**HRA Corporate Risk Register Overview – Quarter 3 2017/18**

**Impact**

**5**

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| **Key:****SIP risk** **Finance risk** **Social Care risk** **Systems risk** **Reputational risk** **Operational risk** **Risk increased since last quarter** **Risk decreased since last quarter** **HRA Controlled Risk****Risk Partially Controlled****Externally Controlled Risk****HRA Approval risk**  |

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| **HRA Approval****508.** Researchers perceive different HRA functions to be disjointed**553.** Stakeholders misunderstand / misinterpret predicted end to end timelines for studies   | **Social Care 288:** Unknown scope and expectations **Transparency / reputation****004.** HRA unable to deliver level of expectation within its role to promote transparency  |  |
|  | **HRA Approval****568.** Sponsors do not follow process for ’35 day no objection’ for amendment **Finance****559.** Long term financial risk  |  |

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| **Removed risks:****Systems risk** **522.** Operational process changes and IT Changes following SIP do not align as quick as required **HRA Approval****563.** Sponsors do not follow process and guidance around working with sites **Finance** **562.** Unable to deliver strategically important change projects due to insufficient resources  |
| **Closed risks:****Systems risk****521.** Lack of clarity re IRAS and HARP developments to align with EU Clinical Trial Portal in time  |

**Likelihood**

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**3**

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**3**

**Likelihood**

**5**

**4**

**Trend analysis**

* A total of six risks have been escalated to the corporate risk register for quarter 3.
* Three risks have been removed and one risk has closed. The closed risk (521) relates to a lack of clarity of what needs to be done on IRAS and HARP to align with the implementation of the EU Clinical Trials Portal and Database with considerable work done in this area to be prepared for the implementation.
* Of the removed risks:
	+ 562 relates to the HRA unable to deliver strategically important projects due to insufficient resources with the business case for the research systems now approved. A related risk with regard to meeting the MHRA timeline has been added.
	+ 563 relates to sponsors not following process and guidance regarding working with sites has been reduced as further work to improve communications and understanding has been completed.
	+ 522 relates to operational and IT process changes as a result of SIP not aligning as quickly as required however work to review necessary resources and ensure capacity for eventualities has bene completed with the risk reduced in score.
* The risk related to unknowns with regard to social care (288) has reduced following the ARC deep dive and subsequent escalation to Board. A number of meetings have taken place to understand the scope better with a Board seminar planned to understand the issues further.
* Risk 559 relating to long term financial risk has also reduced with the research systems business case receiving support and the business plan for 2018/19 and associated budget drafted and in line with anticipated expenditure.