**HRA Corporate Risk Register Overview – Quarter 1 2018/19**

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**Impact**

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| **Key:****GDPR risk** **UK wide compatibility risk** **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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| **Transparency / reputation - 004.** HRA unable to deliver level of expectation within role to promote transparency **UK wide compatibility 626.** Political pressure and Brexit adversely affecting delivery of key programmes of work and cross border compatibility **GDPR - 627.** Delivering guidance, training and responding to queries taking up resource **Systems risk - 588**. IRAS replacement not delivered on time due to lack of capacity within RS team  | **HRA Approval - 608.** Delay in research starting at participating NHS organisations due to sites refusing to receive local info packs   |  |
|  | **SIP - 537.** Insufficient people resource to deliver SIP**HRA Approval 568.** Sponsors do not follow process for ’35 day no objection’ for amendment **Social Care 288:** Unknown scope and expectations  |  |

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| **De-escalated risks:****HRA Approval****553.** Stakeholders misunderstand / misinterpret predicted end to end timelines. **614.** Insufficient number of applications received into clinical trials pilot to test process   |
| **Closed risks:****GDPR - 628.** Guidance to research community inaccurate or misunderstood **Systems risk - 590.** IRAS replacement not delivered on time as no supplier meets necessary delivery criteria  |

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**Likelihood**

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**Likelihood**

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**Trend analysis**

* A total of eight risks are included on the corporate risk register for quarter 1.
* Two risks have closed and two de-escalated from the register. No new risks have been escalated to the corporate risk register this quarter.
* Of the two closed risks:
* 628 relating to GDPR guidance being inaccurate or misunderstood – this risk has occurred and is now an issue. Whilst our guidance on GDPR is compliant with the ICO requirements a number of commercial sponsors, whose headquarters are based elsewhere in Europe, are making different interpretations of GDPR and are therefore not complying with our guidance. We are therefore now in a position where approvals could be delayed. In relation to ongoing studies, for most sponsors this is not yet an issue as they are continuing as they have been, but one sponsor is stopping recruitment. Members of Janet team are working hard to resolve the issue with the ICO and their international experts.
* 590 relating to no IRAS supplier being identified as unable to meet delivery criteria – this risk has closed as the procurement process has successfully taken place with the chosen supplier Pega now on board.
* The two removed risks relate to HRA approval with the risks having decreased sufficiently to no longer warrant escalation.
* One risk has increased in score to 16 – 608. This risk relates to sites refusing to receive local info packs resulting in delays to research starting. This has increased as a result of the recent communications from the Central Commissioning Facility in relation to the removal of the 70 day benchmark for performance in initiating clinical trials not being understood which is taking time to resolve.