

Standard Code of Practice for the HSE Research Governance, Management and Support Function – Finance

Finance

The Financial responsibility for a Study at the research site can be complex as Research Studies may sit within larger projects and/or may be multi-site studies. For clarity, it is best to look at the entire picture, moving from the funding source downwards to examine where responsibilities lie. Research studies may receive funding from a number of sources for example, internal commissioning, grant funding (exchequer and non-exchequer) or commercial entities such as pharmaceutical companies. In certain circumstances, and subject to the Funders' Terms and Conditions a study may receive funding from more than one Funder providing the activities funded are complementary (co-funded study).

For commercially funded studies, the commercial company is usually the Legal Entity responsible for ensuring that the agreed funding is in place for the entire study and continues to be available for the duration of the study. The lines of responsibility then follow any agreements, letters of understanding etc. in place which should also echo the flow of funding. For example funding may be transferred directly to the site, under an agreement, for the conduct of the study at site, the site PI would then have accountability for spend and budget at the site, also, if relevant, any reporting and invoicing required. The site is then the entity responsible for site finances and for meeting the terms and conditions of the agreement under which the funding was transferred.

For grant funded research studies, the Lead institution (The institution who has been awarded the grant) is the Legal Entity responsible for ensuring that, subject to the terms and conditions of the Research Grant, the funding is in place and continues to be available for the duration of the project. The lines of responsibility then follow any agreements, letters of understanding etc. in place, which should also echo the flow of funding. For example funding may be transferred, under an agreement, to an academic institution aligned to the site to support the conduct of the study at site. The institutional PI then has accountability for spend and budget at the site and any relevant reporting and invoicing required. The academic partner is then the entity responsible for site finances and for meeting the terms and conditions of the agreement with the lead institution, for example the funder may require for segregated 'study specific' accounts to be set up, or appropriate segregation/recognition of study specific expenditures.

Note: Currently the HSE is not an approved Host Institution under Funding Schemes run by certain Irish research funding agencies for example HRB and SFI. A Host Institution is a research performing organisation (RPO) that is approved by a funding body for the purpose of receiving and administering grant funding.

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When assessing the funding available for the conduct of a study at site it is important to both examine if the overall funding available is in keeping with the scope, requirements of the study and also if the funding available to site is sufficient to conduct the study at site, for example if additional (to standard of care) assessments, blood tests etc. are required is funding available to cover the cost implications or has the site agreed to cover the cost.

The case of In-Kind contribution, alone or as co-funding: It is important to note that even when the HSE does not receive or provide cash funding towards a study, it always provides in-kind contribution through the time spent (unless salaries are paid/reimbursed from the Funder) by the HSE PI, HSE team members, including auxiliary functions for example for European Commission projects the Project Legal Signatory (PLSIGN) and Project Financial Signatory (PFSIGN) involved in the study. In-kind contribution may be either reported or used as Co-Funding when required by Funders. Specific records such as time-sheets, copy of payslips, etc. may apply.

As with any agreement with financial implications expert advice should be sought as to whether the contract/grant agreement is VATable at if so what rate of VAT should apply.