Risk Register:	Corporate Risk Register
Date updated:	For ARC and Board review Q1 2017/18

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
HRA553	App134	Approval - Programme	22/05/2017	**Risk:** Risk that people may misunderstand and misinterpret predicted end to end timelines for studies **Cause:**Cause end to end timelines include activity from both parties and are intended as predictions not targets **Effect**:reputational damage to HRA and UK health research of not achieving perceived target timelines	Imminent	4	4	16	Jme	**RM1:** communication, work with DH and CRN on review of current benchmarks, testing and iteration of new methodology	30/09/2017	JM	3	4	12	New	6	HRA Approval		26/07/2017
HRA559	FIN37	Finance	Jun-17	**Risk**: Longterm financial risk **Cause:** Spending review and current external environment **Effect:** Unable to deliver on strategic and statutory requirements	Long term	5	5	25	KW	**RM1:** Financial strategy and strategic plan will identify funding opportunities and efficiencies to address fiscal constraints **RM2:** SIP will identifiy opportunities for efficiencies and economies **RM3:** Continued to drive for economy, efficiency and effectiveness in all that we do	Dec-17	KW	3	4	12	New	12	Leadership team Board	Financial strategy Savings contingency plan	26/07/2017
HRA562	FIN38	Organisational capacity	26/07/2017	**Risk:** Scale, complexity and number of change programmes planned are not deliverable in the required timescales **Cause:** A number of strategically important change projects need to be implemented to meet external need however HRA does not have sufficient resources (people and financial) to deliver these quickly at this scale. **Effect:** HRA fails to meet research sector requirements which are developing at pace but remain uncertain	imminent	4	4	16	KW	**RM1:**. Business cases have been submitted to DH to seek funding for SIP and Executive Restructure **RM2:** PA Consulting have been appointed to review research systems supplementing our own resources. **RM3:** Funds have been released from BAU £100k to focus on SIP – however reduced level will impact on our speed of delivery and do not include costs for research systems improvements.	RM1: March 17 RM2: July 17 RM3: March 2017	1. KW 2. TA 3. KW	3	4	12	NEW	8	Leadership Team		26/07/2017
HRA548	SIP10	Service Improvement	19/04/2017	**Risk:** UK wide compatability adversly affected **Cause:** Unable to reach agreement regarding SIP proposals which impact on UK wide working **Effect:** UK wide relationships damaged and unable to deliver cross country compatability	Medium-term	4	4	16	TA	RM1: Strong relationships in place RM2: UK wide compatability programme to improve cross border working and agree proposals RM3: MC appointed to UK wide post to facilitate improvements and compatability across the DAs RM4: Additional 4 Nations meeting held to discuss SIP proposals RM5: SIP PID shared with DAs 01/08 4 Nations meeting	May-17	1. SMG 2. MC 3. MC 4. ST 5.IC	3	4	12	⇊	8	SIP / UKECA		26/07/2017

HRA508	App121	Approval - Programme/Projects Assurance	01/09/2016	**Risk:** External stakeholders perceive different HRA functions (Assessment/REC/CAT) to be disjointed. **Cause:** Siloed communication to applicants caused by timing differences in process delivery **Effect**: Reputational risk for HRA	Imminent	4	4	16	Jme	**RM1:** Service improvement work to be undertaken so that there is more efficiency within process to support joined up delivery **RM2:** Clear written processes **RM3**: Empowerment of staff to liaise on an operational level effectively **RM4**: Clear communication to staff about communication pathways **RM5:** re-visit interactions with RES colleagues to ensure opportunties for joined up comms are maximised (e.g. REC opinion communication linked to HRA Approval outcome) **RM6:** SIP underway (noted at LT19/04). **RM7:** Interim work in more joined up validation	30/06/2017	Jme	3	4	12	⇆	6	HRA Approval/RES/CAT		26/07/2017
HRA521	RSB003	Systems	15/12/2016	**Risk:** Lack of clarity on what needs to be done on IRAS and HARP to align with implementation of EU Clinical Trials Portal and Database in time to meet the EU implementation timetable **Cause:** Capacity for HARP and IRAS development, BA resource and testing is insufficient to deliver the process changes users require. **Effect:** Failure to schedule required HARP and IRAS work within required timsecales	Imminent	5	4	20	GCP	**RM1** : UK wide EU Clinical Trials Team **RM2** :Any scheduling clashes are brought to management attention for decision. **RM3:** Discussions for Brexit are ongoing. **RM4:**interaction with MHRA and the design of MHRA system. **RM5:** Early warning on development from EMA. **RM6:** Reviewing our BA test resource and ensuring capacity for eventualities	RM1: Oct-17 RM2: Oct -17 RM3: Oct-17 RM4: Oct-17 RM5: Oct-17 RM6: July-17		4	4	16	⇆	4	UK wide EU clinical trials team RSB		26/07/2017
HRA522	RSB004	Systems	15/12/2016	**Risk:**: Operational process changes for Service Improvement work and supporting IT changes do not align as quickly as users need. **Cause:** Capacity for HARP and IRAS development, BA resource and testing is insufficient to deliver the process changes users require **Effect:** : Frustration across HRA about the speed of development and the gap between specification and IT delivery is perceived as delaying operational development	Imminent	5	4	16	JM	**RM1** :: Joint planning between SI programme lead and RS team ~~**RM2:** March 2017 planning meeting with BGO~~ **RM3:** Any scheduling clashes are brought to management attention for decision. ~~**RM4:**Add Placeholder for EDP for service improvement work~~ **RM5:** Review our BA Test resource and ensuring capacity for eventualities	RM1: July-17 RM2: Closed RM3: July-17 RM4; Closed RM5: July-17		4	4	16	⇆	6	RSB		26/07/2017
HRA500	APP117	Approval - Projects/Assessments	08/08/2016	**Risk:** Applicants and NHS not following the HRA Approval process **Cause:** Lack of understanding about both the high level process and the detail **Effect**: Confusion across stakeholder community leads to delayed research with negative impact on HRA	Imminent	5	3	15	Jme	**RM1:** Review of website **RM2:** Clear communication of high level messaged with link to details **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. **RM4:** Regular workshop with commercial sponsors to ensure full understanding of operational processes. **RM5**: Mirror commercial workshops in academic environment to ensure broader understanding of HRA process. **RM6 –** Assessment team increasingly managing to follow the process we have set out for applications will make it easier for applicants to see how the process works	01/04/2017	Jme	4	3	12	⇆	6	Approval Projects Group/ HRA Assessment Group		26/07/2017

HRA288	EMT2 (now moved to Policy)	Social Care	04.02.2015	**Risk:** Unknowns around scope and expectations for extended remit to Social Care and uncertainty of funding to deliver. **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	TA	**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 with agreement of funding for 2016-2017. **RM4:** Awaiting report from open University. Researchers requested further deep dive on what to be considered social care with report delayed and likely to be available in Summer.	01/08/17	AH	4	4	16	↑↑	10	LT		26/07/2017
HRA004	**IMG 9** (HRA004) **formerly IMG**		03/05/2013	**Risk:** HRA unable to deliver to the level of expectation of stakeholders within its role to promote transparency in research **Cause:** Timescales of moving forward with stakeholders, interdependency of work streams, capacity and environment appetite for change whilst not disadvantaging UK. In addition risk of not implementing the new EU Clinical Trial Regs as a result of Brexit and not having access to the EU portal or the EMA will result in loss of transparency of CTIMPs. Currently investigators are obliged to send summaries of results to EMA and there will be a more formal process for sharing both technical and lay summaries of CTIMP results with new EU CT Regs. Transparency of CTIMPs is of the highest priority due to the demand for systematic review and meta-analysis. **Effect:** Reputation of HRA damaged	Medium	4	4	16	BD	RM1: Extensive engagement and position statement prepared in collaboration with stakeholders RM2: Easter 2014 - document re REC declaration and reporting/publication expectations issued for comment. Timeframe for feedback extended to 28 July '14. September workshop planned RM3: Aug '14 Positive feedback received on call for comments re proposals for REC Declaration -Workshop planned for Sep RM4: Sep '14 Sponsor DEC updated, further changes having been notified to research community for April '15, via HRA latest (Nov '14) & HRA/ IRAS websites RM5: Feb '15 Transparency workshop held- working with stakeholders to consider further registration of research, other than Clinical Trials and reporting / publication RM6: July '15 - Review and action to follow noting Judicial Review outcome. RM7: Aug '15 - Transparency policy remains unchanged. Information cascaded via website RM8: Oct '15 - New format Transparency Forum held Sep'15, active engagement from stakeholders RM9: Jan'16 - Consideration in respect of publication/ reporting evaluation - wider than peer reviewed publications RM10: April'16 - Article developed in anticipation of request for publication, further active auditing of requirements planned RM11: July '16 Partner Forum meeting to update on developments and workstreams being undertaken RM12- Oct'17 - EQUATOR undertaking two project for HRA to develop proportional transparency RM13- Jan '17 - EQUATOR project re reporting / publication reporting recommendations to HRA by March '17 RM14 – 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.	July	BD	4	4	16	↑↑	6	Preparing paper on reporting (publishing) and REC declaration in order to move forward with stakeholders to increase transparency whilst ensuring confidence		26/07/2017