

1. INTRODUCTION

- 1.1. Currently, Clinical Physics activities are performed at the set-up stage of a project and involve a combination of:
 - Standard governance activities (performed by the Clinical Physics governance section).
 - Equipment testing i.e. visual checks, function and electrical safety testing where applicable (performed by the clinical engineering section).
 - Enhanced governance and equipment activities.
- 1.2. A fee is applied to all device studies (device-supporting and device-centred) requiring Clinical Physics support.
- 1.3. The fees are documented in the NIHR's Interactive Costing Tool (iCT), (see <https://www.nihr.ac.uk/how-interactive-costing-tool-ict-calculates-costs-studies-sites>) for the different types of activities that Clinical Physics performs.
- 1.4. Occasionally, studies may require additional support during the study e.g. equipment maintenance, replacement or disposal. A fee is applicable for these additional services, which is also documented in the iCT.
- 1.5. Justifications for the fees are presented in Table 1 with the applicable fees presented in Table 2. These are also available in the iCT.
- 1.6. For studies where Barts Health is the lead site, the fees as detailed in this document apply.
- 1.7. For studies that are not led by Barts Health i.e. where Barts Health is one of the sites, Clinical Physics must be informed if the sponsor/leading organisation makes any amendments to the tariffs.

2. SCOPE

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

3. DEFINITIONS

- 3.1. **CE/UKCA-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. **Model agreements:** signed agreement between Barts Health and the sponsor

4. RESPONSIBILITIES

4.1. JRMO and Clinical Physics are jointly responsible for identifying research studies that should be charged and informing the research team of the costs involved.

5. PROCEDURE

Activity	Details
(A) Standard equipment governance activities This work is typically carried out by a HCPC registered Clinical Scientist or a Clinical Engineering Governance and Quality Lead.	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 model agreements. Checking maintenance and training requirements: - Equipment maintenance requests are reviewed on a case-by-case-basis depending on availability of resources and standardisation of equipment. - 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. - An in-house training team is available to assist research teams with training advice and requests. However, as with maintenance, these will need to be reviewed on a case-by-case basis. 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.
(B) Clinical engineering	Trust medical equipment policy states that all CE/UKCA-marked equipment brought into the Trust for use on patients (regardless of clinical/research use)

equipment testing This work is typically carried out by Clinical engineering technicians within the workshop.	needs to be visually checked, followed by electrical safety testing (EST). • Function testing services and any requests during the study period e.g. maintenance, replacement or disposal can also be provided, depending on capacity and capability and number of devices to be tested. • The checks are either performed at the site-based workshops or engineers may travel to sites if requested. • Acceptance processes are followed including tagging and logging onto the Trust Equipment Database for governance, traceability and compliance.
(C) Enhanced equipment governance activities including testing This work is typically carried out by a HCPC registered Clinical Scientist or a Clinical Engineering Governance and Quality Lead.	Depending on the service's capacity and capability, in-depth technical risk assessments to meet regulatory requirements (e.g. for clinical investigations) and study reviews are performed for device-supporting studies of the following types: • Clinical investigation of a non-CE/UKCA marked device. • Pre-CE/UKCA marking proof of concept device study with no commercialisation intent. The work within this category entails: • Standard governance activities (as above). • Enhanced equipment governance activities to meet device regulatory requirements. This includes (but is not limited to) performing: ○ In-depth technical risk assessments against the medical device risk management standard (ISO 14971) and development of the risk management file (RMF). ○ Standards assessments against the relevant standards e.g. for electrical safety (IEC 60601), medical device software (IEC 62304) etc. depending on the device. ○ Support on completing MDR essential requirements/GSPR checklists ○ Advice and support on technical file development ○ Support with compliance with Clinical Investigations standard (EN ISO 14155) ○ Where relevant, providing support with developing the clinical investigation plan (CIP) and investigator's brochure (IB). ○ Electrical safety testing to IEC 60601 / IEC 62353 standard

Table 1: Justification of Clinical Physics Set-up fee

Activity description	Time (minutes)	Justification and services involved
NIHR_GPC_050: Device/Clinical Equipment A: Review of New CE/UKCA-marked equipment provided on loan or free transfer for the purposes of research (including Device Supporting or Device Centred studies) or standard of care. Up to 3 devices only.	450	Activities (see Table 1 for details): (A) Standard equipment governance activities (B) Clinical engineering equipment testing Services involved: - Clinical Physics Governance Team - Clinical Engineering Workshops
NIHR_GPC_051: Device/Clinical Equipment B: Documentation review of New CE/UKCA-marked equipment provided on loan or free transfer for a device-centred study, including a clinical investigation and device-supporting study. No requirement for equipment testing.	240	Activities (see Table 1 for details): (A) Standard equipment governance activities Services involved: Clinical Physics Governance Team
NIHR_GPC_052: Device/Clinical Equipment C: Review of non-CE/UKCA marked device requiring clinical investigation (for device centred studies) includes document review & electrical safety testing). Up to 3 devices only	450	Activities (see Table 1 for details): (A) Standard equipment governance activities (B) Clinical engineering equipment testing Services involved: - Clinical Physics Governance Team - Clinical Engineering Workshops
NIHR_GPC_099: Device/Clinical Equipment D: Review of pre-CE/UKCA marking device study for MHRA clinical investigation or proof-of concept where no commercialisation is intended. For up to 3 devices only.	7200	Activities (see Table 1 for details): (A) Standard equipment governance activities (C) Enhanced equipment governance activities including testing Services involved: - Clinical Physics Governance Team - Clinical Engineering Workshops
NIHR_GPC_100: Device/Clinical Equipment A: Each additional CE/UKCA-Marked Device. Must be paired with review fee.	30	Activities (see Table 1 for details): (B) Clinical engineering equipment testing Services involved: Clinical Engineering Workshops
NIHR_GPC_101: Device/Clinical Equipment C/D: Each additional non-	60	Activities (see Table 1 for details): (B) Clinical engineering equipment testing

CE/UKCA marked or pre-CE/UKCA marked proof of concept Device. Must be paired with review fee		Services involved: - Clinical Physics Governance Team - Clinical Engineering Workshops
NIHR_GPC_053: Device/Clinical Equipment A/C/D: Device Management fee per month per site (chargeable monthly in arrears). This can also include device maintenance, replacement disposal or any device-related additional requests during the study.	120	Activities (see Table 1 for details): (C) Standard equipment governance activities (D) Clinical engineering equipment testing Services involved: - Clinical Physics Governance Team - Clinical Engineering Workshops

Table 2: Applicable fees by study type, as documented in the NIHR industry costing template