**Future version of IRAS – summary of stakeholder engagement to date**

*Deputy Director – Research Systems, February 2017*

**History of IRAS**

IRAS was launched in 2008 with its origins in the NRES online forms system and later with a combined R&D form.

IRAS was originally developed by Infonetica but following sale of the company some management changes impacted detrimentally meaning that support for IRAS wasn’t in the strength required and some key Infonetica staff moved into the CRN, working alongside HRA staff whilst others set up a new company, BGO Software, specialising in systems from the heath research sector. Once the HRA was set up, a competitive tender process was won by BGO Software to work as the software partner for HARP and IRAS development.

IRAS has a lot of history; where some significant changes have been attempted but with incremental tweaks being more manageable, however this has made the system more complex than really intended.

**Overview of current contractual arrangements**

On 1 April 2016, a new contract was successfully awarded to BGO Software of Bulgaria, to work in partnership with the Research Systems function in the delivery of robust systems for the HRA (predominantly HARP and IRAS). The contract is for a period of 3 years from 1 April 2016, with the option of two extensions, each being one year in length, so up to five years in total. The contract states that there will be a reduction in maintenance and development costs from Year 3 onwards, hence during 2016, BGO were asked to develop a proposal of technical developments to help realise this cost benefit within the required timescale. Hence, a scoping project termed ‘IRAS 6’, now known as Future IRAS , was commissioned to provide the detail.

In order to manage expectations as to what the main phases of this work will be, moving forward through the 2017/18 EDP, the Deputy Director made these plans known to the HRA Board, RSB and IRAS Partners and in doing so stimulated a great deal of interest this work and several additional requirements being expressed, which are currently out of scope of the above.

Hence, it has been recognised that in addition to the HRA’s need for the cost savings to be realised, that there are a number of aspirational requirements that are emerging from other groups of stakeholders about IRAS that are being captured and which will be very likely to increase given the evolving Service Improvement Programme (SIP) and strategic planning by the HRA Board.

**Annual costs of the contract from BGO Software for the HRA’s research systems**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Years** | **2016/2017****(Year 1)** | **2017/2018****(Year 2)** | **2018/2019****(Year 3)** | **2019/2020****(Year 4)** | **2020/2021****(Year 5)** |
| **Development Costs** | 721,620 | 721,620 | 624,720 | 527,820 | 527,820 |
| **Support Costs (servers and Help Desk)** | 119,760 | 119,760 | 119,760 | 119,760 | 119,760 |
| **Annual Totals** | **841,380** | **841,380** | **744,480** | **647,580** | **647,580** |

**Clarification of what is currently in scope for the 2017/18 EDP**

Following the initial scoping by BGO as described above, active steps are being taken to identify ways in which use of new technologies, improved infrastructure and database design could drive system improvements in terms of functionality, performance, stability, ease of maintenance and cost savings from Year 3 of the contract. This work can be considered as being ‘under the bonnet’ for IRAS and will lead to several, complex requirements being fulfilled within the contract as part of the annual Essential Delivery Plan (EDP) process, which is governed internally by the Research Systems Board and externally with the IRAS Partners Board. This will involve changes to systems architecture, IRAS administrative modules, question logic, dependencies and system rules hence will not be obvious in the user interface but which will make for a more robust system that is more straightforward to maintain.

Stakeholder engagement will continue as detailed below and as depicted on the attached stakeholder map.

**Stakeholders**

The Deputy Director of Research Systems has developed a stakeholder map to convey the span of interest in IRAS and hence the level of engagement necessary for any significant, longer term changes.

*This diagram has been attached separately for reference and has been updated to show the level of current coverage as reflected in this paper..*

Initial engagement with some stakeholders has been undertaken to provide reassurance that although the current work on IRAS is for the above purposes, that the Deputy Director wishes to build up an awareness of what aspirations there are for IRAS longer-term, acknowledging the challenges that factors such as Brexit and the EU Clinical Trials regulations will bring.

The following questions were asked but at this stage responses have been fairly free form. With regard to the future for IRAS:-

* What outcomes are required and how would these be measured?
* What advantages would these bring for the HRA?
* What is required and why, what would be the perceived benefits?

**Summary of key points captured to date:**

*(Please note that numbering and order do not reflect priority or precedence)*

1. It is important to make the differentiation between what is happening currently with IRAS, especially round bringing maintenance costs down by Year 3 of the current contract with BGO, in balance with aspirations for the future in line with the evolving HRA strategy and the service improvement programme (SIP).
2. A review of business processes via the SIP will drive out new requirements which must be stable prior to any major decisions being made around the longer term future design of IRAS.
3. That the HRA Board has a great desire to be bold and innovative about IRAS development in the longer-term, with Brexit being a significant factor in ensuring the UK becomes an even more attractive destination for health research to be conducted;
4. It is acknowledged that IRAS has evolved for a number of reasons as stated above but that the incremental approach has added to the system’s overall complexity, which means it can be burdensome and somewhat off-putting for users.
5. Resourcing, both staffing and budgeting, will be challenging and will need innovation in order to move forward. This could mean working in partnership with a number of organisations to plan the future state of IRAS whilst balancing current needs and work in progress for researchers using IRAS as it is now. This will need to be explored in depth for the most appropriate model to be designed for delivery.
6. A number of other influences include changes in the health sector around personalised medicine, complex research such as regenerative medicine and the technical challenges of an increased need for interoperability in the emerging health information ecosystem, ‘Big Data’ and increasing usage of cloud-based resources.
7. The Research Systems function and SRO undertake a significant amount of collaboration across several governance groups and boards drives IRAS development and serves as a key mechanism for identifying large and complex requirements. Several large items are already being scoped for the 2017/18 EDP and these include new functionality to support UK-wide e-submission of the IRAS form and amendments, scoping of NIHR/HRA BI to support the research community to show timelines across the whole study lifecycle; merging REC and HRA Approval for improved clarity and efficiency of processes; Improvement of online guidance and exploring the possibility of introducing a guidance management tool so that IRAS can become a single point of reference for research related guidance, providing researchers with a clearer, centralised system; Creation of a document manager that will enable better version control of supporting documents in IRAS and support e-submission of amendments and to be able to associate multiple applications
8. The Research Systems team have considered some future requirements as possible including further development to facilitate IRAS being used on handheld devices such as telephones and tablets, the archiving of form and project data and for IRAS to become more of an essential reference point for guidance and support as well as a longer term desire to redesign the user interface once evolving business processes have been stabilised.
9. All stakeholders have emphasised the need for greater consistency, which is recognised and that to get to a simpler system, simplification of processes and achievement of a greater degree of UK wider consistency will form the foundations for making IRAS a more streamlined system.
10. In terms of IRAS what the forthcoming EU Clinical Trials Regulations will demand is that IRAS can no longer be the application system for clinical trials but might become the potential destination for document templates that are subsequently uploaded to EU portal. Hence IRAS could become the ‘go to place’ to obtain templates even if IRAS would not be where these would be submitted. If in due course we no longer have the ability for applications to be submitted to or templates to be accessed from EU portal then IRAS would become the ‘Plan B.’.
11. Major influence around how the HRA will work with NHS Digital and with patients across a single healthcare system and ‘Big Data’ having greater significance.
12. Researchers need IRAS to support them more than currently by way of screening questions, asking the right questions and more prompts and increased validation, mandatory questions and form intelligence.
13. Any future version of IRAS needs to take into account the importance of time amongst stakeholders in filling in the forms – an SME will have tighter timescales than an academic organisation.
14. A lot of observations were made about the user interface and how off-putting this can be to researchers as well as time consuming. Questions were asked about high volume, low risk applications having a more straightforward process.
15. Post Brexit – to potentially license IRAS for others to use to generate consistent protocols and to promote interoperability. Trusts could use it and export to it. IRAS could be saleable outside of the UK. Need a large scale, commercial development partner.
16. It is recognised that IRAS needs to add value to researchers in a number of ways which would include it playing more than one role, to be able to generate documents e.g. a draft contract that could be adapted, to support protocol formulation.
17. IRAS could be built to include other functionality such as management of references using the Harvard style of referencing so that data is only put in once and to enable sponsors to manage research.
18. Examples of some members of a potential future IRAS consortium could be The Office for Life Sciences, NICE and MHRA. The HRA has an opportunity not to be ‘hamstrung’ by the past – new opportunities, new politics.
19. Discussion with IRAS Partners has shown a desire to consider enterprise architecture and interfaces as a key requirements, also how IRAS can feature as part of the ‘digital research ecosystem. ’Interoperability and compatibility with other systems is key.

**Conclusion**

It has been acknowledged that there are a number of stakeholder groups and there are a great deal of external influences including the NHS IT Strategy with its emphasis on cloud computing; more research is moving into digital spaces which would be a factor in considering the implication for the HRA and its data.

In planning the future for the HRA there it is acknowledged that IRAS needs to be futureproofed but it is currently unknown as to what this would mean in terms of overall scope, hence parallel running and how much system flexibility would be expected in relation to personalised medicine, for all research to be registered in IRAS hence the system’s purpose evolving, what to do with the massive amounts of data and more emphasis on patients rather than sites.

The current complexity in IRAS is linked directly to the complex business processes it supports. The number of forms will be reduced in line with how process changes evolve.

It is acknowledged that a significant visioning exercise is needed, which has begun with this stakeholder engagement work being led by the Deputy Director of Research Systems and this will need to work alongside the SIP (service improvement programme) as a key work stream. It is understood that the HRA Board will be revisiting the SWOT exercise during the first quarter of the new financial year (May 2017) and further visioning for IRAS needs to be built into this and the HRA Board working up the 5-year strategic plan. Some key considerations around this could include the following:

* Possibly securing some independent external guidance
* A consideration of creating a brand new IRAS or working with what exists now
* Resourcing of current and evolving work in addition to planning the future for IRAS
* Potentially join a group of collaborators as funding critical and how to secure

**Next steps**

1. Stakeholder engagement will continue and further updates will be planned and communicated. This is an important task.
2. Output from the SIP (service improvement programme) will be tied in with the above.