

Risk Register:	Corporate Risk Register
Date updated:	October 2018 for ARC & Board (Q2 2018/19)

HRA Risk Reference	Directorate Risk Reference	Risk Category	Date Raised	Risk Description	Timing	Inherent Likelihood Score	Inherent Impact Score	Inherent Risk Score	Risk Owner	Controls and Mitigations	Implementation date	Action Owner	Residual Likelihood Score	Residual Impact Score	Residual Risk score	Trend	Target Residual Risk Score	Assurance group / source	Contingency	Date risk last reviewed
HRA537	SIP 3	Service Improvement	23/02/2017	Risk: Insufficient 'people' resource to deliver service improvement programme Cause: Resources being directed to maintaining BAU as agreed as business priority, well-being of individuals impacted as stretched across too many pieces of work Effect: Will hinder speed of implementing change & could have a negative impact of health and well-being of individuals	Medium-term	4	4	16	JM	RM1: identify back fill resource to ensure necessary capability is freed up (use of SIP budget and reserves) RM2: Ensure SIP requirements are clearly detailed and part of an agreed resource management process RM3: Action on homework flex progressing RM4: Focus on addressing vacancies early RM 5: Re-prioritisation of work	01/09/2017 1/11/17	Leadership Team	3	4	12	↕	8	Transformation Board & Workforce Board		20/09/2018
HRA288	PPA013	Policy	04.02.2015	Risk: Unknowns around scope around Social Care and uncertainty of funding to deliver mean we may not be fulfilling our statutory responsibilities Cause: Despite the HRA listening exercises there remains significant unknowns about the volume of social care research and mixed views on how the HRA should implement its role for adult social care Effect: HRA may be seen to have failed to embrace the broader remit, equally in bringing in to remit beyond the current Social Care REC there are risks associated with a significant programme of change	Imminent	5	4	20	JT	RM1 - Clear messaging to set out the current objectives and focus of HRA Approval on NHS. RM2 - Maintaining Social Care REC within the overall Research Ethics Service. RM3 - Further listening and scoping activity to define options on further activity which will need to be considered. RM4 - Roundtable with key stakeholders planned for July 2018	Ongoing	AH	4	3	12	↕	10	Board and LT		10/07/2018
HRA004	PPA014	Policy	03/05/2013	Risk: HRA unable to promote transparency to the satisfaction of stakeholders. Cause: Timescales of moving forward with stakeholders, interdependency of work streams, capacity and environment appetite for change whilst not disadvantaging UK. Uncertainty around EU Clinical Trial Regs and potential for not having access to the EU portal and resulting loss of transparency of CTIMPs. Effect: Reputation of HRA damaged	Medium	4	4	16	BD	RM1 - Recommendations from Equator report on IRAS question A51 to be taken into account as part of IRAS redevelopment RM2 - Jan '17 - EQUATOR project re reporting / publication reporting recommendations to HRA by March '17 -- Complete RM3 – Brexit planning for no deal or deal which involves no access to EU portal will need to include alternative equivalent arrangements for investigators to upload summary results and other key documents. This is being taken into account as part of IRAS redevelopment. RM5: Paper to March board meeting setting out plans for 2018/19 agreed by HRA board and briefed to partners/stakeholders (4 Nations, Transparency Forum, P1AG)	RM5: March 18	BD	3	4	12	↕	6	Board and LT		30/01/2018

HRA568	App143	Approval - Projects	15/06/2017	<p>RISK: Sponsors and host do not follow process for “35 day no objection” for amendments. Cause: Host sites have not amended process to align with “35 day no objection” and undertaking a review of the amendment outside capacity and capability. Sponsors not aligning process and requesting confirmation (letter/email) from R&D for amendments. Sponsors not providing complete amendment pack to both R&D and research team. Effect: Lack of consistency and confusion with regard to the implementation of amendments</p>	Imminent	4	4	16	JMe	<p>RM1: Education through training and workshops. (JH ongoing review- 31/12/2017 - webinars hosted on monthly basis) RM2: Change Manager to follow-up with organisations identified as not following process. (JH ongoing review-31/12/2017) RM3: Targeted communications on process for amendments (JH 31/12/2017) - COMP RM4: Webinars to support amendment training (JH 31/12/2017) - ongoing webinars until October 2018 RM5: updated templates for sponsors to use - completed RM6: website section being updated - completed RM7: JH to focus training webinars for Trusts on appropriate circumstances for requesting more time RM8: wider amendments project underway</p>	18/10/2018	JH	4	3	12	↔	6	HRA Approval Projects Group		25/07/2018
HRA608	App155	Approval - Projects	08/02/2018	<p>Risk: delay in research starting at participating NHS organisation Cause: sites refusing to receive local information packs because they are not ready to start and perceive a negative impact on the metrics they are required to report Effect: researchers not seeing the benefits of HRA Approval in terms of improving study set up times and also seeing different processes emerging when working with NHS organisations</p>	Imminent	4	4	16	JMe	<p>RM1: Local information packs incorporated into IRAS, ensuring phrasing for rejection states "we do not wish to participate" rather than provide means to reject/delay involvement because site not ready (end of Sept 2018) RM2: JH to continue working with NHS organisations and also raise with R&D Champions Group - COMP (JH has raised with R&D Champions Group) RM3: Further development of UK-wide metrics to address behaviour RM4: communications and work with CRN on reporting of high level objectives to make sure don't drive people to rejects packs</p>	18/10/2018	JH	4	4	16	↔	4	HRA Approval Projects Group		09/08/2018
HRA591	RSB013	Financial	03/08/2017	<p>Risk: Future running costs cannot be accommodated in HRA spending review allocation Cause: Life cycle costs of the project are prohibitive, initial investment meets requirements but future ongoing costs fail to reduce day to day running costs for the HRA Effect: HRA unable to provide core services to the research sector within allocated resources.</p>	Longterm	5	5	25	KW	<p>RM1: Full life cycle costs of the system (forecasting models and assessment) will be built into the procurement process RM2: Simplification of the process will include automation (for users and HRA) which will release resource from other areas within the HRA RM3: Strong financial management and business partnering processes already in place at the HRA RM4: Deputy director of finance will take an active role in the procurement and ongoing management of the project RM5: Further business case for additional resources agreed</p>	<p>Mar '18</p> <p>RM2: Apr '19</p> <p>RM3: Ongoing</p> <p>RM4: Ongoing</p> <p>RM5: Dec 19</p>	<p>KW</p> <p>JM</p> <p>SH</p> <p>SH</p> <p>KW/I C</p>	4	4	16	NEW	4	RSB/SLT / Board	SLT / Board	16/10/2018
HRA654	RSB019	Financial	01/10/2018	<p>New Risk: Unable to complete due to not being able to procure the necessary resources Cause: increased scope (scale/interfaces) Effect: Not able to support rollout of pilot</p>	Imminent	5	5	25	IC	<p>RM1: Negotiate with Pega RM2: look at delivery options RM3: Further business case for additional resources to be agreed</p>	<p>RM1: End Oct</p> <p>RM2: End Oct</p> <p>RM3: Jan 19</p>	<p>SLT</p> <p>GCP/ NH</p> <p>IC/K W</p>	4	4	16	New	6	SLT		

HRA655	RSB020	Delivery	01/10/2018	New Risk: Inability to meet demands of current and new systems Cause: Two suppliers with different delivery models Effect: Increased complexity and cost unable to deliver new system to time and quality parameters	Imminent	5	5	25	IC	RM1: Short term - develop resourcing model which covers period up to March 19 which clearly identifies/quantifies roles and responsibilities RM2: Implement effective governance structure that is able to lead/manage the complexity	RM1: End Oct RM2: End Oct	GCP/ NH IC	3	4	12	New	6	?		
HRA598	IT001	IT	13/10/2017	Risk: The IMS3 contract with ATOS is until April 2020. There are concerns whether there is realistically enough time for FSP to fully deliver all that it needs to satisfy all the requirements, given the FSO (Future Service Organisation) would cover thousands of users Cause: External deadline, complex contract, extensive programme, 4 consuming organisations, delay in approving PBC, impact of IR35 Effect: Programme not delivered to timescales, IT service doesn't meet need	Longterm	3	3	9	GCP / KW	RM1 HRA IT Strategy and roadmap . RM2: HRA agreed to be part of FSP RM3: Active engagement in programme to ensure meets timelines and necessary approvals RM4: ITESGB provide governance route	Jun-19	KW / GCP	4	3	12	↕	6	ITESGB / LT / SLT	DH/NHS E commitment to FSP will include contingency planning	02/08/2018