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An Academic Partner of Trinity College Dublin

Ospidéal
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Thamhlachta



Research Office

Project ID: 0215

Approval Date: 23 August 2021

Submission Number: 294

Submission Title: Establishment of an upper gastrointestinal from patients undergoing endoscopy or surgery to study diseases of the upper GI tract

Submission Date: 21/07/2021 11:14

Dear Dr Zaki,

On behalf of the Chair and members of the SJH/TUH Joint Research Ethics Committee I wish to inform you that the amendment to the above study has received **FULL APPROVAL**.

The following comments were made:

| Title | Comment |
|--|--|
| 5.1.1 Please upload any documents you feel are relevant to this submission | Noted: It has been noted that myeloid cells are already available from the deposited samples. The addition of this testing does not change the overall context of testing being conducted. |
| 5.1.1 Please upload any documents you feel are relevant to this submission | Noted: The applicant has been notified that new clinicians may need data protection training as per SJH requirements. |
| 5.1.1 Please upload any documents you feel are relevant to this submission | Noted: Referencing Hanahan and Weinberg (2011) serves to further support the scientific argument for the investigations which are being conducted using the material in the biobank. Article includes critical marker(s) of this condition. |
| 5.1.1 Please upload any documents you feel are relevant to this submission | Noted: Only samples/data which will be prospectively collected will be shared with the below non-academic partners. Outlined in previously approved PIL although companies not named. Mirai Medical = https://eporetherapy.com/ Remedy Bio = https://remedybiologics.com/ |

The following documents were reviewed and approved:

| Document | File Name | Date | Version |
|----------|-----------|------|---------|
|----------|-----------|------|---------|

| Type | | |
|---------|--|----------------|
| Default | 2021 REC Amendment 2019-07 List 25 (27)Upper GI Biobank | 17/05/2021 1.0 |
| Default | PIL_ICF_V1_Upper GI Biobank Normal Surgical Resection_2019-07 List 25(27)_GDPR_HRR May 2021 | 17/05/2021 1.0 |
| Default | TrackChanges PIL_ICF_V4_Upper GI Biobank Pre-Tx_REC_2019-07 List 25(27)_GDPR_HRR | 20/07/2021 |
| Default | TrackChanges PIL_ICF_V5_Upper GI Biobank Surgical Resection_REC_2019-07 List 25(27)_GDPR_HRR | 20/07/2021 |

Please note that ethical approval for this study is only active under the following conditions:

1. *Applicants must submit an annual report for ongoing projects.*
2. *Applicants must submit an end of study declaration/end of study report upon completion of the study.*
3. *All adverse events must be reported to the JREC.*
4. *All changes (minor and substantial) to documentation/study must be submitted to the JREC using the amendment request form and the changes must be tracked/highlighted clearly. Approval from the JREC is required before implementation of the changes.*

It is the responsibility of the researcher/research team to ensure all aspects of the study are executed in compliance with the General Data Protection regulation (GDPR), Health Research Regulations and the Data Protection Act 2018.

Yours sincerely,

Ms Chita Murray

Research Ethics & Clinical Trials Manager,

SJH/TUH Joint Research Ethics Committee

The SJH/TUH Joint Research and Ethics Committee operates in compliance with and is constituted in accordance with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 & ICH GCP guidelines.