop - MT

Summary of Actions:

Ref.	Action	Who
1.1	Working Group to review the IGT application form and feed comments back to BK or MT	All
1.2	A list of University coordinating contacts on IGT will be created as a point of reference for HSCIC and any new University applicants.	MT
1.3	Develop a mapping between ISO 27001/2 requirements and the IGT	BK
1.4	Review existing guidance around use of safe havens in relation to secure transfer of patient data between the NHS and research and education organisations.	MT
1.5	Raise the issue of the potential DPO bypass in incident reporting with the ICO and NHS England and report back	VK
1.6	The Working Group will include in its output guidance on local formal notifications to the DPO as at least a stop gap measure.	BK
1.7	Requests will be made for resources that IGT applicants are willing to share to the wider community	SL
1.8	Feedback on frequently found issues reported to HSCIC to be shared	VK
1.9	The NIHR CRN IGT training package will be made available to others	KBH
1.10	Raise the idea that the MHRA might include the IGT in their audits of CTU's etc.	JM
1.11	Arrange follow-up meetings and workshop	MT