The Association of Stoma Care Nurses UK

Dear Members

**Request for Stoma Nurses to join the MHRA Register of Experts**

I am contacting you to ascertain whether you may be interested in becoming an expert assessor for the UK Competent Authority for medical devices (MHRA) with respect to undertaking assessment of applications for clinical investigations of new or modified medical devices. We also utilise our external experts for specific ‘ad hoc’ advice from time to time. If you agree to become an expert assessor, you will only be asked to assess applications with regards to your specific speciality and this may take the form of a technical or clinical assessment.

I have set out below some information relating to the process for reviewing clinical trial applications and I have attached a document with more information

1.Once we receive a clinical investigation application that requires assessment relating to your specialty, we will email or telephone you to seek confirmation of your availability to assess the application within a specified deadline (normally 14 days). Please note the MHRA must make a final decision on the application within 60 calendar days (this is a statutory deadline that we are legally required to meet) therefore we ask that you advise us immediately whether you will have any difficulty in meeting the deadline given to you.

Prior to you accepting a submission we will also need to know whether there are any potential conflicts of interest. It is very important that you let us know before accepting to review the application if there will be any conflicts of interest if you do so.

Possible conflicts of Interest include you having been previously employed by the manufacturer responsible for the application, having personal ties with the principal clinicians or the manufacturer involved with the proposed study, you working within close proximity to/within the proposed clinical investigation study site etc. (please note this is not an exhaustive list).

2. Once you have accepted our request, we will send all relevant documents electronically.

3. We will advise you of the timelines for you to provide additional questions to put to the manufacturer, or for providing your final report (usually within 14 days),If for any reason you are unable to meet the deadlines please contact the assigned MHRA regulatory specialist immediately.

3a. Please note if you have questions for the manufacturer these must be channelled through the MHRA. No manufacturers should be contacted directly via an expert assessor. We will in turn obtain the answers to your questions and relay the response so that you are able to either provide us with further questions or complete your final report.

4. You will be paid £800 per application assessed. We will provide you with information on the accepted format for submitting an invoice once you have completed your final assessment of the application. Note – there is no fee payable for any ‘ad hoc’ advice.

4a. Please note we will process the payment of your fee once the MHRA has made a final decision on the clinical investigation application.

Our guidance document (attached) provides some background regarding clinical assessments and the process. However, if you any questions, please contact us so we may assist you in understanding the task/role of being an expert assessor for the Medicines and Healthcare products Regulatory Agency (MHRA).

**MHRA process**

For any trial application it must be validated by MHRA to ensure we have all the information we need to conduct an assessment. Under the current EU regulation, we have 60 working days to give a final decision (approve or reject).

As part of our review process we share the application and have clinical and tech input along with stats, biocompatibility etc as and when required. The application is assigned a ‘handler’ who manages all the paperwork etc and is the liaison for the expert reviewer. The handler will supply all the necessary documents along with an overview.

Following the initial review, the expert can ask questions of the sponsor and these questions are submitted back to MHRA for us to submit to the sponsor, there is no direct communication between the assessor and the sponsor. Once the expert is satisfied or otherwise, we conclude our reviews and provide a final decision to the applicant. If we have grounds for objection, we inform the sponsor to afford them sufficient time before the deadline time to remedy any issues before a formal objection. Once you have completed your review, we ask for a report (we provide the template) from you and you will be paid a fee of £800 for this report.

**If you are interested in joining the register, please complete the relevant forms that have been provided to the Association and return directly to me for processing**

Yours sincerely

Mark Grumbridge

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Clinical Governance and Audit Lead

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MHRA

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Please note – I do not work on a Monday

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