

**HRA CORPORATE RISK REGISTER: Risks 12 and above accepted by EMT**

Version Control	Version <b>Oct-15</b>	Board	Stephen Tebbutt	Date	09/11/2015
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HRA Risk Ref	Dept risk register	Risk type	Date Raised	Last Reviewed (by Board)	Risk Description	Timing	Likelihood	Impact	RAG Status & Trend	Status Change	Risk Owner	Risk Mitigation and Intended Impact	Action Owner	Due date for actions	Target residual risk RAG status	Impacted Projects / Areas	Assurance sources
HRA344	App61	Approval - Change Management	02/09/2015	NEW	<p><b>Risk:</b> NIHR CRN staff unclear about the decision of new roles and responsibilities associated with NIHR CRN Study Support Service and alignment with HRA Approval.</p> <p><b>Cause:</b> Lack of understanding about R&amp;D and NIHR CRN Study Support Service interface for study delivery and alignment with HRA Approval.</p> <p><b>Effect:</b> Confusion and duplication of activities around local study setup and delivery.</p>	Imminent	4	3	12	New	Jme	<p><b>RM1:</b> HRA Approval case studies to be made available to organisations.</p> <p><b>RM2:</b> Ongoing meetings / discussions between Change Leads and local R&amp;D staff</p> <p><b>RM3:</b> Closer NIHR CRN interface relating to HRA Approval and NIHR CRN Study Support Service process development</p> <p><b>RM4:</b> HRA Change Leads, Study Support Links, Research Champions and RM&amp;G Leads liaising on a local level.</p> <p><b>RM5:</b> NIHR CRN has appointed a HRA Approval Business Lead who will work alongside the HRA Change Leads.</p>	Jme	31/03/16	6	HRA Approval	Change Management Project Board / HRA Approval Programme Board
HRA348	CAT21	CAG	8.10.15	NEW	<p><b>Risk:</b> HRA CAG unable to effectively deliver its new advisory function under the Care Act</p> <p><b>Cause:</b> Regulations setting out factors CAG to consider deferred pending National Data Guardian review on consent/objections</p> <p><b>Effect:</b> CAG will have to advise in the absence of that clear structure. Reputational issues and consequences if precedents set ahead of new factors identified through the review.</p>	Imminent	5	4	20	NEW	ND	<p><b>RM1:</b> Good channels of communication with DH and the risk is understood and the national review is to be welcomed.</p> <p><b>RM2:</b> No studies have been submitted yet and numbers may be small but will need careful handling.</p> <p><b>RM3:</b> Unhelpful timing for the new CAG members who will also need to be supported.</p> <p><b>RM4:</b> Ultimately it is advice not a decision and although unhelpful that the factors may change it is not unique that considerations for the dimensions of ethical or other considerations change as a consequence of an external factor or response to an event as such considerations are not static.</p>	DH Sponsor	16.10.15	12	CAG advisory role to HSCIC	DH Sponsor meetings
HRA349	CAT22	CAG	8.10.15	NEW	<p><b>Risk:</b> CAG workload being driven by advice provided by HSCIC (Health and Social Care Information Centre) ahead of the position being agreed between the organisation and others.</p> <p><b>Cause:</b> HSCIC responding to applications directly and inconsistently regarding the role of CAG.</p> <p><b>Effect:</b> Influx of applicants creating additional workload. Management time being taken up in responding and liaising with applicants and HSCIC. Applicants coming with the perception that the referral to CAG is causing a delay and creating reputational risk for HRA.</p>	Imminent	4	4	16	New	ND	<p><b>RM1.</b> Channels of engagement open with HSCIC.</p> <p><b>RM2.</b> Meetings scheduled at senior (CE) level</p> <p><b>RM3.</b> Training session planned with HSCIC Nov-15.</p> <p><b>RM4.</b> HRA to update website information to make clear that data controllers expected to liaise directly with applicants.</p>	ND	Nov-15	12	CAG advisory role to HSCIC	Senior CE meetings
HRA350	App064	Approval - Assessment	30/09/2015	NEW	<p><b>Risk:</b> HRA Approval acceptance varies significantly across the NHS due to differing perceptions of its impact on different areas of the research community.</p> <p><b>Cause:</b> Perception of the research community in how HRA Approval processes impact on local systems, process and resource, for study development, setup and delivery.</p> <p><b>Effect:</b> Negative impact on HRA reputation and variable change of processes to support research as a whole in the NHS.</p>	Medium	3	4	12	New	JMe	<p><b>RM1:</b> Ensure appropriate messaging / communications are provided via Change Leads, Champions for Research and NIHR CRN Lead RM&amp;Gs / Study Support Service leads</p> <p><b>RM2:</b> Support requirements to be assessed as part of NHS Readiness survey for Cohort 3</p> <p><b>RM3:</b> Non-commercial sponsor training / workshop put in place for 15 October 2015.</p>	JMe	31/03/16	8	HRA Approval	HRA Assessment Project Board / HRA Approval Programme Board

HRA352	App066	Approval - Technical Assurances / Assessment	02/10/2015	04.11.15	<p><b>Risk:</b> Process variance makes the implementation of a UK-wide compatible process challenging for the technical assurance components of HRA Approval.</p> <p><b>Cause:</b> Necessary operational differences (within the UK wide compatibility frameworks) across the 4 Nations</p> <p><b>Effect:</b> A disjointed UK Wide approach would lead to disproportionate burdens for review and slow down studies recruiting across the 4 Nations. Negative impact on HRA reputation if Approval seen to be the cause of what would be a significant backward step.</p>	Medium	4	4	16	New	JMe	<p><b>RM1:</b> Devolved Administrations have nominated Pharmacy Leads to lead on the operational aspects once the strategy is agreed.</p> <p><b>RM2:</b> Radiation Leads being identified across the Devolved Administrations to lead on the operational elements, once the strategic approach has been agreed</p> <p><b>RM3:</b> Technical Assurances is an element of the ongoing discussions on UK-wide working.</p>	JMe	31/03/16	10	HRA Approval	HRA Technical Assurances Project Board / HRA Assessment Project Board / HRA Approval Programme Board
HRA353	App067	Approval - Technical Assurances / Assessment	02/10/2015	NEW	<p><b>Risk:</b> Acceptance and understanding by RECs and sites of the new Radiation process is inconsistent.</p> <p><b>Cause:</b> Use of generic risk statements and PIS text as outputs of the Radiation Review will be unfamiliar and possibly conflated with overall risk/benefit reviews by RECs.</p> <p><b>Effect:</b> Negative impact on HRA reputation. Researchers may be asked to alter IRAS statements / PIS text, contrary to the radiation assurance process, leading to QC findings.</p>	Medium	3	4	12	New	JMe	<p><b>RM1:</b> Technical Assurances Officers and MPEs / CREs given a slot at NREAP-hosted Chairs meetings to present updated process and rationale for generic statements.</p> <p><b>RM2:</b> Change Leads continue to promote engagement with the process.</p> <p><b>RM3:</b> Evaluation due November 2015 to demonstrate benefit of standardised risk statements.</p> <p><b>RM4:</b> Explore the addition of a component around Radiation and Pharmacy into the information provided from the Assessment Team.</p>	JMe	31/03/16	11	HRA Approval	HRA Technical Assurances Project Board / HRA Assessment Project Board / HRA Approval Programme Board
HRA341	EMT007	Judicial review	20/08/2015	04.11.15	<p><b>Risk:</b> HRA programmes of work and day to day business affected by requirement to focus on outcomes of judicial review</p> <p><b>Cause:</b> Richmond Pharmacology return to challenge the completion of remedial action from the judicial review</p> <p><b>Effect:</b> Senior management and other staff required to work on outcome of judicial review neglecting other areas of business</p>	Imminent	4	3	12	↕	JW	<p><b>RM1:</b> EMT and Board to consider paper reviewing consequences of judicial review at September meetings and agree action plan.</p> <p><b>RM2:</b> HRA has paid costs as advised by legal team but costs not yet settled.</p>	JW	16.09.15	8	BAU	KPIs Maintained, EMT
HRA325	App58	Approval - Change Management	21/07/2015	16/09/2015	<p><b>Risk:</b> High expectation of delivery and improvement as HRA Approval is implemented, may not be realistic.</p> <p><b>Cause:</b> There may not be understanding for the reason of a controlled and lengthy rollout of HRA Approval, especially for secondary care organisations and time gap between cohort 1</p>	Imminent	4	4	16	↕	JMe	<p><b>RM1:</b> Communications</p> <p><b>RM2:</b> Stakeholder engagement</p> <p><b>RM3:</b> Cohort definitions and implementation plan communicated.</p>	Jme	31/03/16	10	HRA Approval	Change Management Project Board / HRA Approval Programme Board
HRA324	App57	Approval - Change Management	21/07/2015	16/09/2015	<p><b>Risk:</b> HRA Approval having a negative impact on performance / metric timelines.</p> <p><b>Cause:</b> Concern about impact on NHS Trust / NIHR CRN metrics and their reputation and / or funding and the loss of like-for-like comparison as a result of HRA Approval implementation</p> <p><b>Effect:</b> Potential poor metrics are assigned as being due to impact of HRA managed change e.g. loss of staff.</p>	Imminent	3	4	12	↕	JMe	<p><b>RM1:</b> Communications</p> <p><b>RM2:</b> Stakeholder engagement</p> <p><b>RM3:</b> Change Leads communicating metrics concepts since March 2015</p> <p><b>RM4:</b> HRA involved in working group to standardise and agree a new set of national performance metrics.</p>	Jme	31/10/16	8	HRA Approval	Change Management Project Board / HRA Approval Programme Board

HRA319	App54	Approval - Staffing	07/05/2015	16/09/2015	<p><b>Risk:</b> Technical Assurance implementation for Pharmacy and Radiation delayed or of poor quality as not all aspects of technical assurance in place by final stage of phased implementation.</p> <p><b>Cause:</b> Manager - Technical Assurance to go on maternity leave before full team is appointed or line manager is in post.</p> <p><b>Effect:</b> Negative reputational risk to the HRA because integral parts of HRA Approval not in place by final stage of phased implementation and sites continue to undertake local reviews, preventing organisational change.</p>	Imminent	3	4	12	↕	JMe	<p><b>RM1:</b> 0.2 wte secondment to manage pharmacy and radiation professional relationships in place until 30 September 2015.</p> <p><b>RM2:</b> Most experienced Technical Assurances Officer taking on an enhanced role within the team to project manage implementation. This role is part of the Approval Team rather than the C&amp;D team to maximise alignment with other HRA Approval operational development.</p> <p><b>RM3:</b> Technical Assurance to become a sub-group of the Assessment Project Board to provide robust governance and oversight of matrix management of staff and process development across the above posts, Head of C&amp;D and Head of Assessment and Assurance.</p> <p><b>RM4:</b> Project Lead for Amendments to be appointed.</p>	JMe	31/03/2016	8	HRA Approval	HRA Technical Assurances Project Board / Staffing Project Board / HRA Approval Programme Board
HRA288	EMT2	Social Care	04.02.2015	04.11.15	<p><b>Risk:</b> Unknowns around scope and expectations for extended remit to Social Care and uncertainty of funding to deliver.</p> <p><b>Cause:</b> 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</p> <p><b>Effect:</b> 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</p>	Imminent	3	4	12	↕	JW	<p><b>RM1:</b> Clear messaging to set out the current objectives and focus of HRA Approval on NHS.</p> <p><b>RM2:</b> Listening event held in February.</p> <p><b>RM3:</b> Further listening events held in September</p> <p><b>RM4:</b> Maintaining Social Care REC within the overall Research Ethics Service.</p> <p><b>RM5:</b> Further listening and scoping activity to define options on further activity which will need to be considered with agreement of funding for 2016-2017.</p>	JW	01/10/15	10	BAU	EMT
HRA282	CSMT022	COM	07/01/2015	16/09/2015	<p><b>Risk</b> Website (and intranet) become out of date, inaccurate or dated, or planned improvements are delayed.</p> <p><b>Cause:</b> Poor maintenance</p> <p><b>Effect:</b> Inconsistent or inaccurate guidance</p>	Long	3	4	12	↕	KG	<p><b>RM1</b> - SOP outlines the responsibilities for content (for content owners and their directors)</p> <p><b>RM2</b> - SLA in development (due mid 15)</p> <p><b>RM3</b> - Digital Programme Board (DPB) gives broader ownership of web and intranet</p> <p><b>RM4</b> - programme of systematic review of web and intranet content guarantees review at least once a year by content owners. Further review of content following outcome of judicial review</p>	GKH	31/08/15	4	Operations team and all site users	CSMT sign-off; DPB's activities, programme structure and terms of reference. CEO sign off and legal.
HRA219	App35	Approval - Programme Board	23/06/2014	16/09/2015	<p><b>Risk:</b> Operational differences across the countries present navigational challenges</p> <p><b>Cause:</b> HRA Approval relates to England, however, researchers want - and the UK needs (including EU Clinical Trial Regulations - 2016/17) - UK-wide compatibility</p> <p><b>Effect:</b> Reputational impact on HRA and UK more generally</p>	Medium	4	4	16	↕	JMe	<p><b>RM1:</b> UK commitment to a UK policy framework with strong links across to colleagues in the DA.</p> <p><b>RM2:</b> Devolved Administration representation on the HRA Approval programme Board</p> <p><b>RM3:</b> Active engagement with Devolved Administration operational leads and the 4 Nations group in decisions around HRA Approval rollout</p>	JW	31/12/2015	8	HRA Approval	4 nations/ HRA Approval Programme Board
HRA204	App20	Approval - Change Management	23/06/2014	16/09/2015	<p><b>Risk:</b> The extent of change may make things feel worse for all stakeholders even if continuity is maintained, before it gets better</p> <p><b>Cause:</b> Natural consequence of a large scale programme of change</p> <p><b>Effect:</b> Negative impact on HRA Reputation</p>	Imminent	4	4	16	↕	JMe	<p><b>RM1:</b> Regular and proactive communication</p> <p><b>RM2:</b> Controlled implementation in phases</p> <p><b>RM3:</b> Use of change leads to communicate messaging on metrics</p> <p><b>RM4:</b> Planning and communication around rollout of Cohorts 3 &amp; 4 will provide detail and help with continuity</p>	MC	31/07/2016	12	HRA Approval	Assessment Project Board/ HRA Approval Programme Board

HRA303	App47	Approval - Staffing / Assessment / Amendment	25/03/2015	16/09/2015	<p><b>Risk:</b> HRA does not have sufficient resources to handle the "new site" amendments relating to legacy studies (i.e. studies that gained NHS permission prior to HRA Approval).</p> <p><b>Cause:</b> The volume of work (in terms of both number of amendments and how much effort each one will take) is unknown so resource required cannot be adequately planned.</p> <p><b>Effect:</b> Cost pressure if require additional resource and reputational risk to HRA for slow/inadequate processing of amendment applications</p>	Medium	4	4	16	↕	JMe	<p><b>RM1:</b> Work with CRN and pull information from HARP to try to better estimate number - will only be an approximation.</p> <p><b>RM2:</b> Work with CRN to access study wide review for studies that have been through CSP in order to be able to do "light touch" review and not repeat work already done.</p> <p><b>RM3:</b> Develop efficient HRA processes for handling of amendments.</p> <p><b>RM4:</b> Closely monitor applications once live</p> <p><b>RM5:</b> Project Lead for Amendments to be appointed</p>	MC	31/03/2017	8	HRA Approval	HRA Approval Amendment Project Board / Assessment Project Board/ HRA Approval Programme Board
HRA099	SDB 4	SDB Part A	SDB Board July	Held on EMT register - to Board	<p><b>Risk:</b> Significant critical issue affects HRA business operations, through reliance upon key systems for desktop and internet access</p> <p><b>Cause:</b> IT failure in OpenService</p> <p><b>Effect:</b> Inability to continue with operational service</p>	Immediate	4	4	16	↕	IC	<p><b>RM1:</b> IT work-off list being jointly managed by HRA, Atos and DH IT.</p> <p><b>RM2:</b> DH contract in place with Atos and escalation routes established between HRA and DH IT</p> <p><b>RM3:</b> HRA has Business Continuity Plan in place</p> <p><b>RM4:</b> May '14 - contingency internet access being procured from NELCSU</p> <p><b>RM5:</b> Aug '14 - OpenService SLA KPIs increasingly being achieved, although inconsistently and not near 100%</p> <p><b>RM6:</b> Nov'14 System stability overall is improving however low level issues persist.</p> <p><b>RM 7:</b> Dec '14 OpenService onshoring of helpdesk complete</p> <p><b>RM 8:</b> April '14 Monthly reporting and meeting between HRA and Atos continue.</p> <p><b>RM 9:</b> November 15, Regular meetings held with regular reporting received.</p>	RA	On-going	8	All	DH Sponsor meetings