

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

Version Control	Version Q4 2015-1 Board	Stephen Tebbutt	Date	20/05/2016
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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
HRA206	App22	Approval - Assessment	23/06/2014	16/09/2015	<p>Risk: Identifying metrics to demonstrate rapid success against baseline to show the value of the HRA Approval programme</p> <p>Cause: Changes to definitions mean using baseline metrics (70 day or CRN metrics) are not compatible</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>	JMe	30/09/2016	10	HRA Approval	Assessment Project Board / HRA Approval Programme Board
HRA376	EMT010	Reputational / UK Wide compatibility	14/12/2015	17/02/2016	<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	4	4	16	↔	JW	<p>M1 – Level of support for decision</p> <p>M2 - Long standing good relations and UK wide compatibility</p> <p>M3 – Handling through UKECA and 4 nations R&D operational group</p>	JM	Jan EMT Jan Board Jan sponsor meeting 26/01 UKECA meeting	12	HRA Approval / UK Compatibility	HRA Approval Programme Board, HRA Board, DH Sponsor
HRA377	EMT011	Stakeholder management / Reputational	05/12/2015	17/02/2016	<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	<p>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.</p>	JW	Stakeholder engagement and comms strategy to Feb 16 Board	9	HRA Approval UK Policy Framework Organisational wide	HRA Approval Healthcheck HRA Board
HRA362	App073	Approval - Amendment (Assessment)	16/10/2015	(NEW - old risk raised)	<p>Risk: Unknown volume of amendments that will need to be handled by the HRA as a whole, irrespective if the studies have been through HRA Approval or not.</p> <p>Cause: Not all amendments are handled through NIHR CSP / R&D Offices therefore there is no clear picture of the potential volume of work that will come to the HRA.</p> <p>Effect: Resource pressure for handling amendments and reputational risk to the HRA for slow / inadequate processing of amendment applications.</p>	Medium	4	4	16	NEW	JMe	<p>RM1: Work with the NIHR CRN and pull information from HARP to try and estimate number of potential amendments.</p> <p>RM2: Develop an efficient process for handling of amendments.</p> <p>RM3: Closely monitor applications once live. RM4: Work closely with R&D Offices to try and estimate number of non-portfolio amendments.</p>	JMe	30/09/16	9	HRA Approval	Amendment Project Board / Assessment Project Board / HRA Approval Programme Board

HRA453	App097	CRN / CCF Interdependencies Board	14/03/2016	NEW	Risk: Potential Impact on HRA reputation relating to new performance measures Cause: Natural consequence of change to performance criteria and definitions made elsewhere but which impact on the HRA Effect: Negative impact on HRA reputation.	Medium	4	4	16	NEW	JMe	RM1: Publication and clarification of data definitions RM2: Communication relating to who is responsible for what metrics.	JMe	01/08/16	9	HRA Approval	HRA Approval Programme Board
HRA375	App085	Approval - Information Governance (Assessment)	25/11/2015	17/02/2016	Risk: HRA Approval acceptance may vary significantly across the NHS due to ongoing information governance work. 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. 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.	Medium	4	4	16	↕	JMe	RM1: Clear communications on the standards developed to support IG assessment. RM2: Stakeholder engagement. RM3: Appropriate management of the IG working group to ensure robust but-in. RM4: Closely monitor applications once live.	JMe	30/09/16	6	HRA Approval	HRA Assessment Project Board / HRA Approval Programme Board
HRA204	App20	Approval - Change Management	23/06/2014	17/02/2016	Risk: The extent of change may make things feel worse for all stakeholders even if continuity is maintained, before it gets better Cause: Natural consequence of a large scale programme of change Effect: Negative impact on HRA Reputation	Imminent	4	4	16	↕	JMe	RM1: Regular and proactive communication RM2: Controlled implementation in phases RM3: Use of change leads to communicate messaging on metrics RM4: Planning and communication around rollout of Cohorts 3 & 4 will provide detail and help with continuity	MC	31/07/2016	12	HRA Approval	Assessment Project Board/ HRA Approval Programme Board
HRA350	App064	Approval - Change Management	30/09/2015	17/02/2016	Risk: Adherence to the HRA guidance on the local implementation of HRA Approval varies significantly across the NHS due to differing perceptions of its impact on different areas of the research community. Cause: Perception of the research community in how HRA Approval processes impact on local systems, process and resource, for study development, setup and delivery. Effect: Negative impact on HRA reputation and variable change of processes to support research as a whole in the NHS.	Medium	4	4	16	↕	JMe	RM1: Ensure appropriate messaging / communications are provided via Change Leads, Champions for Research and NIHR CRN Lead RM&Gs / Study Support Service leads. RM2: Support requirements to be assessed as part of NHS Readiness survey for Cohort 3. RM3: Non-commercial sponsor training / workshop put in place for 15 October 2015.	JMe	31/07/2016	8	HRA Approval	HRA Change Management Project Board / HRA Approval Programme Board
HRA303	App47	Approval - Amendment (Assessment)	25/03/2015	17/02/2016	Risk: 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). Cause: 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. Effect: Cost pressure if require additional resource and reputational risk to HRA for slow/inadequate processing of amendment applications	Medium	4	4	16	↕	JMe	RM1: Work with CRN and pull information from HARP to try to better estimate number - will only be an approximation. RM2: REC and R&D data to be collated to get an estimate in the number of amendments. RM3: Develop efficient HRA processes for handling of amendments. RM4: Closely monitor applications once live RM5: Project Lead for Amendments to be appointed RM6: Work with local R&D offices to try to better estimate number of non-portfolio amendments - including new sites. RM7: 4 Amendment Coordinators appointed	MC	30/09/2016	8	HRA Approval	HRA Approval Amendment Project Board / Assessment Project Board/ HRA Approval Programme Board
HRA471	FIN32	Finance	12/04/2016	NEW	Risk: Risk of shift of forecast position . Cause: Due to lack of sharing of intelligence by Budget Managers. Effect: Contributing to an unexpected shift in the position resulting in reputational damage.	Medium	3	4	12	NEW	DC	RM1: Regular evidenced Budget Manager meeting. RM2: Quarterly forecast return from Budget Managers to evidence. RM2: Additional training and support to budget managers held RM4: Continued review at EMT on monthly basis, and monthly budget management meeting.	DC/SH/CKA/Dc e	Monthly	6	All	Finance Reports

HRA288	EMT2	Social Care	04.02.2015	17/02/2016	<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>	JW	01/03/16	10	BAU	EMT
HRA452	App096	Approval - Amendment (Assessment)	14/03/2016	NEW	<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	NEW	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>	JMe	31/07/16	8	HRA Approval	HRA Approval Programme Board
HRA456	App100	Approval - Programme Board	18/04/2016	NEW	<p>Risk: Complex or confusing arrangements for site level information for cross-border studies.</p> <p>Cause: 4 Nations unable to agree new arrangements for site level information</p> <p>Effect: Reputation damage to the UK</p>	Medium	3	4	12	NEW	JW	<p>RM1: Interim policy position agreed and published w/c 11/09/2016</p> <p>RM2: UK wide SSI workshop scheduled for 29/04/2016</p>	JW	30/09/16	4	HRA Approval	HRA Approval Programme Board/4 Nations policy group
HRA319	App54	Approval - Technical Assurances (Assessment)	07/05/2015	17/02/2016	<p>Risk: 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>Cause: Manager - Technical Assurance to go on maternity leave before full team is appointed or line manager is in post.</p> <p>Effect: 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>	medium	3	4	12	↕	JMe	<p>RM1: 0.2 wte secondment to manage pharmacy and radiation professional relationships in place until 30 September 2015. This role was undertaken by Claudio Melchiori, who is now a project board member.</p> <p>RM2: 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&D team to maximise alignment with other HRA Approval operational development.</p> <p>RM3: 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&D and Head of Assessment and Assurance.</p> <p>RM4: Project Lead for Amendments has been appointed and will ensure the Technical Assurances process is integrated into the amendments process.</p>	JMe	30/09/2016	8	HRA Approval	HRA Technical Assurances Project Board / Staffing Project Board / HRA Approval Programme Board
HRA324	App57	Approval - Change Management	21/07/2015	17/02/2016	<p>Risk: HRA Approval having a negative impact on performance / metric timelines.</p> <p>Cause: 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>Effect: 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>RM1: Communications.</p> <p>RM2: Stakeholder engagement.</p> <p>RM3: Change Leads communicating metrics concept since March 2015.</p> <p>RM4: HRA involved in working group to standardise and agree a new set of national performance metrics.</p>	Jme	31/10/2016	8	HRA Approval	Change Management Project Board / HRA Approval Programme Board

HRA219	App35	Approval - Programme Board	23/06/2014	17/02/2016	<p>Risk: Operational differences across the countries present navigational challenges. Agreement in place on a policy level.</p> <p>Cause: HRA Approval relates to England, however, researchers want - and the UK needs (including EU Clinical Trial Regulations - 2016/17) - UK-wide compatibility</p> <p>Effect: Reputational impact on HRA and UK more generally</p>	Medium	3	4	12	↓↓	JMe	<p>RM1: UK commitment to a UK policy framework with strong links across to colleagues in the DA</p> <p>RM2: Devolved Administration representation on the HRA Approval programme Board</p> <p>RM3: Active engagement with Devolved Administration operational leads and the 4 Nations group in decisions around HRA Approval rollout</p>	JW	31/07/2016	8	HRA Approval	4 nations/ HRA Approval Programme Board
HRA344	App61	Approval - Change Management	02/09/2015	17/02/2016	<p>Risk: Due to local politics and specific individuals some NIHR LCRN staff unclear about the decision of new roles and responsibilities associated with NIHR CRN Study Support Service and alignment with HRA Approval.</p> <p>Cause: Lack of understanding about R&D and NIHR CRN Study Support Service interface for study delivery and alignment with HRA Approval.</p> <p>Effect: Confusion and duplication of activities around local study setup and delivery.</p>	Imminent	3	4	12	↓↓	Jme	<p>RM1: HRA Approval case studies to be made available to organisations.</p> <p>RM2: Ongoing meetings / discussions between Change Leads and local R&D staff.</p> <p>RM3: Closer NIHR CRN interface relating to HRA Approval and NIHR CRN Study Support Service process development</p> <p>RM4: HRA Change Leads, Study Support Links, Research Champions and RM&G Leads liaising on a local level in order to manage individual interventions as required.</p> <p>RM5: NIHR CRN has appointed a HRA Approval Business Lead who will work alongside the HRA Change Leads.</p> <p>RM6: HRA Approval HealthCheck Part 2 to include the NIHR LCRNs.</p> <p>RM7: Direct interaction with any areas or organisations where concerns are raised.</p> <p>RM8: NIHR CRN have put in place LCRN HRA Approval Readiness framework that PCRNs report on a fortnightly basis to the NIHR CRN CC, to ensure appropriate oversight.</p>	Jme	31/07/16	6	HRA Approval	Change Management Project Board / HRA Approval Programme Board
HRA389	CAT24	CAG	03.02.15	17/02/2016	<p>Risk: HRA/CAG unable to effectively deliver CAG's advisory function on HSCIC dissemination</p> <p>Cause: HSCIC's CAG referral policy does not allow workload to be calculated</p> <p>Effect: Volume/nature of HSCIC 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 HSCIC (replacement of HRA348) 	Imminent	3	4	12	↔	JK	<p>RM1: Continue to work with HSCIC 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 HSCIC until its CAG referral policy is fit for purpose</p> <p>RM4: Flagging to DH sponsors</p>	ND	01/03/16	10	CAG Advisory role to HSCIC	CAG EMT DH sponsor
HRA436	CAT25	CAG	8.3.16	NEW	<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	NEW	JMe	<p>RM1: Facilitated session once Associate Director for OD returns</p> <p>RM2: Performance management to be undertaken</p> <p>RM3: Recruitment taking place</p>	ND	30/08/16	8		
HRA437	CAT26	CAG	8.3.16	NEW	<p>Risk: Unable to deliver CAG functions in a timely way</p> <p>Cause: Over reliance on long term members and training and development of new members delayed.</p> <p>Need to deliver actions arising from ISO9001 and internal DH audit.</p> <p>Effect: Not meeting KPIs, unable to meet workload, increase in complaints.</p>	Imminent	3	4	12	NEW	JMe	<p>RM1: Engagement with CAG members to assist with backlog of amendments.</p>	ND	30/08/16	8		

HRA468	IRAS 045	IRAS	Jan '16 IRAS board	NEW	<p>Risk - Operations requirements of/ to and technical aspects of IRAS may not be aligned</p> <p>Cause - Pace of change required over this year and requirement for series of linked /dependant conversations</p> <p>Effect - Issues arise between expectations of and delivery in IRAS</p>	Imminent	4	3	12	NEW	All IRAS Partners	RM 1 : Jan '16 Membership of IRAS iMB and IRAS Partners Board overlaps with Operations/ HRA Approval and Partners to facilitation linked communication flows.	All	Review May Board	4		
HRA282	CSMT022	COM	07/01/2015	17/02/2016	<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	3	4	12	↓↓	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 - Digital Programme Board (DPB) gives broader ownership of web and intranet nb currently suspended, but update programme continuing</p> <p>RM4 - programme of systematic review of web and intranet content guarantees review at least once a year by content owners</p>	KG	Ongoing	4	Operations team and all site users	CSMT sign-off; DPB's activities, programme structure and terms of reference