

## ECTU Central Office POL05: Health Economics Activity Classification

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Authorship and Approval			
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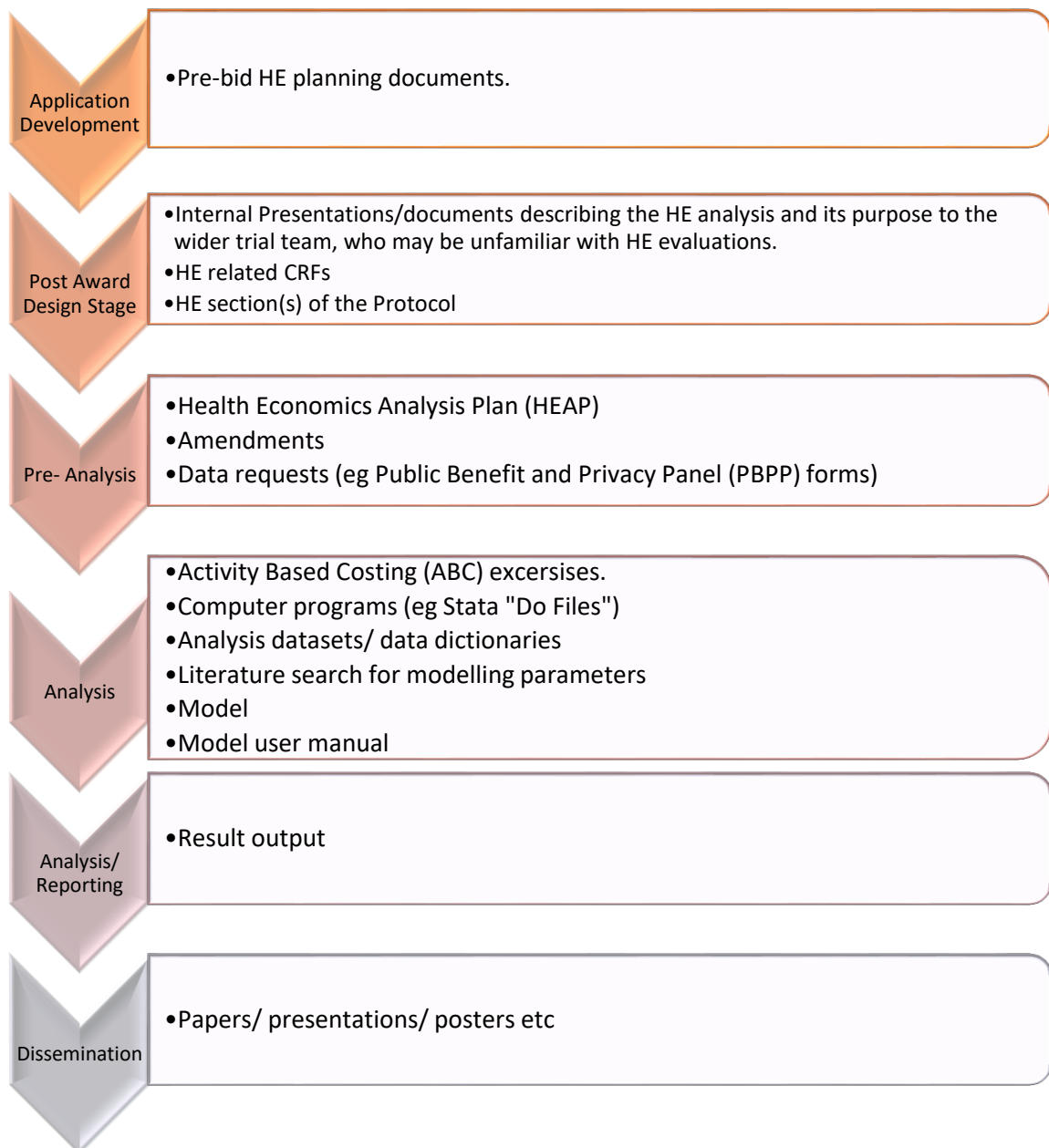
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1.0	18 Dec 2024	Initial Creation

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## 1.0 PURPOSE

Health economics evaluation alongside clinical trials can serve as an important tool to assess the cost effectiveness of any health technologies, services, and/or procedures being assessed. It provides key information to aid policy makers in decisions about which interventions to licence/rollout when new evidence is generated.

As the ICH guidelines for Good Clinical Practice and The Medicines and Healthcare Products Regulatory Agency (MHRA) have not clearly specified their requirements in this department, this policy aims to map out the health economic evaluation processes typically undertaken for an adopted ECTU project in order to identify a standardised structure for planning, designing/ modelling, analysing, and recording/ storing project documentation.



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## 2.0 SCOPE

This policy applies to all health economics employees working for the University of Edinburgh at the Edinburgh Clinical Trials Unit (ECTU).

This policy will be reviewed every 2 years.

## 3.0 POLICY

Some of the key health economics evaluation processes mapped out graphically above, have been detailed below:

Title	Description
<b>Planning Documents</b>	The health economics Planning Documents refers to any materials generated during the grant application process when the initial study designs are being discussed. They often contain summaries and diagrams of design plans which are maybe developed, and adapted to form sections of the HEAP (Health Economics Analysis Plan) and/or the protocol in order to maintain consistency across the project with what was promised in the grant application.
<b>Health Economics Related CRFs</b>	The Case Report Form (CRF) is used for the collection of data within the project and this information can be used to guide the analysis specified in the HEAP. The health economists use a wide variety of the data from the project in their analyses particularly when using models. They may need to add additional variables, particularly health care resource use/cost, to data collection when the economist is involved in a project. As such, the Lead Economist for the project should be involved in the development of the CRFs.
<b>HEAP (Health Economics Analysis Plan)</b>	The purpose of the HEAP is to describe the analysis and reporting procedure intended for the economic analyses to be undertaken. The analysis plan is designed to ensure that there is no conflict with the protocol and associated SAP and it should be in conjunction with them.
<b>Computer programs used to run analysis</b>	Refers to the programming code used to format data for analysis and run within a project analysis. For example, Stata' "Do Files" or "R Scripts".
<b>Modelling</b>	Decision analytic modelling in this context refers to a suite of simulation modelling techniques used to combine and synthesise evidence, potentially from a broad range of sources, to undertake economic evaluations. In the field of clinical trials, this is commonly undertaken to extrapolate health outcomes beyond what is feasible to observe within the trial to account for the long-term outcomes of treatments, such as survival rates after successful cancer treatment. Such

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	extrapolations often necessitate assumptions, and the modelling frameworks allow transparency and scrutiny of the methods employed.
<b>Result output</b>	This represents the final outcome of the analysis and reporting. There are various formats that the result output can be presented in the HEAP (for example, documents, tables etc). This will form a part of the final project report.
<b>Filing and Storage</b>	The health economics files will be saved in the appropriate section of the TMF (Section 9) and archived.

#### 4.0 RELEVANT DOCUMENTS AND REFERENCES

- <https://www.gov.uk/guidance/health-economics-a-guide-for-public-health-teams>
- [https://methods.cochrane.org/sites/methods.cochrane.org/economics/files/uploads/ccemg\\_website\\_glossary.pdf](https://methods.cochrane.org/sites/methods.cochrane.org/economics/files/uploads/ccemg_website_glossary.pdf)
- <https://pubmed.ncbi.nlm.nih.gov/33840432/>

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Final Audit Report

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