**Coordinator/administrator:**

**Telephone Number:**

**E-Mail:** **Website:** [**https://www.nhsggc.org.uk/about-us/professional-support-sites/research-innovation**](https://www.nhsggc.org.uk/about-us/professional-support-sites/research-innovation)

**Research & Innovation**

**Floor 2, Admin Building,**

**Gartnavel General Hospital**

**1053 Great Western Road,**

**Glasgow, G12 0YN**

Date

PI Name

PI Address

**NHSGGC Board Approval**

Dear PI Surname

|  |  |
| --- | --- |
| **Project Title:** |  |
| Principal Investigator: |  |
| NHSGGC Site: |  |
| Sponsor: |  |
| R&I reference: |  |
| REC reference: |  |
| Protocol no: |  |

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study. Approval relates to all documents ethically approved prior to the date of this letter.

**Conditions of Approval**

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004

* 1. During the life span of the study NHSGGC requires the following information relating to this site
     1. Notification of any potential serious breaches.
     2. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the NHSGGC GCP policy ([www.nhsggc.org.uk/media/271192/nhsggc-research-innovation-gcp-training-policy-v30.pdf](http://www.nhsggc.org.uk/media/271192/nhsggc-research-innovation-gcp-training-policy-v30.pdf)) evidence of such training to be filed in the site file. Researchers must follow NHSGGC local policies, including incident reporting.

First study participant should be recruited within 30 calendar days of site activation by Sponsor and the study must work in accordance with the current NHSGGC guidelines and principles.

1. **For all studies** the following information is required during their lifespan.
   1. Notification of the date of the first patient recruited
   2. Recruitment Numbers on a monthly basis, and any change to Recruitment End Dates
   3. Any change to local research team staff should be notified to R&I team
   4. Any amendments – Substantial or Non Substantial
   5. Notification of Trial/study end including final recruitment figures
   6. Final Report & Copies of Publications/Abstracts (for studies sponsored by NHSGGC only)
   7. You must work in accordance with the current NHSGGC guidelines and principles.

**Please add this approval to your study file as this letter may be subject to audit and monitoring.**

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

**Research Facilitator**

**CC:**

|  |
| --- |
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