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DRAFT STATUTORY INSTRUMENTS

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**2021 No.**

The Medical Devices (Northern  
Ireland Protocol) Regulations 2021

PART 3

Clinical investigations under Regulation (EU) 2017/745

**Ethical review of clinical investigations**

**11.**—(1) A sponsor proposing to conduct a clinical investigation of a device in Northern Ireland must apply to an ethics committee for an ethical review of the proposed clinical investigation.

(2) The sponsor must submit to the Secretary of State a copy of the opinion of the ethics committee as soon as it becomes available and before the clinical investigation is started.