

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

Version Control	Version	September Board	Stephen Tebbutt	Date	12/09/2016
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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
HRA485	App114	Approval - Projects	20/06/2016	NEW	<p>Risk: Researchers are confused and frustrated by operational and policy differences across the UK</p> <p>Cause: Differing processes for study set up and study wide review across the UK</p> <p>Effect: Reputational risk for the HRA and the UK as a whole as researchers want and the UK needs (new EU CT Regs) consistency across the UK</p>	Imminent	4	4	16	NEW	JW	<p>RM1: UK commitment to UK policy framework with strong links to colleagues in DAs</p> <p>RM2: DA representation on Programme Board</p> <p>RM3: Active engagement with DA operational and policy leads</p> <p>RM4: DA facing Q&As</p> <p>RM5: Clear communication and guidance on website and in Q&As</p> <p>RM6: 4 nations local info package working group.</p> <p>RM7: 4 nations amendments working group.</p> <p>RM8: Request to UKECA for 4 nations EU CT Regs working group.</p> <p>RM9: Good progress made through various work streams.</p> <p>RM10: Progress to be communicated with indicative timings</p>	Jme/MC	30/09/16	8	HRA Approval	UKECA/HRA Approval Programme Board
HRA486	App115	Approval - Programme	20/06/2016	NEW	<p>Risk: NHS organisations may perceive timelines will be longer and show fall in performance</p> <p>Cause: Natural consequence of change, confusion over meaning of published metric information from CCF and CRN, confusion over pre-HRA Approval studies and metrics, and misunderstandings relating to HRA Approval not being issued until after REC FO.</p> <p>Effect: Perceived poor performance will negatively impact HRA reputation and may prevent NHS organisations making required changes</p>	Imminent	4	4	16	NEW	JW	<p>RM1: Clear communications about who is responsible for what and signposting to CCF and CRN</p> <p>RM2: R&D management engagement through embedding change work</p> <p>RM3: HRA involvement in working group standardising and agreeing new set of national performance metrics</p> <p>RM4: Data definitions have been published by CCF</p> <p>RM5: Clear communication and guidance on website and in Q&As</p> <p>RM6: 4 nations local info package working group</p> <p>RM7: 4 nations amendments working group.</p> <p>RM8: Request to UKECA for 4 nations EU CT Regs working group.</p>	Jme	30/09/16	8	HRA Approval	Approval Projects Group/HRA Approval Programme Board
HRA500	APP117	Approval - Projects/Assessments	08/08/2016	NEW	<p>Risk: Applicants and NHS not following the HRA Approval process</p> <p>Cause: Lack of understanding about both the high level process and the detail</p> <p>Effect: Confusion across stakeholder community leads to delayed research with negative impact on HRA</p>	Imminent	4	3	12	NEW		<p>RM1: Review of website</p> <p>RM2: Clear communication of high level messaged with link to details</p> <p>RM3: In the communications regarding roll out make clear which studies include technical assurance as part of HRA Approval and which HRA Approval applies only</p>			6	HRA Approval	Approval Projects Group/ HRA Assessment Group
HRA204	App20	Approval - Programme	23/06/2014	04/05/2016	<p>Risk: The extent of change may make things feel worse for all stakeholders even if continuity is maintained, before it gets better</p> <p>Cause: Natural consequence of a large scale programme of change</p> <p>Effect: Negative impact on HRA Reputation</p>	Imminent	4	4	16	↔	JMe	<p>RM1: Regular and proactive communication</p> <p>RM2: Controlled implementation in phases</p> <p>RM3: Use of change leads to communicate messaging on metrics</p> <p>RM4: Planning and communication around rollout of Cohorts 3 & 4 will provide detail and help with continuity</p> <p>RM5: Communications issued addressing initial implementation teething problems</p>	MC	30/09/2016	12	HRA Approval	Approval Projects Group/ HRA Approval Programme Board

HRA206	App22	Approval - Projects	23/06/2014	04/05/2016	<p>Risk: Identifying metrics to demonstrate rapid success against baseline to show the value of the HRA Approval programme may not be possible</p> <p>Cause: Changes to definitions mean using baseline metrics (70 day or CRN metrics) are not compatible and resources to develop may not be available</p> <p>Effect: Stakeholders and government may not perceive HRA to have achieved aims of programme</p>	Medium	4	5	20	↔	JMe	<p>RM1: Use funder and industry timelines which currently measure more of the process in the UK</p> <p>RM2: Use case study examples of improvement as early good news stories</p> <p>RM3: use evidence of front line savings through the early clinical review roll out</p> <p>RM4: Progress being made by the NIHR CRN / CCF / HRA Metrics sub group reported to the Interdependencies Board</p> <p>RM5: Ongoing clarification communications from CRN and CCF to community around changes in definitions.</p>	JMe	30/09/2016	10	HRA Approval	Approval Projects Group/HRA Approval Programme Board
HRA282	CSMT022	COM	07/01/2015	12/09/2016	<p>Risk: Website (and intranet) become out of date, inaccurate or dated</p> <p>Cause: Content not reviewed or maintained adequately</p> <p>Effect: Inconsistent or inaccurate guidance</p>	Short term	4	4	16	↑↑	KG	<p>RM1 - SOP outlines the responsibilities for content (for content owners and their directors)</p> <p>RM2 - Corporate and CSMT KPIs now in place</p> <p>RM3 - Web content reviews & update programme with content owners continuing. as part of programme of systematic review of web and intranet content which guarantees review at least once a year by content owners</p> <p>RM5 Website Improvement Project set up to take forward work for future web direction. Project brief approved by EMT PID in draft. Product delivery manager starting in August.</p> <p>RM 6 Discussions underway with HRA Approval team as concern is that this is currently a vulnerable area. Comms manager proposing changes and working with team to review and update.</p>	KG	Ongoing	4	Operations team and all site users	CSMT sign-off; DPB's activities, programme structure and terms of reference
HRA288	EMT2	Social Care	04.02.2015	04/05/2016	<p>Risk: Unknowns around scope and expectations for extended remit to Social Care and uncertainty of funding to deliver.</p> <p>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</p> <p>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</p>	Imminent	3	4	12	↔	JW	<p>RM1: Clear messaging to set out the current objectives and focus of HRA Approval on NHS.</p> <p>RM2: Maintaining Social Care REC within the overall Research Ethics Service.</p> <p>RM3: 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>	AH	18/10/16 - PDMT meeting	10	BAU	SEMT, PDMT
HRA375	App085	Approval - Information Governance Projects	25/11/2015	04/05/2016	<p>Risk: HRA Approval acceptance may vary significantly across the NHS due to ongoing information governance work.</p> <p>Cause: Various ongoing IG issues that still require to be actioned in order to implement a quality driven, robust national process. Poor buy-in from the IG Working Group.</p> <p>Effect: Negative impact on HRA reputation. Benefits from a new process for IG may not be recognised by the NHS and therefore local systems and processes are still followed.</p>	Medium	4	4	16	↔	JMe	<p>RM1: Clear communications on the standards developed to support IG assessment.</p> <p>RM2: Stakeholder engagement.</p> <p>RM3: Appropriate management of the IG working group to ensure robust but-in.</p> <p>RM4: Closely monitor applications once live.</p> <p>RM6: Close working with and support from the HRA Approval / Assessment team to ensure IG questions are finalised and standards / assessment criteria agreed in order to meet introduction of Cohort 4.</p> <p>RM7: Other means than IRAS of obtaining the answers to the questions explored by the Assessment Team.</p> <p>RM8: Ensure that when HRA Approval is issued all documents are clear and all issues addressed.</p>	JMe	30/09/16	6	HRA Approval	Approval Projects / HRA Approval Programme Board

HRA376	EMT010	Reputational / UK Wide compatibility	14/12/2015	04/05/2016	<p>Risk: HRA and Devolved Administrations may not be able to continue to agree on a single approach to the handling of operational items that are expected by stakeholders e.g. site specific information following the call for comments, the combined form</p> <p>Cause: The different drivers and buy in to change and outcomes expected from it</p> <p>Effect: Reputation of HRA, or HRA relationships with Devolved Administrations, may be adversely affected. Resource burden of management intervention to maintain effective compatibility.</p>	Imminent	3	4	12	↓	JW	M1 – Level of support for decision M2 - Long standing good relations and UK wide compatibility M3 – Handling through UKECA and 4 nations R&D operational group	JM	26/09/16 - 4 Nations meeting	8	HRA Approval / UK Compatibility	HRA Approval Programme Board, HRA Board, DH Sponsor, 4 Nations
HRA377	EMT011	Stakeholder management / Reputational	05/12/2015	04/05/2016	<p>Risk: The HRA has a large number of stakeholders with different levels of understanding across and within them. Whilst detailed stakeholder mapping has been undertaken there is a risk that even with the mapping and attempts to target information appropriately across and within stakeholders that stakeholders do not get the information they need and gain the understanding required.</p> <p>Impact: the issues are largely reputational but with possibility of material consequences if the lack of buy in or understanding leads to a perception of failure to deliver. It is unlikely that, for example, a researcher lack of understanding is going to impact on their ability to navigate the new processes such that they don't gain Approval. It may well impact on how smoothly that goes and interactions they have in confirming permission locally. The same applies for other areas, e.g. the policy framework if there is not an awareness of and understanding of the benefits of what is being delivered.</p>	Medium	4	4	16	↔	JW	The HRA has a number of good tools in place, the stakeholder mapping, organisational credibility, individuals credibility, stakeholder engagement and practical support e.g. Industry, and change leads but even with that it will be a challenge to cover all at the level of detail required. Further resource is being identified to improve the management of and cascade of information. Stakeholder management forum established.	JW	Stakeholder engagement and comms strategy to Feb 16 Board	9	HRA Approval UK Policy Framework Organisational wide	HRA Approval Healthcheck HRA Board
HRA389	CAT24	CAG	03.02.15	04/05/2016	<p>Risk: HRA/CAG unable to effectively deliver CAG's advisory function on V=0) dissemination</p> <p>Cause: V=0) 's CAG referral policy does not allow workload to be calculated</p> <p>Effect: Volume/nature of V=0) referrals to CAG exceeds resources/capability. Reputational damage and other consequences if this:</p> <ul style="list-style-type: none"> • hampers data dissemination • undermines confidence in CAG • frustrates CAG members/CAT staff • breaches HRA's legal duty to appoint a CAG to advise V=0) (replacement of HRA348) 	Imminent	3	4	12	↔	JMe	<p>RM1: Continue to work with V=0) to elicit a CAG referral policy that is fit for purpose</p> <p>RM2: Visible to CEs</p> <p>RM3: Visible to DH sponsors</p> <p>RM4: Refuse to accept referrals from V=0) until its CAG referral policy is fit for purpose</p> <p>RM5: Flagging to DH sponsors</p>	ND	01/12/16	10	CAG Advisory role to V=0)	CAG, SEMT, EMT, Board
HRA436	CAT25	CAG	8.3.16	04/05/2016	<p>Risk: Unable to deliver CAG functions</p> <p>Cause: Staff vacancies (numerous)</p> <p>Effects: Not meeting KPIs, unable to meet workload, increase in complaints</p>	Imminent	3	4	12	↔	JMe	<p>RM1: Facilitated session to take place</p> <p>RM2: Performance management to be undertaken</p> <p>RM3: Recruitment taking place with appointments being made</p>	ND	01/10/16	8	CAG	CAG, EMT, SEMT
HRA452	App096	Approval - Projects	14/03/2016	04/05/2016	<p>Risk: Reputational risk to HRA around confused or incorrect communication to applicants about amendments</p> <p>Cause: Lack of clarity across HRA staff team about what amendments processes for different scenarios</p> <p>Effect: Negative impact on HRA reputation.</p>	Medium	3	4	12	↔	JMe	<p>RM1: Amendment process flowcharts published</p> <p>RM2: Amendment SOP</p> <p>RM3: Amendment letter templates refined</p> <p>RM4: Amendment training across teams</p> <p>RM5: UK wide clarification to be issued Sept 2016</p> <p>RM6: UK wide work to review amendment handling in preparation for e-submission</p>	JMe	26/09/16 - 4 Nations meeting	8	HRA Approval	HRA Approval Programme Board, 4 nations group

HRA471	FIN32	Finance	12/04/2016	04/05/2016	<p>Risk: Risk of shift of forecast position .</p> <p>Cause: Due to lack of sharing of intelligence by Budget Managers.</p> <p>Effect: Contributing to an unexpected shift in the position resulting in reputational damage.</p>	Medium	3	4	12	↔	DC	<p>RM1: Regular evidenced Budget Manager meeting.</p> <p>RM2: Quarterly forecast return from Budget Managers to evidence.</p> <p>RM3: Additional training and support to budget managers held</p> <p>RM4: Continued review at EMT and SEMT on monthly basis, and monthly budget management meeting.</p> <p>RM5: Board oversight at each Board meeting.</p>	DC/SH/CKA/Dce	Monthly	6	All	EMT, SEMT, Board Finance Reports
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