This pack contains example documents to support training on HRA Approval. It contains the following documents:

1. Checklist for applying for HRA Approval
2. Checklist of documents for the Local Information Pack to provide to participating organisations
3. Example HRA Initial Assessment Letter (note this is an example and there will continue to be variations to the wording over time)
4. Example HRA Approval Letter (note this is an example and there will continue to be variations to the wording over time)

Please note that these documents are not relevant to requests for HRA Approval for an existing study where new sites are being set up. These studies do not use the checklist to apply for HRA Approval, do not receive an initial assessment letter and have a different HRA Approval letter that makes clear it relates to an existing study.

Application package to HRA

Before submitting your application, please review the information about the standards against which the HRA will review applications in HRA assessment: http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/hra-assessment-criteria-and-standards/

The following information should be uploaded to the IRAS checklist for the IRAS application form (combined REC and R&D form) and submitted electronically. This list combines the documents previously used for the separate REC and R&D forms.

Project Information: **(All documents must be dated and/or have version numbers)**
Covering letter on headed paper
Research protocol or project proposal
Summary CV for Chief Investigator (CI)
Participant information sheet (PIS)
Participant consent form
Letters of invitation to participant
GP/consultant information sheets or letters
Sample diary card/patient card
Validated questionnaire
Non-validated questionnaire
Referee's report or other scientific critique report
Summary, synopsis or diagram (flowchart) of protocol in non-technical language
Details of any Data Monitoring Committee
Investigator's brochure / IMP Dossier

Summary of product characteristics (SmPC)
Copies of advertisement materials for research participants
Letter from sponsor
Letter from funder
Letter from statistician
NIHR Industry costing template (validated) - commercial projects
Template model Contract/Study Agreement – where applicable
Template Schedule of Events (see HRA website) – non-commercial studies
Template Delegation log including PI declaration – commercial studies
Template Statement of Activities (see HRA website) – non-commercial studies
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only)
Summary CV for student
Summary CV for supervisor (student research)

Local Information Package

The sponsor should provide the following information to the site by sending an email to the following at the same time:

- PI and any local research nurse/ study coordinator
- NHS R&D office (see http://www.rdforum.nhs.uk/content/contact-details/)
- LCRN contact (see https://www.crn.nihr.ac.uk/networks/#tab-2)

Information package to be provided to sites after receipt of the initial assessment letter from HRA:

Copy of IRAS application form (combined REC and R&D form) as submitted for HRA Approval
Protocol
Any amendments
Participant information and consent documents (without local logos/ headers)
Relevant model agreement (where applicable)
NIHR Costing template (validated) – commercial studies
Schedule of Events (see HRA website) – non-commercial studies
Delegation log including PI declaration (standard template available) – commercial studies
Statement of Activities (see HRA website) – non-commercial studies
Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
Copy of HRA Initial Assessment letter

To be provided once available:

HRA Approval letter and final document versions

Health Research Authority

Dr Arthur Smith
Red Heath Hospital NHS Trust
Red Heath Road
London
L1 4TT

Email: hra.approval@nhs.net

6 February 2016

Dear Dr Smith,

Initial Assessment Letter

Study title:	**DUMMY STUDY: To determine whether Drug A is more effective than Drug B in Chronic Heart Failure.**
IRAS project ID:	**502136**
EudraCT number:	**1111-100000-22**
Protocol number:	**XX1234**
REC reference:	**16/HRA/9999**
Sponsor:	**Red Heath Hospital NHS Trust**

Thank you for your application of the above referenced study for HRA Approval for the above referenced study. You will have already received notification that your application is valid for REC and proceeding to a REC meeting.

I, (Ms Ann Assessor – hra.approval@nhs.net) have been assigned to this application and have undertaken my initial assessment, the findings of which are detailed in *Appendix B*. Please note that **this is not a letter of HRA Approval**, and the research should not begin at any participating NHS organisations in England before HRA Approval is issued.

Purpose

The purpose of this letter is to provide initial information from the HRA assessment to you, the sponsor and participating NHS organisations in England to enable the process of arranging capacity and capability to begin.

You should now provide a copy of this letter and the local document package to participating NHS organisations in England, and work with them to coordinate local arrangements in preparation for HRA Approval on the basis described in this letter, even where certain arrangements detailed in *Appendix B* are still to be finalised.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Notification of Outcomes

I will continue to work with you to resolve any outstanding questions whilst local arrangements are finalised prior to HRA Approval. I may contact you by phone or email to seek clarification as I complete my assessment.

You will receive written notification of HRA Approval once the assessment has been completed and subsequent to any regulatory approvals required for your study (e.g. REC favourable opinion, MHRA Clinical Trial Authorisation etc.). HRA Approval will not be issued until any specific conditions on these approvals have been met.

There is no need for you to send me the REC opinion or any other regulatory approvals, as I will receive these directly, although I may contact you to confirm that any applicable conditions have been met.

Appendices

This Initial Assessment Letter contains the following appendices:

- A – List of documents to be reviewed during HRA assessment
- B – Summary of initial HRA assessment

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

HRA training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/.

Your IRAS project ID is **502136.** Please quote this on all correspondence.

Yours sincerely

Ms Ann Assessor

Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Richard Trust, Red Heath Hospital NHS Trust, Sponsor Contact*

Dr B Jones, R&D Department, Red Heath Hospital NHS Trust, Lead R&D Contact

Appendix A - Documents received

The documents to be assessed as part of HRA Approval are as follows.

Document	*Version*	*Date*
GP/consultant information sheets or letters	1.0	13 January 2016
Letter of invitation to participant	1.0	13 January 2016
Validated questionnaire [Quality of Life Questionnaire]		
Participant consent form	1.0	13 January 2016
Participant information sheet (PIS)	1.0	13 January 2016
IRAS Form		1 February 2016
Research protocol or project proposal	1.0	13 January 2016
Summary CV for Chief Investigator (CI)	Dr Arthur Smith	8 January 2016
Template Agreement [model non-commercial agreement]		
SmPC [Drug A]		16 March 2015
SmPC [Drug B]		17 May 2015
Statement of Activities [Host Organisation]		13 January 2016
Schedule of Events [Host Organisation]		13 January 2016
Statement of Activities [Participant Identification Centre]		13 January 2016
Schedule of Events [Participant Identification Centre]		13 January 2016
Statement of Activities [Blood Collection Centre]		13 January 2016
Schedule of Events [Blood Collection Centre]		13 January 2016

Appendix B – Information for Sponsors and Participating NHS Organisations

The appendix below provides all parties with information that will be beneficial when discussing the arranging of capacity and capability with participating NHS organisations in England. The information in this appendix is intended to be an accurate reflection of the study at the time of issue of this letter. As part of the HRA Approval process, details may change prior to a Letter of HRA Approval being issued. NHS organisations should be assured that the HRA will continue to work with the sponsor on any HRA assessment criteria which are 'pending', and this should not impact on the arranging or capacity and capability.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Dr B Jones, Red Heath Hospital NHS Trust, Tel: 0011123459, Email, b.jones@redheath.nhs.uk.

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Pending	It is unclear on the participant information sheet what the end of study arrangements in relation to provision of the investigational medicinal products, and who will have access to personal data of participants for research purposes. This will be clarified.
3.1	Protocol assessment	Pending	The protocol is contradictory with other documentation about the end of study arrangements for provision of the investigational medicinal products, as well as the provisions in place to protect personal identifiable data of the participants.
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor intends to use a model non-commercial agreement with host NHS organisations in England. Following review of the supplied template, the HRA has confirmed that

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
			the agreement is an unmodified version of the model non-commercial agreement. **Participant identification centres** and **blood collection centres** are not expected to formally confirm capacity and capability. Although formal confirmation of capacity and capability is not expected of all or some organisations participating in this study (see Confirmation of Capacity and Capability section for full details), and such organisations would therefore be assumed to have confirmed their capacity and capability should they not respond to the contrary, we would ask that these organisations pro-actively engage with the sponsor in order to confirm at as early a date as possible. Confirmation in such cases should be by email to the CI and Sponsor confirming participation based on the relevant Statement of Activities and information within this Appendix B.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	At the time of issue of the Initial Assessment letter the sponsor has indicated that they will provide the following funds to participating NHS organisations in England, as detailed in the Statement of Activities: • **Host Organisations** - £200 set up plus £500 per participant completing all study activities, paid pro-rata if the participant withdraws early. The Statement of Activities and model non-

Section	HRA Assessment Criteria	Compliant with Standards?	Comments
			commercial agreement provide full details for host organisations. • **Participant Identification Centres** – £1.50 per invitation mailed • **Blood collection centres** - £10 per blood draw
5.1	Compliance with the Data Protection Act and data security issues assessed	Pending	Clarification will be sought on whether the sponsor will routinely have access to personal data of participants or if data will be pseudonymised, and whether collection of date of birth is necessary (or if age will suffice).
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Pending	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Pending	REC favourable opinion has yet to be issued. HRA Approval will not be issued until this is in place.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Pending	MHRA Clinical Trial Authorisation is not yet in place. HRA Approval will not be issued until this has been given.
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Yes	No comment

Clinical Support Service Assurance

A	Pharmacy technical assurance	Pending

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There are potentially up to three types of participating NHS organisations in this study:

- **Host organisations** – these organisations will recruit and consent participants, dispense the investigational medicinal products, and undertake all study activities, unless one of the following types of organisations is involved.
- **Participant Identification Centres (PICs)** – these organisations will deliver community heart failure services as part of routine clinical care. If the host organisation requests assistance in inviting potential participants, staff at community heart failure services may undertake a database search and mailshot. However, all further study related activities will occur at the host organisation.
- **Blood collection centres** – Nine study visits involve a blood draw only. If the participant prefers, this blood draw may be undertaken by their GP. The sponsor will provide blood collection kits and postage material, with the sample sent to the host organisation for analysis.

Study documents will not be shared with **blood collection centres** in England because activities are limited to a blood draw only, it is not known which centres will be involved until participant consent, and the GP will be provided with a letter from the host organisation following consent from the participant. No specific arrangements are expected to be put in place at each organisation to deliver the study.

The Chief Investigator or sponsor should share study documents with **host organisations** and **participant identification centres** in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England that are **host organisations will be expected to formally confirm their capacity and capability** to host this research.

- The sponsor should ensure that participating NHS organisations are provided with a copy of this letter and all relevant study documentation, and work jointly with NHS organisations to arrange capacity and capability whilst the HRA assessment is ongoing.
- Further detail on how capacity and capacity will be confirmed by participating NHS organisations, following issue of the Letter of HRA Approval, is provided in the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this appendix.

- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Participating NHS organisations in England that are **participant identification centres or blood collection centres are not expected to formally confirm their capacity and capability to host this research**.

- The HRA has informed the relevant research management offices that you intend to undertake the research at their organisation. However, you should still support and liaise with these organisations as necessary.
- It is expected that these organisations will become participating NHS organisations 35 days after the date of issue of this letter (no later than **12 March 2016**):
    - You may not include the NHS organisation if they provide justification to the sponsor and the HRA as to why the organisation cannot participate
    - You may not include the organisation if they request additional time to confirm, until they notify you that the considerations have been satisfactorily completed.
    - You may not begin the research at any participating NHS organisation in England until a Letter of HRA Approval has been issued.
- You may include NHS organisations in this study in advance of the deadline above where the organisation confirms by email to the CI and sponsor that the research may proceed, and a Letter of HRA Approval has been issued.
- The document "ADD TITLE AND LINK" provides information for the sponsor and NHS organisations on working collaboratively with NHS organisations in England where no formal confirmation of capacity and capability is expected, and the processes involved in adding new organisations.

Principal Investigator Suitability

This confirms whether the sponsor's position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England, and the minimum expectations for education, training and experience that PIs should meet (where applicable).

The sponsor position on training expectations (as detailed on the statement of activities) for all three types of participating NHS organisations in England are appropriate for this study. That is:

- **Host organisations** – A local PI is expected for host organisations. The PI and local research nurse will be provided with study specific training. Both will require GCP training, and the sponsor will accept evidence of NIHR CRN training in GCP.
- **Participant Identification Centres (PICs)** – no PI or LC is expected at PICs. Staff at PICs will receive guidance on eligibility criteria and general information about the study, but no further study training is expected. GCP is not a training expectation.
- **Blood collection centres** – No PI or LC is expected at blood collection centres. No formal study training is expected, although GPs will be given general study information, and information about potential blood draws upon participant consent, with details to contact the host organisation if further information is requested.

GCP training is not a generic training expected, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken.
The sponsor has confirmed that, in all three types of participating NHS organisations in England, local staff who have a contractual relationship with the organisation will undertake the expected activities. Therefore no honorary research contracts or letters of access are expected for this study.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England in study set-up.
• The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

Health Research Authority

Dr Arthur Smith
Red Heath Hospital NHS Trust
Red Heath Road
London
L1 4TT

Email: hra.approval@nhs.net

17 March 2016

Dear Dr Smith,

Letter of HRA Approval

Study title:	**DUMMY STUDY: To determine whether Drug A is more effective than Drug B in Chronic Heart Failure**
IRAS project ID:	**502136**
EudraCT number:	**1111-100000-22**
Protocol number:	**XX1234**
REC reference:	**16/HRA/9999**
Sponsor:	**Red Heath Hospital NHS Trust**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/.

Your IRAS project ID is **502136.** Please quote this on all correspondence.

Yours sincerely

Ms Ann Assessor

Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Richard Trust, Red Heath Hospital NHS Trust, Sponsor Contact*

Dr B Jones, R&D Department, Red Heath Hospital NHS Trust, Lead R&D Contact

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
GP/consultant information sheets or letters	1.0	13 January 2016
Letter of invitation to participant	1.1	22 February 2016
Validated questionnaire [Quality of Life Questionnaire]		
Participant consent form	1.1	27 February 2016
Participant information sheet (PIS)	2.0	27 February 2016
IRAS Form		1 February 2016
Research protocol or project proposal	2.0	27 February 2016
Summary CV for Chief Investigator (CI)	Dr Arthur Smith	8 January 2016
Template Agreement [model non-commercial agreement]		
SmPC [Drug A]		16 March 2015
SmPC [Drug B]		17 May 2015
Statement of Activities [Host Organisation]		13 January 2016
Schedule of Events [Host Organisation]		13 January 2016
Statement of Activities [Participant Identification Centre]		13 January 2016
Schedule of Events [Participant Identification Centre]		13 January 2016
Statement of Activities [Blood Collection Centre]		13 January 2016
Schedule of Events [Blood Collection Centre]		13 January 2016

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *agreement* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Dr B Jones, Red Heath Hospital NHS Trust, Tel: 0011123459, Email, b.jones@redheath.nhs.uk.

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No Comments
2.1	Participant information/consent documents and consent process	Yes	The participant information sheet has been updated to make clear to the participant the end of study arrangements in relation to provision of the investigational medicinal products. It has also been altered to clearly detail who will have access to their personal data for research purposes.
3.1	Protocol assessment	Yes	The protocol has been updated to clearly detail the end of study arrangements for provision of the investigational medicinal products, as well as the provisions in place to protect personal identifiable data of the participants.
4.1	Allocation of responsibilities and rights are agreed and	Yes	The sponsor intends to use a model non-commercial agreement with **host NHS organisations** in England.

Section	HRA Assessment Criteria	Compliant with Standards	Comments
	documented		Following review of the supplied template, the HRA has confirmed that the agreement is an unmodified version of the model non-commercial agreement. **Participant identification centres** and **blood collection centres** are not expected to formally confirm capacity and capability. Although formal confirmation of capacity and capability is not expected of all or some organisations participating in this study (see Confirmation of Capacity and Capability section for full details), and such organisations would therefore be assumed to have confirmed their capacity and capability should they not respond to the contrary, we would ask that these organisations pro-actively engage with the sponsor in order to confirm at as early a date as possible. Confirmation in such cases should be by email to the CI and Sponsor confirming participation based on the relevant Statement of Activities and information within this Appendix B.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	At the time of issue of the HRA Approval letter the sponsor has indicated that they will provide the following funds to participating NHS organisations in England, as detailed in the Statement of Activities: • **Host Organisations** - £200 set up plus £500 per participant

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			completing all study activities, paid pro-rata if the participant withdraws early. The Statement of Activities and model non-commercial agreement provide full details for host organisations. • **Participant Identification Centres** – £1.50 per invitation mailed • **Blood collection centres** - £10 per blood draw
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	It was unclear whether the sponsor will have access to personal identifiable information of participants. The sponsor has confirmed that they will only have access to pseudonymised data, and have changed data collection methods so to collect the age of the participant rather than the date of birth. This has been clarified in the participant information sheet and protocol
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Yes	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC favourable opinion with conditions was issued on 21 February 2016 with the conditions confirmed as met on 23 February 2016. A substantial amendment was submitted to the REC regarding the changes described above in 2.1, 3.1 and 5.1. Favourable opinion for the substantial amendment was issued by the REC on 16 March 2016.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Yes	No comments

Section	HRA Assessment Criteria	Compliant with Standards	Comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Yes	No comments

Clinical Support Service Assurance

A	Pharmacy technical assurance	Complete

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There are potentially up to three types of participating NHS organisations in this study:

- **Host organisations** – these organisations will recruit and consent participants, dispense the investigational medicinal products, and undertake all study activities, unless one of the following types of organisations is involved.
- **Participant Identification Centres (PICs)** – these organisations will deliver community heart failure services as part of routine clinical care. If the host organisation requests assistance in inviting potential participants, staff at community heart failure services may undertake a database search and mailshot. However, all further study related activities will occur at the host organisation.
- **Blood collection centres** – Nine study visits involve a blood draw only. If the participant prefers, this blood draw may be undertaken by their GP. The sponsor will provide blood collection kits and postage material, with the sample sent to the host organisation for analysis.

Study documents will not be shared with **blood collection centres** in England because activities are limited to a blood draw only, it is not known which centres will be involved until participant consent, and the GP will be provided with a letter from the host organisation following consent from the participant. No specific arrangements are expected to be put in place at each organisation to deliver the study.

The Chief Investigator or sponsor should share study documents with **host organisations** and **participant identification centres** in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from by participating NHS organisations in England.

Participating NHS organisations in England that are **host organisations will be expected to formally confirm their capacity and capability to host this research**.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Agreement* section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

The HRA has determined that participating NHS organisations in England that are **participant identification centres or blood collection centres are not expected to formally confirm their capacity and capability to host this research,** because a formal agreement with the sponsor is not expected for these types of activities.

- Sponsors should now provide a copy of this letter to those NHS organisations in England that it intends to work with. These NHS organisations should have already received the initial assessment letter from the HRA in order to assess or arrange capacity and capability.
- As stated in the Initial Assessment Letter (dated 6 February 2016), it is expected that these organisations will become participating NHS organisations 35 days after issue of the Initial Assessment Letter (no later than **12 March 2016**):
    - You may not include the NHS organisation if they provide justification to the sponsor and the HRA as to why the organisation cannot participate
    - You may not include the NHS organisation if they request additional time to confirm.
- You may include NHS organisations in this study in advance of the deadline above where the organisation confirms by email to the CI and sponsor that the research may proceed.
- The document "ADD TITLE AND LINK" provides further information for the sponsor and NHS organisations on working with NHS organisations in England where no formal confirmation of capacity and capability is expected, and the processes involved in adding new organisations. Further study specific details are provided the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this Appendix.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
The sponsor position and training expectations (as detailed on the statement of activities) for all three types of participating NHS organisations in England are appropriate for this study. That is: • **Host organisations** – A local PI is expected for host organisations. The PI and local research nurse will be provided with study specific training. Both will require GCP training, and the sponsor will accept evidence of NIHR CRN training in GCP. • **Participant Identification Centres (PICs)** – no PI or LC is expected at PICs. Staff at PICs will receive guidance on eligibility criteria and general information about the study, but no further study training is expected. GCP is not a training expectation. • **Blood collection centres** – No PI or LC is expected at blood collection centres. No formal study training is expectation, although GPs will be given general study information, and information about potential blood draws upon participant consent, with details to contact the host organisation if further information is requested. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken.
The sponsor has confirmed that, in all three types of participating NHS organisations in England, local staff who have a contractual relationship with the organisation will undertake the expected activities. Therefore no honorary research contracts or letters of access are expected for this study.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
• The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio. .