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Information and guidance for primary care sites on the purpose of a research CV

The purpose of this guide is to provide primary care research staff with guidance on the creation and maintenance of research CVs. It also explains how a research CV can be used by sponsors to verify the appropriateness of an individual person's role in a research project.

1. What is a CV?

A CV (also known as a Curriculum Vitae, or résumé), is a written overview of a person's skills, education, and work experience.

2. Why are CVs required for research?

Good Clinical Practice states that the Principal Investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the study and should provide evidence of such qualifications through an up-to-date curriculum vitae.

3. Why is a research CV different?

Normally a CV is an entire record of someone's experience and career, including publications and can be several pages long. However, for the purposes of research only relevant experience needs to be demonstrated so the CV is usually a maximum of 2 pages.

4. Who else needs to provide a research CV?

The study sponsor will specify which additional members of the local study team need to provide a CV. These CVs demonstrate that each member of the study team at site is qualified by education, training, and experience to conduct the research. The CV supports

their ability to carry out tasks that are delegated to them by the Principal Investigator. The national template should be used unless a research sponsor provides their own CV template.

5. Where are research CVs stored?

The Principal Investigator's CV is an essential document required prior to study set up. A signed copy is stored in the sponsor's Trial Master File. A signed copy of the PI and study team CVs are also filed in the Investigator Site File (ISF)/electronic ISF at the study site.

6. How often do research CVs need updating?

At study set-up the study sponsor will ask for a current research CV. This should be signed and dated. The sponsor may also ask for the research CV to be periodically updated annually. If there are no changes to the content, it can simply be re-signed and dated.

7. Where can I find out more about research CVs?

Further information regarding research CV and template can be found at:

<https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/> (accessed 06/02/2023).

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-good-clinical-practice-e6r2-step-5_en.pdf section 4.1.1 (accessed 06/02/2023).

8. Who do I contact if I have further questions?

For any questions, please email: rdu@shsc.nhs.uk