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| **Agenda item:** | **12** |
| **Attachment:** | **F** |

**HRA BOARD COVER SHEET**

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| **Date of Meeting:** | 18 October 2017 |

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| **Title of Paper:** | HRA Endorsement of registries in England and associated principles  Plus Terms of Reference for the panel |
| **Purpose of Paper:** | To propose the establishment of a new panel to give HRA endorsement to databases/registries set up to recruit people into research under a ‘consent for consent’ or ‘consent to be approached ‘ model and to set out accompanying principles for the panel. The paper has been revised following comments from NREAP. |
| **Reason for Submission:** | The Board reviewed the proposal at the July Board meeting and requested further detail in relation to Terms of Reference and recommended input from the NREAP.  Board approval to move forwards with this approach is now sought following input from NREAP with ToR and further details attached. |
| **Details:** | We have a number of organisations that are seeking HRA approval or endorsement of their approach to recruiting patients into trials. These are usually Trust based or disease based recruitment registries like that set up under Joint Dementia Research (JDR) and we have learnt a lot form the good practice undertaken in some established registries such JDR. These are usually known as ‘consent for consent’ consent to be approached’ models.  The proposal is that if we can give HRA endorsement to a particular recruitment model, then RECs will not need to review the recruitment aspects of individual study applications, every time. This would remove unnecessary duplication and comment from the system. Establishing a panel will allow us to take a consistent approach to reviewing these models. This is supported by UKECA and we have agreed mutual recognition across the UK for this process. In addition the UK Clinical Trials Gateway (UKCTG) will be coming to us for formal endorsement of their model later this year.  We have been working on this concept for over two years now and have had a lot of input from a variety of stakeholders including researchers, existing registries, REC members, the general public and NREAP, together with legal advice. Comments received from NREAP were overwhelmingly positive.  We have a backlog of registries who would like to seek endorsement and we are working closely with the Ops team to operationalise this. The Ops team are currently developing their approach to operationalise this process.  The Policy team are currently drafting some guidance to support researchers, registries and others on good practice in seeking consent to be approached. |
| **Time required for item:** | **15 mins** |

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| **Recommendation / Proposed Actions:** | **To Approve** | |  |
| **To Note** | |  |
| **For Discussion** | | **x** |
| **Comments** |  | |

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| **Name:** | Amanda Hunn |
| **Job Title:** | Joint Head of Policy |
| **Date:** | 11.10.17 |