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| **Agenda item:** |  **9** |
| **Attachment:** | **C**  |

**HRA BOARD COVER SHEET**

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| **Date of Meeting:** | 26 March 2014 |

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| **Title of Paper:** | Update on the Transparency agenda, as at March 2014 |
| **Purpose of Paper:** | To provide a summary update on the Transparency agenda at Q4 2013/’14 |
| **Reason for Submission:** | To seek that the HRA Board note and confirm developments, next steps proposed and positioning of Transparency with wider stakeholders. |
| **Details:** | Paper below  |
| **Suitable for wider circulation?** | Yes, following submission to Board |

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| **Recommendation / Proposed Actions:** | **To Approve** | No |
| **To Note** | Yes |
| **Comments** | Board is asked to note the progress to date and the direction for development |

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| **Name:** | Janet Wisely |
| **Job Title:** | Chief Executive |
| **Date:** | 17/03/2014 |

**Transparency**

**Introduction**

EMT and the HRA Board will be familiar with our Transparency programme and the work undertaken to date in working with key partners in order to drive our ambition of making the UK a great and safe place to undertake research.

The HRA set out plans in the document published in May 2013 ‘The HRA interest in good research conduct’. <http://www.hra.nhs.uk/documents/2013/08/transparent-research-report.pdf>

We have also fully participated in the parliamentary sub-committee looking at transparency within Clinical Trials. Our plans and proposals are compatible with the recommendations of the House of Commons Science and Technology Committee report into Clinical Trials. <http://www.hra.nhs.uk/blog/news/2013/09/16/hra-responds-to-house-of-commons-science-and-technology-committee-report-into-clinical-trials/>

**Summary of developments**

Within Transparency, as an organisation, the HRA’s leadership roles are particularly in the registration of studies and the publication of results.

From 30 September 2013, we have required as a condition of the favourable ethics committee approval that clinical trials be registered on a publically accessible register.

We recognise that other studies should be registered but these need individual consideration, the first step has been to make a simple condition that clinical trials as defined by the first 4 categories of IRAS must be registered within 6 weeks of first participant recruitment in the UK. In recognition of the need to ensure transparency as well as maintaining UK competitiveness applicants may request to defer registration and the HRA is maintaining a register of these requests. This means the HRA will know that studies are registered, or that a request has been made to defer registration and be in a position to potentially expose the poor practice of failing to register.

We are taking a lead role in publication; what this means and what is effective for different audiences; those who have taken part in research, patients and the public, researchers, clinicians and commissioners of health care. We have a stakeholder workshop later this month to understand what we collectively understand by the term publication and to move to establish standards we can then monitor against; this will help us develop plans which are actionable. We are developing mechanisms for monitoring compliance so we can gather evidence of compliance and build confidence in clinical research in the UK.

The HRA has signed up to Alltrials, and have proactively gained significant positive coverage in specialist media (and Twitter) around our Transparency agenda. We have also fully participated in the Parliamentary sub-committee looking at transparency as part of the Clinical Trials remit. Our plans and proposals are compatible with the recommendations of the House of Commons Science and Technology Committee

It is recognised that the HRA cannot alone make all the advances required and as such, where appropriate we have been working with others where they lead, for example with ABPI on their work on Transparency within historical clinical trials and the Institute of Medicine and (most notably) the Wellcome Trust for Responsible Clinical Trial data sharing and with the MRC in connection with proposals for a research tissue registry, which could in due course potentially be a condition of a favourable ethical opinion.

**Clinical Trial Registration**

The Board will be aware that the HRA received very strong support from Sense about Science, Ben Goldacre, Sir Iain Chalmers and indeed wider specialist media in connection with this key initiative that for all REC approvals of clinical trials from September 2013, failure to register will be a breach of the REC opinion.

There was, it is acknowledged a small amount of concern that the UK lead would result in a lack of competitiveness although once fully understood the pragmatic approach to request a simple deferral has meant good ‘buy-in’ including from the HRA Phase 1 working group. As at 24 February 2014, the HRA has only received 14 requests to defer registration, all of which have been for Phase 1 Healthy Volunteer studies and agreed to, these requests being internally reviewed, monthly. For one study the issue has been in respect to an existing contract with another party stating non-registration until Phase 2, for all other requests the reasoning has been commercial sensitivity. It is worth reiterating that the deferral is only for a defined period of time, until the study moves to Phase 2 or with immediate effect should the study be terminated early due to safety concerns. The new EU regulation expected to come into force in 2016 will not allow a delay or exception for Phase 1 Healthy Volunteer studies. Identifying practical constraints now will ensure UK competitiveness when these come into force.

The next step of this work will be to bring medical device clinical investigations into a similar timeframe for registration. Timeframes for registration of such studies are set out in the Model Clinical Investigation Agreement (mCIA) for medical technology sponsored research in NHS Trusts and the HRA were keen to work with relevant stakeholders to agree appropriate timeframes for registration. The timelines in the agreement were shorter than that set out by HRA, but any decision to not register for reasons set out in the agreement was an internal consideration. This initiative was supported by the medical technology companies involved and agreement was reached for registration of medical device clinical investigations to be in line with other clinical trials. As with Phase I clinical trials, requests to defer registration will be considered on a case by case basis. The expectation is that the revised mCIA and registration being a condition of the favourable ethical opinion for medical device clinical investigations will be implemented in April 2014.

Ahead of the EU Clinical Trials regulation, for which we anticipate implementation being in 2016, the HRA is openly seeking feedback on the barriers experienced since September 2013 in registering clinical trials. Feedback from the February 2014 Phase 1 meeting, noted that commercial sensitivity and Intellectual Property concerns as the most concerning to researchers however this feedback will be further added to via a request in HRA Latest to the wider research community, with feedback anticipated around the end of May 2014.

Moving forward, the HRA can then look to engage with trial registries on the basis of actual experiences and issues encountered by researchers in order to further transparency and openness whilst not seeking to add to the burden for researchers and sponsors.

It is also envisaged that after September 2014, one year on from the requirement to register all new clinical trials, that the HRA will undertake an audit against compliance.

The HRA is keen to explore the opportunities to link trial registration to IRAS, so information can be transferred through from IRAS, to the clinical trial registries. Most information for registration is already on IRAS however work is needed to agreed standard fields across registries to enable this to happen and to reduce the practical burden of registration on researchers.

**Publication**

The HRA has publically stated our commitment to develop what we mean and understand by publication. To this end a group of key stakeholders have been invited to comment upon a draft paper (previously shared with EMT and the Board) building upon preceding work. This worksteam will be refined and consolidated ahead of a planned workshop on 20 March 2014, before a paper is issued for wide consultation.

It is hoped that from this work, we can as a research community have a more specific definition of what we mean by publication, in an increasingly digital age and the timeframes from which we should look to see publications made.

The HRA has in conjunction with the University of Portsmouth been undertaking an audit of publications resulting from REC approvals from Southampton A REC. This audit specifically relates to research that completed between Jan 2010 – Dec 2011. We are expecting the final audit report around September this year at which point, we naturally will seek to disseminate findings.

The interim report should be available internally in March 2014 and will be made available to the Board.

**REC declaration requirements**

The HRA has become aware that in some areas incorrect assumptions are being made about the REC declaration requirements following on from the requirement to register all clinical trials. Therefore this will also be considered during the March workshop and in parallel with our publication standards work area. Once again, an early draft has been shared with the Board.

**Summary / conclusions**

The Board are asked to;

* Note the developments HRA have taken over the last 12 months
* Support the direction in working with key stakeholders where they are the leading partners
* Endorse the approach to working with Trial registries in reducing the burden on researchers with respect to the REC requirement for registration of clinical trials ahead of the EU Clinical Trials directive
* Endorse the approach taken to developing what we mean by publication and developing the REC declaration requirements.

**Janet Wisely and Tom Smith**

**17 March 2014**