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Statement on Good Clinical Practice Training

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Overview of Training

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

National Institute for Health Research (NIHR) GCP training includes the following areas:

- regulatory requirements and how GCP standards were initiated;
- study roles and delegation;
- participant eligibility and consent;
- study delivery and data collection;
- safety reporting;
- and study closure (including archiving).

Each of these sections addresses the research journey and gives examples and real-life instances that enhance learning.

Regarding the accreditation of NIHR GCP training, the following statement appears on the NIHR website: '(NIHR GCP) training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

This training has been certified by The CPD Certification Service. 4 CPD points are applicable to the e-learning course, and 6 points are applicable to the workshop[1].' In addition, the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA) endorse GCP training having reviewed and contributed to the training materials, securing its status as a nationally recognised research standard.

Locally, BU's Clinical Governance Advisor facilitates NIHR GCP face-to-face training sessions (both full day and half day 'refresher' sessions) alongside colleagues at Royal Bournemouth and Christchurch Hospital and Poole General Hospital. The dates for these sessions are decided each year by the three facilitators. The face-to-face training allows researchers and research staff to openly discuss clinical research, their experiences, and their ideas. The training is also available via e-learning. All training is free of charge to those involved in healthcare research.

Overview of BU's Role within the Research Landscape

As a Sponsor, Bournemouth University has obligations under GCP and relevant regulations (depending on the nature of the study), to act as the organisation that takes on overall responsibility for the research, and for proportionate, effective arrangements being in

[1] https://www.nihr.ac.uk/our-faculty/clinical-research-staff/learning-and-development/national-directory/good-clinical-practice/our-courses/introduction.htm [Accessed 01/08/2018]

place to set up run and report a research project (Department of Health's UK Policy Framework for Health and Social Care, 2017).

The same framework stipulates that universities should accept the role of Sponsor for all educational research conducted by its own students, with the exception of a student being employed by a health or social care provider that would prefer to undertake the role. In sponsoring educational research, the framework emphasises the importance of the Sponsor ensuring that supervisors have the capacity and expertise to fulfil their role, and can adequately oversee the project in terms of location. Should the Sponsor not be satisfied, then it may agree co-supervision with a local care practitioner.

NIHR GCP training is a valuable tool in helping attendees to familiarise themselves with the NHS research environment. As per NIHR guidelines and at the time of writing, NHS Trusts are expected to meet key metrics in confirming their capacity and capability to deliver a given study. These metrics are monitored by the NIHR Clinical Research Network Wessex.. GCP training likewise addresses the procedures and preparations NHS Trusts are expected to finalise prior to opening a given study at site. This again is invaluable background knowledge, and can give researchers a better awareness and understanding of the pressures that NHS Trusts face, and what is expected from them throughout the life of a research project.

As mentioned at the beginning of this document, the full training and refresher training is available online and is likewise delivered face-to-face. When a BU researcher, or BU member of staff (contributing to, or leading the research as a Chief Investigator) is undertaking GCP training for the first time, where feasible and available, the full day face-to-face training is strongly advised. If the physical training is not available locally, then the full online course may be undertaken, provided the researcher/staff member books a place on the next local face-to-face course. This will be mandated in order to provide them with the opportunity to consolidate their learning and to fill any gaps in knowledge (from prior experience, due to the amount of information provided, the physical training can be more effective).

Up to date GCP accreditation will be sought from the individual every 2 years (this requirement is discussed later in this document). Compliance will be managed by the Clinical Governance Advisor via a central record of training dates, with an expectation that the BU researcher or member of staff takes responsibility for their own learning. In order to refresh their training, they will be signposted to the available online training and local face-to-face dates. Similar to the requirements surrounding full training, where possible the face-to-face sessions will be favoured.

<u>Joint Statement on GCP Training Requirements</u>

In October 2017, the Health Research Authority (HRA), Medicines and Healthcare products Regulatory Agency (MHRA), and the Devolved Administrations for Northern Ireland, Scotland and Wales, released a joint statement on *the Application of Good Clinical Practice to Training for Researchers*. In referring to ICH GCP, this likewise refers to NIHR GCP training, which as seen above, is recognised as a comparable standard. It is important to note that the joint statement refers throughout to 'GCP' and does not distinguish between the two programmes.

Within this document, they negate the need for GCP training in studies that are not identified as CTIMPs (Clinical Trials of Investigational Medicinal Products), stating that there is no legal requirement for other types of research to comply with GCP, or for staff to be trained in the guidelines. The statement does not dismiss the notion of researchers being appropriately trained, in that there is still the expectation that the research is conducted so as to ensure the rights, safety and wellbeing of research participants and ensure that research data are reliable. In saying this, the two key learning points and considerations of GCP training, are the aforementioned assurances, therefore GCP training is a comprehensive and recognised resource that addresses these concerns.

As BU is relatively new to its role as Sponsor and with a growing portfolio encompassing varying study types, phases and clinical areas, it is advisable, and in the interest of continuity, for all BU staff involved in research projects, to hold up to date GCP certification. GCP addresses key areas that research staff are expected to know and comply with in introducing their research to NHS Trusts and social care organisations. In approaching Research Development & Support (RDS)int

with requests for sponsorship of their clinical research, applicants will be asked to provide their certificate, and if not available, will be signposted to the necessary training.
What's more is that in contacting NHS Trusts, the majority of R&D offices will request this certification for their records.

<u>The Joint Statement and Bournemouth University as Sponsor</u>

The following quotations, in italics, are taken from the aforementioned joint statement:

- *Sponsors of CTIMPs which are not to be included as part of a marketing authorisation application can choose to comply with ICH GCP as a standard in its entirety or they can take a more proportionate approach depending on the nature of the trial. Further information about this can be found in the MHRA guidance on risk adapted approaches in the management of CTIMPS.*[2]

In response to this, the requirement with interventional studies (in addition to CTIMPs) with regard to safety reporting, include highly specific criteria and often it can be quite complex to reach a decision on how to identify an untoward event during the research.
NIHR GCP training addresses these categories of safety reporting, and the rationale as to why decisions are made. The training also provides opportunities that allow the staff member to practice identifying events, having been provided with scenarios that they may be faced with.
At BU and with interventional studies run by the Orthopaedic Research Institute (ORI) for example, in using devices, both CE marked and non-CE marked, this area of learning is essential in terms of patient safety and high quality data.

- *The training required does not need to follow a generic syllabus, format or prescribed timing, but should be appropriate and proportionate to the activities undertaken by staff involved (in the clinical trial). It should be tailored to the specific roles and responsibilities being undertaken by an individual.*

[2] MHRA - Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products, Oct 2011.

Although GCP is a *generalised* approach to research training, it is tailored to specific roles and responsibilities through the interactive exercises accompanying the course material. Often the facilitator will also tailor specific examples to course attendees and likewise will invite attendees that may have already been involved in research, to outline their study-specific responsibilities to the rest of the group. The training also incorporates learning on what is required to evidence a staff member's training and expertise, in satisfying a monitor or Inspector.

Despite GCP training likewise employing a generic syllabus, and format, it is well-regarded as a comprehensive, accessible and useful resource for all staff working in healthcare research.
Staff compliance to the training is subject to expiration; nationally there is no stipulated frequency for updating GCP accreditation, however the recommended timeframe is every 2 – 3 years. At BU, due to the timeframes required by our neighbouring NHS Trusts, it will be requested that GCP accreditation is updated every 2 years.
This requirement provides organisations and staff alike with stability in ensuring that their training is up to date, enduring and well applied to their work in clinical research. What's more, by maintaining compliance to GCP training, this likewise ensures that working relationships are maintained between those within the research community, from all organisations, and between all types of staff.

- *Training/awareness in the aspects of GCP relevant to that role would be considered acceptable (for example, recording of adverse events, documentation of activities in source notes or case report form (CRF), escalating any issues they identify as appropriate).*

There are some circumstances in which staff may not require GCP training, for example if a chemotherapy nurse was administering *standard care* treatment to a trial patient, for the purposes of the trial, then they would be undertaking tasks within their everyday professional role.
However, if a member of staff is recording adverse events or completing Case Report Forms, then training in just that aspect of GCP, does not make the staff member aware of *why* this activity is carried out in this way.

- *It should be noted that there is no legal requirement for other types of research (i.e. studies which are not clinical trials of investigational medicinal products) to be conducted in accordance with the conditions and principles of GCP. However, it is still important that such research is always conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable.*

In considering the statement above, a well-established, enduring and comprehensive programme such as Good Clinical Practice satisfies this requirement. GCP training is in place in order to promote a culture amongst staff that work in healthcare research, to conduct their study activities in a way that assures the rights, safety and wellbeing of research participants, in turn ensuring that the research data are reliable and scientifically sound.

Conclusion

From a staff development stance, the training offers CPD points for completion. Additionally, the training will give staff not entirely familiar with research within a healthcare setting, an insight into what they may expect. It may also provide them with a better understanding when it comes to designing their next study.

With a growing clinical research portfolio at BU, GCP training is advisable from a clinical governance point of view, in order to provide a standardised and widely-accepted and ratified training programme.
The content and activities that form the training likewise invite discussion amongst the attendees that can enhance learning, and enhance appreciation of the importance of the guidelines in clinical studies. By meeting the facilitators, staff may also grow their research network and make important ties with Trust R&D departments and clinical colleagues.