**CGF 153 - Authorisation for clinical study or research activity**

This form must be used to ensure that National Ambulance (NA) follows best ethical practices and protocols for proof of concept studies, clinical projects and research activities. The form should be read alongside the NA Ethics Policy and Procedure CGP109 which focuses on the concept of primum non nocere (Do no harm), it aims to protect Patient Rights including confidentiality and privacy of patient related information.

The ethics elements of all NA clinical studies and research activities are considered by the Medical Director (MD) completing this form; if required they are considered further by the NA Clinical Ethics working group (Internal) or Clinical Ethics Committee (including external) as per Appendix 1. Any risks identified may be included on the NA Risk Register. This form is to be used purely for clinical ethical matters, it is not to be used to consider any financial matters.

|  |  |
| --- | --- |
| Name of study/project |  |
| Study design e.g. Cross sectional |  |
| Hosted/organised by |  |
| Period of study |  |
| Population of study |  |
| Methods |  |
| Risks and risk management |  |

|  |  |  |
| --- | --- | --- |
| Authorized by Medical Director | Yes | No |
| Referred to Clinical Ethics working group (internal) | Yes | No |
| Referred to Clinical Ethics committee (including external) | Yes | No |
| Comments | | |

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Dr. Ayman Ahmed Medical Director

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DOCUMENT CONFIGURATIONS CONTROL DATE

A review and update of this document will take place as necessary, when changes occur that identify the need to revise thisPolicy such as changes in roles and responsibilities, release of new legislative or technical guidance, or identification of a new policy area.

This document ownership for editing is identified as:

Title Format

**Medical Director Change Brief**

|  |  |  |
| --- | --- | --- |
| **Version No.** | **Date** | **Changes** |
| 1 | 28 January 2016 | New Document to support CGP109 |
| 2 | October 2020 | Change the roles and responsibilities to Medical Director |
| 3 |  |  |
|  |  |  |

Review & Approval:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dr. Ayman Ahmed Medical Director Date: