**Minutes Quality Assurance Committee, September 2022**

Present: Laure Wynants, David Shaw, Mark Spigt, Bart Penders, Gerard van Breukelen, Carmen Dirksen

**1. Minutes**

The previous meeting’s minutes were accepted, with DS noting that the action on non-WMO statements had not been implemented (see below).

GB suggested that all members (rather than only the Quality Officer and Chair) should approve the minutes before they are posted on the website. This was agreed.

*Action: All minutes to be circulated to QAC for corrections before publication.*

**2. Committee** **Procedures and Membership**

LW informed the committee that Sandra Zwakhalen has agreed to a new term on the committee.

DS presented the draft committee operating procedures, and following discussion (notes below) several points were added.

GB said perhaps desirable if each department has representation.

CD said it may not be necessary to have reps from all departments.

CD asked about official support for committee and DS said we should get procedures approved by School Council.

LW asked about how to recruit new members. DS said we could advertise once a year, CD said that we might get too many members then.
GB said open advert isn’t so important, it’s about filling expertise.

DS said we could ask CAPHRI PhD reps to ask someone to do it.

*Action: DS to send procedures to Director for approval at School Council and ask PhD reps to identify potential student to join QAC.*

**3. Data management support services**

DS presented the table completed by staff of CTCM, MEMIC and Datahub.

CD said the table does not represent the different services provided by MEMIC and CTCM in a way that is understandable for researchers.

GB said KEMTA and statistical support were missing, and data analysis should maybe be there as well.

DS said all this indicates it will be difficult to design any type of simple guide for researchers. It might be better to have simple sentences as a guide to researchers. MS said that a qualitative approach based on discussion would be more informative.

MS said Datahub and MEMIC attended school council and supported finding a data steward within each department. DS said that is a good idea.

MS added that the person could also be a departmental QA support.

DS added that data stewards often don’t give advice on data protection.

BP said data stewards often won’t be allowed to give legal advice.

CD said data stewards should know privacy guidance etc.

DS said that stewards should ideally be able to at least point researchers towards a specific DPO.

DS said that smaller departments might find it harder to find someone able/willing to be a data steward.

BP said that it might be beneficial for other departments.

*Action: DS to talk to providers and develop simple descriptions/narratives to aid researchers.*

**4. Research Quality manual**

Laure described the background: CTCM is helping several departments who do research in MUMC to develop a research quality manual. This is a requirement of the Board of Directors.

DS described how departments are developing this themselves, with support from CTCM.

CD elaborated that the manual project arose because of Inspectorate recommendations. Primary scope is WMO but many procedures/topics apply to nWMO as well.

All the departments that agree will share their manual on the Quality System Research page (https://qsmumc.ctcm.nl/).

DS asked if METC is involved in setting up the quality manual as important to keep REC guidance clear.

MS said the Dept. of Family Medicine manual was developed using the CAPHRI QM guidance.

LW asked whether DS should provide support to those developing manuals.

MS suggested that QAC and Officer are already providing input via QA pages.

BP said HES hasn’t been invited to produce a manual.

*Action: DS to liaise with Annika and check that departments are aware of existing CAPHRI guidance.*

**5. Brief updates**

Outreach: DS gave second CAPHRI webinar in the spring, and was about to give another for internal and external PhD students within Family Medicine. Departments contacted regarding quality presentations: in September DS will present to HES October he will give a presentation on RQ at the HISP research meeting. DS will ask previously audited researcher to talk about experiences for CAPHRI researcher.

Audit: Another eight audits performed so far this year. Some researchers still slow to respond to invitation.

Common audit issues: DS said the three most common issues were optimal duration of data storage, use of Surfdrive (cloud storage) without justification, and researchers thinking that a non-WMO statement is an ethics approval.

With regard to Surfdrive, MS said that one reason for this is it’s apparently challenging for IT services to create folders on secure servers for some people so it’s pragmatic to use Surfdrive instead. BP remarked that Surfdrive was still accessible during the UM hack as a reason to use it, in an appeal to feasibility/risk avoidance.

DS said that may be reasonable in certain circumstances but not ideal in terms of data protection policy.

GB pointed out that it may depend on the type of data, whether it’s anonymised or not.

CD said MEMIC could offer help with this issue.

**6. Non-WMO statements and ethics review.**

DS described discussion with outgoing Chair of FHML-REC. It might not be best practice to recommend not applying to METC for a non-WMO statement as some researchers may want it for legal security, and indeed others are obliged to apply for one if doing non-WMO research with MUMC patients.

CD said that a non-WMO statement is indeed not the same as an ethics approval, but any recommendations regarding this should be institution-wide, not solely CAPHRI.

MS said legally you don’t need FHML REC approval.

DS said that’s true. However, UM requires ethics review for all studies in FHML. (UM website states: “All research involving human participants or personal data conducted in FHML/ Maastricht UMC+ should be submitted for ethics review” and a non-WMO declaration is not ethics review.)

CD also highlighted the Executive board requirements regarding BoD approval before starting a study..

*Action: DS to continue conversations and ensure that any statements on CAPHRI RQ page are harmonised with FHML, MUMC and UM requirements.*

**7. Other business**

MS raised issue of support for external PhD students.

DS said he’ll raise issue when asked to do departmental or other presentations.

MS suggested webinar specifically for external students might be a good idea.

BP raised issue of law enforcement seeking access to data; legal advice is that the data is just handed over. This happens regularly in law faculty empirical research.

BP suggested we might mention on website that there are situations where guidance does not apply; DS said it would probably be better not to do so as such cases are rare, can be dealt with by REC, and researchers might seek exceptions to rules where they are not justified.

Action: *DS to ask PhD representatives about webinar for external students.*