Harmonised approach to **E**arly **F**easibility **S**tudies for Medical Devices in the **E**uropean **U**nion **(HEU-EFS)**

WP6 - Methodology development: ethical and legal aspects

DELIVERABLE 6.2

Set of templates for the EU EFS Programs – Insurance Agreement Guideline

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Insurance agreement Guideline

When considering insurance contracts for subjects participating in Early Feasibility Study (EFS) on Medical Devices, several preliminary considerations must be made.

Firstly, it is important to highlight that sponsors and investigators typically have limited negotiation in early feasibility contracts, as contractual terms are generally dictated by the insurance companies through standardised conditions.

Secondly, due to the specific and innovative nature of EFS, only a limited number of insurance providers may be willing to underwrite the associated risks. This can lead to a lack of competition in the insurance market and reduced options for coverage.

Therefore, to strike the various interests at stake–namely, securing comprehensive protection at a reasonable cost while ensuring broad coverage – it is advisable to opt for insurance policies that explicitly cover damages arising from the use of the investigational device. Such policies should ideally include:

- Coverage for the risk of the subject's death and related damages, including compensation to relatives;
- Coverage for the risk of serious injury to the subject;
- Coverage for the risk of minor injury;
- Coverage for the costs of medical care in the event of both serious and minor injuries.

In all cases, the damage must be a direct consequence of the use of the investigational device.

It is also worth noting that insurance contracts frequently include exclusions for events deemed foreseeable based on known or knowable effects. However, given the exploratory nature of EFS—where data on potential adverse events or harmful effects is often scarce or unavailable—it is recommended that such exclusions be minimised as much as possible to ensure adequate protection for study participants.

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