RATE-AF Randomisation Form

PLEASE COMPLETE BEFORE RANDOMISATION

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

SITE DETAILS

Name of person completing this form: .....

Referring site:	UHB ☐	SWBH ☐	HEFT ☐	GP ☐ (*please specify*) .....

PATIENT IDENTIFICATION DETAILS

Date of birth:	D D / M M M / Y Y Y Y
Hospital number:	☐☐☐☐☐☐☐
NHS number:	☐☐☐☐☐☐☐☐☐☐
Gender:	Male ☐ Female ☐

ELIGIBILITY CHECKLIST

If any of the shaded boxes are ticked, the patient is **NOT** eligible to be randomised into the RATE-AF trial

	No	Yes
Is the patient aged 60 years or over?	■	☐
Does the patient have permanent AF, characterised (at time of randomisation) as a physician decision for rate-control with no current plans for cardioversion, anti-arrhythmic medication, or ablation therapy?	■	☐
Does the patient have symptoms of breathlessness (New York Heart Association Class II or more)?	■	☐
Is the patient able to provide written, informed consent?	■	☐
Does the patient have an established indication for beta-blocker therapy, e.g. myocardial infarction in the last 6 months?	☐	■
Does the patient have known contraindications for therapy with beta-blockers or digoxin, e.g. a history of severe bronchospasm that would preclude use of beta-blockers, or known intolerance to these medications?	☐	■
Does the patient have a baseline heart rate <60 bpm?	☐	■
Does the patient have a history of second or third-degree heart block?	☐	■
Does the patient have supraventricular arrhythmias associated with accessory conducting pathways (e.g. Wolff-Parkinson-White syndrome) or a history of ventricular tachycardia or ventricular fibrillation?	☐	■
Is the patient awaiting pacemaker implantation (including cardiac resynchronisation therapy), have a pacemaker-dependent rhythm or a history of atrioventricular node ablation?	☐	■
Is there a history of decompensated heart failure (evidenced by need for intravenous inotropes, vasodilators or diuretics) within 14 days prior to randomisation?	☐	■
Does the patient have a current diagnosis of obstructive hypertrophic cardiomyopathy, myocarditis or constrictive pericarditis?	☐	■
Has the patient undergone heart transplantation, or is on a waiting list for heart transplantation?	☐	■
Is the patient receiving renal replacement therapy (haemodialysis or peritoneal dialysis)?	☐	■
Is there a history of major surgery, including thoracic or cardiac surgery, within 3 months of randomisation?	☐	■

ELIGIBILITY CHECKLIST

If any of the shaded boxes are ticked, the patient is **NOT** eligible to be randomised into the RATE-AF trial

	No	Yes
Does the patient have severe, concomitant non-cardiovascular disease (including malignancy) that is expected to reduce life expectancy?	☐	☒

Eligibility criteria confirmed by (name):
This **must** be confirmed by a **medically qualified doctor** who has signed the delegation log .....

MODIFIED EHRA SCORE

Modified EHRA score: 1 ☐ 2a ☐ 2b ☐ 3 ☐ 4 ☐

Guidance on selecting modified EHRA score:

1: *None; AF does not cause any symptoms*

2a: *Mild; normal daily activity not affected; patient not troubled by symptoms*

2b: *Moderate; normal daily activity not affected; patient troubled by symptoms*

3: *Severe; normal daily activity affected by symptoms relating to AF*

4: *Disabling; normal daily activity discontinued*

CONSENT DETAILS

Has the patient given informed consent to participate in the study? (if no, this patient cannot be randomised) **No** ☒ **Yes** ☐

Version of informed consent form used: ☐☐ . ☐☐

Date of patient consent: D D / M M M / Y Y Y Y

Optional consents

Has the patient given permission for their blood samples to be stored for future genetic tests?	**No** ☐	**Yes** ☐
Has the patient consented for their blood samples to be stored for future biochemical tests?	**No** ☐	**Yes** ☐
Has the patient given permission for their data on central NHS databases to be included in the analysis data set?	**No** ☐	**Yes** ☐
Has the patient given permission to be contacted by the Research Team regarding participation in a focus group	**No** ☐	**Yes** ☐
Has the patient given permission for them to be contacted about further studies?	**No** ☐	**Yes** ☐
Has the patient agreed to participate in the sub-study of physical activity and heart rate monitoring?	**No** ☐	**Yes** ☐
Has the patient agreed to participate in the sub-study of nerve activity and heart rate?	**No** ☐	**Yes** ☐

RANDOMISATION TO TREATMENT ALLOCATION

Online randomisation: www.trials.bham.ac.uk/rate-af **(24hrs)**
Log on to the **RATE-AF** database and follow the instructions on screen
OR
Telephone randomisation: 0800 953 0274 **(UK toll free), 9am to 5pm Mon-Fri.**

RANDOMISED TREATMENT ALLOCATION (please tick one):

Digoxin ☐ **OR** **Bisoprolol** ☐

RATE-AF Trial Number: ☐☐☐☐

Date of randomisation: D D / M M M / Y Y Y Y

Randomisation Form completed by:
You **must** have signed the trial signature and delegation log

Date: D D / M M M / Y Y Y Y **Signature: ……..**

Please return this completed form to the RATE-AF Trial Office, University of Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT