1. INTRODUCTION

1.1. A fee is applied to all device studies (device-supporting and device-centred) requiring Clinical Physics support. The fees are determined using the NIHR set-up fees and industry costing template.

1.2. Currently, Clinical Physics activities are performed at the set-up stage of a project and involve a combination of governance activities (performed by the Clinical Physics governance section) and equipment checks i.e. visual checks, function and electrical safety testing where applicable (performed by the clinical engineering section). Justifications for the fees are presented in Table 1.For studies where no equipment checks are required, only governance activities fees will be applied. In cases where more than 3 devices require testing and for device-centred studies requiring in-depth risk assessments, a different fee structure will be applied, depending on the study type. A breakdown of the various applicable fees by study type is presented in Table 2.

2. SCOPE

2.1. This procedure applies to all studies that require a Clinical Physics review.

3. DEFINITIONS

3.1. **CE-marked equipment** as defined in the EU Medical Device Regulations (MDR 2017/745):
'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation (MDR) and other applicable Union harmonisation legislation providing for its affixing;

3.2. **Clinical investigation** as defined in the EU Medical Device Regulations (MDR 2017/745):
'clinical investigation' means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device;

3.3. **EST:** Electrical Safety Testing

3.4. **MHRA:** Medicines and Healthcare products Regulatory Agency.

3.5. **MIA:** Master Indemnity Agreement (see https://www.gov.uk/government/publications/master-indemnity-agreement-mia).

3.6. **mCTA:** model clinical trial agreement.

4. RESPONSIBILITIES

4.1. Clinical Physics is responsible for identifying research studies that should be charged and informing the requester of the costs involved and where necessary, justifying the costs as detailed in Table 1.

5. PROCEDURE

Activity	Details
Standard Clinical physics equipment governance activities	**Review study documentation and feasibility** • Performed to determine study type and the intended use of the device which informs the checks to be carried out and whether Clinical Physics has the capacity and capability to undertake the work. • Reviewing the protocol also helps identify any additional devices that need to be assessed, which may not have been identified in initial discussions. **Indemnity cover:** • Majority of equipment provided for use in research is provided on a loan basis. For this reason, indemnity cover should be in place as the equipment is not owned by the Trust. This check involves ensuring adequate indemnity is place either through the Master Indemnity Agreement (MIA), mCTA or in-house agreements. **Checking maintenance and training requirements:** • Currently, Clinical Physics is unable to provide maintenance or training on research devices due to inadequate resources, however researchers can request for advice on this and Clinical Physics may be able to support certain studies, depending on capacity and capability. This check helps to clarify the level of support Clinical Physics can provide. **Additional activities:** • Supporting local review and approval processes • Communication with sponsor/study team • Attendance at relevant research meetings • Where necessary, development of documents, SOPs etc. • Report generation/admin - updating EDGE/local reports and general admin.
Clinical engineering equipment checks	Electrical safety test (EST), basic visual and functional check (where possible – depends on capacity and our capability and number of devices to be tested).Trust medical equipment policy states that all CE-marked equipment brought into the Trust for use on patients (regardless of clinical/research use) needs to be visually checked, followed by electrical safety testing. Where possible, function testing is also performed. The checks are either performed at the site-based workshops or engineers may travel to sites if requested.
Enhanced Clinical physics equipment governance activities (including testing)	Where requested, in-depth risk assessments and study reviews in addition to the above are performed for device-supporting studies of the following types: • Clinical investigation of a non-CE marked device (risk assessment & EST) • Pre-CE marking proof of concept device study (in-house or external). No commercialisation intent These fees are comparable to the fees the MHRA charges to review clinical investigations. See https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees.

Table 1: Justification of Clinical Physics Set-up fees

Study Type as defined by device use		Actual time taken to assess study and test up to 3 devices (hours)	Cost calculated using NIHR template	Added time for additional devices (per device)	Turnaround Time (working hours)[1]
Device supporting studies	CE-marked equipment purchased/already owned by the Trust, used within its intended purpose (research of standard of care).	N/A	N/A	N/A	N/A
	New CE-marked equipment provided on loan or free transfer for the purposes of: Research of standard of care or supporting a study.	6 hours	£495.00	½ hour (£41)	24 hours – for 1 device For > 1 device, Clinical Physics will advise accordingly
Device Centred studies	New CE-marked equipment provided on loan or free transfer for the purposes of: Device clinical evaluation studies	6 hours	£495.00	½ hour (£41)	24 hours – for 1 device For > 1 device, Clinical Physics will advise accordingly
	Clinical investigation of a non-CE marked device (document review only)[2]	4 hours	£330.00	N/A	24 hours
	Clinical investigation of a non-CE marked device (document review & electrical safety testing - on request only)	6 hours	£495.00	1 hour (£82)	24 hours – for 1 device For > 1 device, Clinical Physics will advise accordingly
	Pre-CE marking proof of concept device study (in-house or external). No commercialisation intended	48 hours	£4235.00	1 hour (£82)	72 hours for 1 device To advise if > 1 device

Table 2: Applicable fees by study type, best on NIHR industry costing template

Notes:

[1]Turnaround time is defined in terms of working hours, excluding weekends, over a two – three week period, depending on the number of devices that need to be assessed. Please note that Clinical Physics will always prioritise clinical workload over research.

[2]Clinical investigation assessments: Clinical Physics will only charge this if input is required, following a brief document review e.g. checking implementation of MHRA recommendations, electrical safety testing of supporting devices etc.