***Extract from the Minutes of the 1089th Licensing Meeting of the Agency was held on 14 June 2022, in EPA Headquarters, Johnstown Castle Estate, County Wexford***

The 1089th Licensing Meeting of the Agency was held on 14 June 2022, in EPA Headquarters, Johnstown Castle Estate, County Wexford.

Directors Present: L Burke (Chair);

G O’Leary & E Cotter.

4. **GMO Notification**

***Deliberate release of a GMO into the environment for purposes other than for placing on the market***

*Notifier*:**Gyroscope Therapeutics Limited**

**Rolling Stock Yard**

**188 York Way**

**London N7 9AS**

**United Kingdom**

*Trial Location:* **UPMC Whitfield Hospital Institute of**

**Eye Surgery**

**2 Butlerstown**

**Waterford**

**X91 DH9W**

*GMO Reg Entry No*:**G0784-01**

The Directors considered a recommendation from the Office of Environmental Sustainability that the Agency approve the recommended consent to conduct a clinical trial using a GMO under the GMO (Deliberate Release) Regulations S.I. No 500 of 2003 for purposes other than placing on the market. The following documentation was submitted: report of the Inspector dated 8 June 2022; and recommended consent for GMO Register No G0784-01; Summary Notification Information Format number B/IE/21/01.

Bernie Murray, Pamela McDonnell and Marie O’Connor gave verbal presentations.

**Inspector’s Report**

The Directors noted the Inspector’s report, detailing the background to the application and the reasons for the recommendation. The Directors also noted the Inspector’s assessment that the risk to human health and the environment from the deliberate release of this GMO is negligible. The Directors further noted the Inspector’s assessment that it is considered unlikely that gene therapy GT005 will have adverse effects on human health or on the environment in the context of the intended clinical trial, provided that the trial protocol, all the proposed conditions of the trial and foreseen safety measures will be applied.

**Recommended Decision**

***Conditions***

**4.4** Amend the condition as follows: ‘The notifier shall provide the name and contact details of ~~a person~~ *persons* in the employ of*:*

* Gyroscope Therapeutics Limited*; and*
* *UPMC Whitfield Hospital Institute of Eye Surgery, Waterford*

~~with~~ *who each have* responsibility for overseeing the performance of this clinical trial at UPMC Whitfield Hospital Institute of Eye Surgery, Waterford. These details shall be submitted to the Agency two weeks prior to the commencement of the clinical trial. Any change to this designation during the trial shall be notified immediately to the Agency.’

*Reason for Decision:*

In the interest of providing clarity.

Following discussion, the Directors approved the Consent with conditions, as modified, for deliberate release of a GMO into the environment for purposes other than for placing on the market to Gyroscope Therapeutics Limited, Rolling Stock Yard, 188 York Way,

London N7 9AS, United Kingdom, GMO, Register Entry No. G0784-01.