



## Reference Research Ethics Committee Midlands Area and Corporate (Regional Health Area B)

### Annual Progress Report (v1.0)

**Please note:**

- The Principal Investigator must submit an Annual Progress Report to the Reference Research Ethics Committee Midlands Area and Corporate (Regional Health Area B).
- It must be submitted:
  - on the anniversary date of the final ethical approval *and*
  - for each year thereafter for the duration of the study.
- All sections of the form should be completed.
- Please email the completed report to [REC.B.CorporateMidlands@hse.ie](mailto:REC.B.CorporateMidlands@hse.ie)

Thank you.

*This report is based on the National Research Ethics Committee (NREC) Annual Progress Report (v.1)*

## 1.0 General information

### 1.1 RRECB application reference (as included on your letter of approval from RREC)

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### 1.2 Date of final ethics approval:

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### 1.3 Principal Investigator details

Name	
Title	
Institution	
Email	

## 2.0 Commencement and termination dates

### 2.1 Has the study commenced?

☐ Yes ☐ No

If yes, what is the actual start date?

If no, what are the reasons for the study not commencing?

What is the expected start date?

### 2.2 Has the study finished?

☐ Yes ☐ No

If no, what is the expected completion date?

If you expect the study to overrun the planned completion date, what are the reasons for this?

If you do not expect the study to be completed, please provide an explanation.

### 3.0 Research registration

#### 3.1 Is your study registered on a publicly accessible database?

☐ Yes ☐ No

If yes, please provide the name of the publically accessible database and the registration number

### 4.0 Study modifications

#### 4.1 Have any **substantial** amendments been made to the study during the preceding 12 months?

☐ Yes ☐ No

If yes, please provide the RRECB amendment code for each substantial amendment made

#### 4.2 Have any amendments or modifications been made to the study that have not required ethical approval during the preceding 12 months?

☐ Yes ☐ No

If yes, please provide details

#### 4.3 Have there been any breaches to the study protocol that RRECB have not been notified of?

☐ Yes ☐ No

If yes, please enclose a report of any serious breaches not already notified to RRECB

## 5.0 Participant recruitment

### 5.1 Recruitment information

Proposed number of participants in the study	
Number of participants recruited to date	
<b>Number of participant withdrawals from study due to:</b>	
<b>A.</b> Number lost due to withdrawal of consent	
<b>B.</b> Number lost to follow-up	
<b>C.</b> Number lost to other causes (& please state the causes)	

### 5.2 Has there been any serious difficulty recruiting participants or accessing samples?

<input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, please provide details	

## 6.0 Safety of participants

### 6.1 Have there been any related and unexpected serious adverse events (SAEs) in this study?

<input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, has the RRECB been notified?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If no, please submit details with this report and give reasons for late notification.	

### 6.2 Have any additional concerns arisen about the safety of participants in this study?

<input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, please provide additional information	
Outline any measures undertaken/proposed to maintain patient safety	

## 7.0 Dissemination and engagement

**7.1** Have any engagement or dissemination activities related to the study been undertaken over the past 12 months?

This can include publications, conference attendance, presentations, outreach activities, data sharing, etc

☐ Yes ☐ No

If yes, please provide details

## 8.0 Additional ethical matters

**8.1** Are there any other developments in the study that you wish to report to this RREC?

☐ Yes ☐ No

If yes, please provide additional information

## 9.0 Declaration of the Principal Investigator

I certify that the information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

Signature

Print name

Date

Please email the completed report to RREC Area B: [REC.B.CorporateMidlands@hse.ie](mailto:REC.B.CorporateMidlands@hse.ie)