NHS
Research and Development Forum

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To whom it may concern,

Re: HSCIC Records Management Code of Practice Consultation
http://systems.hscic.gov.uk/infogov/iga/consultations/codeofpractice.docm

Please find below a response to the above HSCIC call for consultation, on behalf of the NHS R&D Forum working groups. The Forum is a professional network for people working in the management and leadership of Health and Care research, and is a not-for-profit organisation. Due to time constraints very few members of the Forum have fed into this response however we should like to emphasize the willingness of our working groups to support any further work in relation to research.

Forum Response

- The code is clear from a general records perspective but makes little reference to research throughout. This may be purposeful but we believe it would be beneficial to explain further how records inform research and that in addition, records are also generated by research. We are therefore very keen that the link to research practice is clearly made in this document to ensure there is a wider understanding across the health and care community of the requirements for good research practice in relation to records.

- A distinction may be drawn between health and care records used to generate data for research, and research-generated records. It is not quite clear from the document how each of these will be handled in the code and we believe the code in its current draft does not quite completely serve either. In addition the document touches on records used to inform the decisions of, for example, research ethics committees but also in the management of research. These can be varied and differ for Sponsors and host organisations so these distinctions may need to be considered further if they are to remain included in the scope.

- The management, storage, archiving and destruction of records used for research must be in compliance with all UK regulations (including the Data Protection Act, UK Clinical Trials Regulations where applicable, Human Tissue Act and Information Governance Standards). This is described in the code, however they should also be in line with accepted principles of good research practice (for example, there are codes of practice for recording and

amending information in the records; identifying research participants; that the Sponsor should sanction destruction of a record wherever possible; treatment of essential documents and records for retention; periods for storage and then archiving; good data management practice and verification of data etc).

- We believe that the section on 'research involving clinical data but not a clinical trial' is confusing and not quite accurate (for example, it appears to make reference to the new clinical trials regulation requirements and Trial Master Files.) The section on Clinical Trials of Investigational Medicinal Products (CTIMPS) should also be looked at further for accuracy.

- With regards to records used and generated in support of CTIMPS the Forum strongly advises close collaboration with the **MHRA** to ensure all references are compliant with current and future anticipated regulation. Reference might also be made to their recently published position statement on Electronic Health Records. All electronic media (for example scans etc) should be considered in the document.

- In summary whilst the Forum welcomes the development of an improved code of practice we believe there are further decisions to be made with regards to the inclusion of research and the guidance related to it. The HSCIC may decide it best to treat all records in this document the same, without any specific reference to research, making clear that any use for research purposes should be made in line with standards of good practice and UK regulations, however this would seem to be a missed opportunity to join things all up together.

We hope that you find this brief response helpful but please do not hesitate to get in touch should you wish to discuss this response further. The Forum working groups would be pleased to feed in to any work to produce subsequent drafts.

With kinds regards

NHS R&D Forum Working Groups