



LEES Chartered Certified Accountants
and Registered Auditors (#0361133)

Karolinska Institutet

Review of NIH Projects for Federal Compliance

1 January 2023 to 31 December 2023



**Karolinska
Institutet**

1. INTRODUCTION

1.1 Letter of Instruction

In accordance with Karolinska Institutet's written instructions dated 23 October 2024, we have conducted a review of arrangements for effective management of research grants from the United States National Institutes of Health.

1.2 Scope of Work and Limitations

Our work focused on the areas specified by Appendix XI – "Compliance Supplement" of Section 2 of the United States Code of Federal Regulations – pt. 200 (2 CFR 200). The management of the Institutet is responsible for the Institutet's compliance with these requirements. We have conducted programme specific audits to test the following:

- The integrity of the financial statements;
- The effectiveness of the internal control structure, including controls over the grants;
- Compliance with the terms and conditions of the grants and other agreements; and
- Follow up of prior audit findings.

The scope of our work has been limited both in terms of the areas and operations which we reviewed, and the extent to which we have reviewed them. There may be matters, other than those noted in this report, which may be relevant in the context of the report and which a wider scope might uncover.

The engagement was performed in accordance with the International Standard on Related Services 4400 "Engagements to Perform Agreed-upon Procedures Regarding Financial Information" and with applicable national standards.

This report is made solely to Karolinska Institutet for the purpose of certifying certain costs claimed and may not be relied upon for any other purpose whatsoever. To the fullest extent permitted by law, we do not accept nor assume responsibility to anyone (including the funding body) other than Karolinska Institutet for this report, or the opinions we have formed.

Our work was conducted remotely for 2023.

1.3 Limitation of Liability

We draw your attention to the limitation of liability clauses in our engagement letter.

1.4 Forms of Report

For convenience, this report may be made available in electronic as well as hard copy format. Multiple copies and versions of this report may exist in different media.

1.5 Confidentiality

This report is confidential and has been prepared exclusively for Karolinska Institutet.

2. EXECUTIVE SUMMARY

2.1 Inherent Risk of Karolinska Institutet

This Single Audit on NIH projects is part of a series of activities undertaken at the Institutet to ensure that research funding is effectively managed and controlled. Karolinska Institutet's dedicated "Research Support" office aims to help researchers manage research funding from a variety of sources. Numerous internal and external audits have been performed at the Institutet, with no material weaknesses identified.

2.2 Testing Sample & Sample Size

We have assessed Karolinska Institutet to be an overall "low-risk" assignment on the basis that NIH reviews have been carried out previously, with no significant findings. Karolinska Institutet's expenditure on active NIH federal awards for 2023 totalled \$5,986,733.31 across 42 projects (Appendix B). Of this, 9 projects were chosen for expenditure sampling. Expenditure was sampled totalling \$2,856,287.30 (47.7%) in accordance with Uniform Guidance pt. 200 (2 CFR 200).

2.3 Single Audit Compliance Requirements

Uniform Guidance compliance covers fourteen key areas, some of which cannot be entirely applied to Karolinska Institutet as an organisation foreign to the US, and subject to Swedish and EU legislation. Each area is summarised below:

	Compliance Requirement	Internal Controls Testing	Compliance Testing
A	Activities Allowed or Unallowed	✓ (Satisfactory)	✓ (Satisfactory)
B	Allowable Costs/Cost Principles	✓ (Satisfactory)	✓ (Satisfactory)
C	Cash Management	✓ (Satisfactory)	✓ (Satisfactory)
D	[Reserved]	N/A – Reserved for possible future compliance	
E	Eligibility	✓ (Satisfactory)	✓ (Satisfactory)
F	Equipment & Real Property Management	✓ (Satisfactory)	✓ (Satisfactory)
G	Matching, Level of Effort, Earmarking	N/A – Not relevant for these awards	
H	Period of Availability of Federal Funds	✓ (Satisfactory)	✓ (Satisfactory)
I	Procurement & Suspension & Debarment	✓ (Satisfactory)	✓ (Satisfactory)
J	Programme Income	N/A – No such income	
K	[Reserved]	N/A – Reserved for possible future compliance	
L	Reporting	✓ (Satisfactory)	✓ (Satisfactory)
M	Sub-Recipient Monitoring	✓ (Satisfactory)	✓ (Satisfactory)
N	Special Tests & Provisions	N/A – No such tests with these awards	

3. INHERENT RISK OF KAROLINSKA INSTITUTET

3.1 Research Support Office

Karolinska Institutet has a dedicated Research Support Office which aims to help researchers manage research funding from a variety of sources.

The Office is responsible for all internal and external reporting on the financial aspects of research, including supporting Principal Investigators in meeting financial assurance requirements. The Office acts as an independent function ensuring financial separation of duties between themselves and the researchers where project delivery takes place.

The Office is separated into several divisions, including the Grants Management Office, responsible for the day-to-day Post-Award financial management of grants, and the Compliance and Data Office who take an institutional role in central policies and regulatory Compliance. Karolinska Institutet have dedicated staff devoted to US grant compliance, and regularly attend training in US grants compliance to ensure continued conformity to regulations.

3.2 Research at Karolinska Institutet

Karolinska Institutet accounts for the single largest share of all academic medical research conducted in Sweden. Research activities span the entire medical field, from basic experimental research to patient-oriented research and global health. The Nobel Assembly at the Karolinska Institutet awards the Nobel Prize in Physiology or Medicine.

The Institutet has over 45 official research centres, including 4 National and International Research Centres of excellence:

- National Centre for Suicide Research and Prevention, NASP
- International Neuroinformatics Coordinating Facility, INCF
- Karolinska Comprehensive Cancer Centre
- Centre of Excellence for Sustainable Health

The Institutet's activities are dominated by research activities, and they comprise approximately 84% of total turnover.

3.3 Project Income

At the end of 2023, Income related to competitive projects across the whole Institute was 3,735,023,000 SEK (approx. \$398m) per appendix A.

5. UNIFORM GUIDANCE COMPLIANCE REQUIREMENTS

Compliance covers fourteen key areas, some of which cannot be entirely applied to Karolinska Institutet as an organisation foreign to the US and subject to Swedish and EU legislation. Each area is identified and documented below.

5.1 Activities Allowed or Unallowed (A)

An understanding of Karolinska Institutet's internal control was obtained to allow us to plan the audit to a "low-risk" assessment. Based on this assessment, each expense activity across all NIH Federal projects reviewed was tested to ensure its activity was allowable (in accordance with the Terms & Conditions of the Grant Award), and properly classified and accumulated into the activity total. No large transfers of funds from programme accounts were identified which may have been used to fund unallowable activities.

CONCLUSION:

- Internal control was assessed and tested as required.
- Each of the samples of Federal awards tested was expended only for allowable activities.

5.2 Allowable Costs/Cost Principles (B)

An understanding of Karolinska Institutet's internal control was obtained to allow us to plan the audit to a "low-risk" assessment. Based on this assessment, each expense cost across all NIH Federal projects reviewed was tested to ensure its cost was allowable (in accordance with the Terms & Conditions of the Grant Award). This covered expense costs such as direct costs, salaries & wages, equipment, and facilities & administrative (indirect) costs.

CONCLUSION:

- Internal control was assessed and tested as required.
- Each of the samples of Federal awards tested was expended only for allowable costs. We noted 3 advisory findings across questioned costs totalling \$172.45, per Section 6.

5.3 Cash Management (C)

An understanding of Karolinska Institutet's internal control was obtained to allow us to plan the audit to a "low-risk" assessment. All 9 of the projects were funded on a reimbursed payment basis. A sample of reimbursement requests were traced to supporting documentation to show that the costs for which reimbursement was requested were paid prior to the date of the reimbursement request. No pre-financing interest was earned on Federal Funds drawn down, as all draw-downs were in arrears.

CONCLUSION:

- Internal control was assessed and tested as required.
- For the sample tested, costs for which reimbursement was requested were paid prior to the date of the reimbursement request.
- One isolated draw-down was irreconcilable, due to a keying error, totalling an under-draw of \$777.03, as stated in Section 6.

5.4 [Reserved] (D)

This Compliance Requirement is no longer applicable to Single Audits conducted under 2 CFR 200.

5.9 Procurement and Suspension and Debarment (I)

An understanding of Karolinska Institutet's internal control was obtained to allow us to plan the audit to a "low-risk" assessment. Karolinska Institutet is required to comply with their own internal procurement procedures and thresholds, which are consistent with 45 CFR 75 §329.

Karolinska Institutet is also required to comply with EU Directive 2004/18/EC, which requires all contracts over €214,000 (\$260,000) for services and supplies, and €5,350,000 (\$6,515,000) for works, to be put out to tender.

CONCLUSION:

- Internal control was assessed and tested as required.
- Karolinska Institutet meets the Federal and EC requirements with regards to public procurement.

5.10 Programme Income (J)

Programme income is gross income received that is directly generated by the federally funded project during the grant period, of which Karolinska Institutet had none for the projects sampled in the year under review. This Compliance Requirement is therefore irrelevant for Karolinska Institutet.

CONCLUSION:

- This Compliance Requirement is not applicable to Karolinska Institutet.

5.11 [Reserved] (K)

This Compliance Requirement is no longer applicable to Single Audits conducted under 2 CFR 200.

5.12 Reporting (L)

An understanding of Karolinska Institutet's internal control was obtained to allow us to plan the audit to a "low-risk" assessment. For the 9 projects reviewed, each declaration of expenditure was verified to the accounting system and supporting worksheets, and mathematically checked for accuracy.

CONCLUSION:

- Internal control was assessed and tested as required.
- Required reports for Federal reports include all activity of the reporting period, which are supported by applicable accounting records, and are fairly presented in accordance with governing requirements.
- We noted over-reporting of eligible costs totalling \$31,530.20 as per Section 6 due to isolated errors.

6. FINDINGS & QUESTIONED COSTS 2023

Compliance Requirement	Finding & Implication	Project Reference	Rating	Proposed Action	Agreed Action
1 B- Allowable Costs/Cost Principles	<p>For 1 of the projects tested, it was noted that the rates charged for the use of some Specialized Service Facilities were inclusive of inallocable indirect costs. The institution's indirect costs associated with these service facilities were not adequately documented for them to be considered eligible. The amounts totalled \$133.29</p> <p>It was noted that usual practice was to remove the indirect costs element of the charges, and thus this error is not systemic.</p>	K830261313 - \$133.29	Actionable	<p>These were isolated errors and the costs will be refunded. KI may opt to review their indirect costs methodology in respect of Specialized Service Facilities such that future charges may become eligible. However, their current intentions are to continue to exclude such costs from charges and claims.</p>	<p>KI will review the charging methodologies and supporting evidence retained for this specific internal service, and continue to ensure that relevant supporting evidence is retained for expenditure reported.</p> <p>These will be deducted from the next claim.</p>
2 B- Allowable Costs/Cost Principles	<p>For 1 of the projects tested, costs totalling \$39.16 lacked sufficient supporting financial evidence</p> <p>This error is not systemic.</p>	C62610133 - \$39.16	Actionable	<p>These were isolated errors and the costs will be refunded. We recommend KI continue to review expenditure ledgers thoroughly before claims are made to ensure that only fully evidenced costs are included in reports.</p>	<p>KI understands that costs can only be claimed on NIH projects that are directly attributed to the project.</p> <p>These will be deducted from the next claim.</p>

Compliance Requirement	Finding & Implication	Project Reference	Rating	Proposed Action	Agreed Action
5 L - Reporting	For 1 Project tested, we noted that Reported costs were overstated due to a calculation error when deriving eligible F&A. F&A costs were double-reported, totalling \$3,994.59. This error is not systemic.	C850068203 - \$3,994.59	Actionable	We recommend that reports are fully reconciled to ledgers prior to making FFRs, and check balances are added to F&A calculations.	KI understands this finding and will ensure requirements are communicated accordingly. The costs will be corrected on future reports.
6 L - Reporting	For 2 Projects tested, we noted that reported costs had been duplicated in error. The double-reported costs totalled \$29,088.56 This error is not systemic.	C850068203 - \$10,487.93 C62610133 - \$18,600.63	Actionable	We recommend that reports are fully reconciled to ledgers prior to making FFRs, including a cumulative reconciliation to ensure that no costs are double-reported.	KI understands this finding and will ensure requirements are communicated accordingly. The costs will be corrected on future reports.
7 L - Reporting	For 1 Project tested, we noted that Reported costs were understated due to a calculation error when preparing the report. The items omitted from the report totalled \$1,552.95. This error is not systemic.	OF14105033 - (\$1,552.95)	Actionable	We recommend that reports are fully reconciled to ledgers prior to making FFRs, including a cumulative reconciliation to ensure a complete picture is retained.	KI understands this finding and will ensure requirements are communicated accordingly. The costs will be corrected on future reports.
TOTAL Actionable	\$30,925.62				

Compliance Requirement	Finding & Implication	Questioned Costs /\$	Rating	Agreed Action	Action Performed?
<p>202203 B – Allowable Costs/Cost Principles</p>	<p>For 1 of the projects tested, it was noted that the rates charged for the use of some Specialized Service Facilities were inclusive of inallocable indirect costs. The institution's indirect costs associated with these service facilities were not adequately documented for them to be considered eligible. The amounts totalled \$6,937.35.</p> <p>It was noted that usual practice was to remove the indirect costs element of the charges, and thus this error is not systemic.</p>	<p>H2416353 - \$6,937.35</p>	<p>Actionable</p>	<p>KI will review the charging methodologies and supporting evidence retained for this specific internal service, and continue to ensure that relevant supporting evidence is retained for expenditure reported.</p> <p>These will be deducted from the next claim.</p>	<p>H2416353 - \$6,937.35 - Correction has been processed and netted from eligible costs in the final draw.</p>
<p>202204 B – Allowable Costs/Cost Principles</p>	<p>For 1 of the projects tested, we noted that costs not in accordance with the Institution's Travel Policies were included, to the value of \$130.26.</p> <p>This error is not systemic.</p>	<p>K926245053 - \$130.26</p>	<p>Actionable</p>	<p>KI will require that department staff certify that they have followed internal policies related to travel before travel costs are charged to Federal Awards. These costs are covered by the favourable finding for this project which will not be claimed, so no repayment is required.</p>	<p>K62995203 - \$130.26 - Refund has been processed.</p>

Compliance Requirement	Finding & Implication	Questioned Costs /\$	Rating	Agreed Action	Action Performed?
202102 B-Allowable Costs	For 1 of the projects tested, costs totalling \$169.93 were found not to be directly related to the delivery of the project. These errors are not systematic.	C173146453 - \$169.93	Advisory	KI understand that costs can only be claimed on NIH projects that are directly attributed to the project. These will be deducted from the next claim.	C173146453 - \$169.93 – Refund has been processed.
TOTAL		2022: 7,599.04 2021: \$181.48			Resolved: \$6,356.70 Unresolved: \$1,423.82

APPENDIX B – SCHEDULE OF EXPENDITURES OF NIH AWARDS 2023

Internal Reference	Federal Agency	FAIN	Prime Awardee	Subrecipients	ALN #	Amount Expended /\$	Amount Provided to Sub-Recipients /\$	Sampled /\$
1	HHS	1R01MH122544	KI	Virginia Commonwealth University	93.242	259,796.46	48,774.71	258,536.23
2	HHS	5R01HD088393	The General Hospital Corporation/The Brigham and Women's Hospital		93.865	17,172.48	-	-
3	HHS	5R01DA048042	Trustees of Indiana University		93.279	101,456.16	-	-
4	HHS	5R01AG060470	The University of Southern California		93.866	89,212.35	-	-
5	HHS	5R01AG059329	The University of Southern California		93.866	60,982.95	-	-
6	HHS	1R01AG068390	The General Hospital Corporation/The Brigham and Women's Hospital		93.866	2,668.35	-	-
7	HHS	1R01MH123724	University of North Carolina at Chapel Hill		93.242	154,437.02	-	-
8	HHS	U01CA164947	Trustees of the University of Pennsylvania		93.393	13,709.72	-	-
9	HHS	5R01MH097849	Ichan School of Medicine at Mount Sinai		93.242	3,001.65	-	-
10	HHS	1R01HD098883	Ichan School of Medicine at Mount Sinai		93.865	103,228.89	-	-



	Internal Reference	Federal Agency	FAIN	Prime Awardee	Subrecipients	ALLN #	Amount Expended /\$	Amount Provided to Sub-Recipients /\$	Sampled /\$
28	C173146413	HHS	1UM1A1144462	Scripps		93.855	90,166.90	-	-
29	C173146453	HHS	1P01A1157299	Scripps		93.855	307,848.07	-	269,250.87
30	C127236443	HHS	R01A115897	Triad National Security, LLC		93.855	228,704.60	-	-
31	C178821363	HHS	1R01CA258324-01	Rockefeller University		93.242	336,351.73	-	-
32	K830261313	HHS	R01AA028549	KI	Scripps; Beckman Research Institute of the City of Hope	93.273	452,962.82	307,408.14	431,447.71
33	H2416363/H165536013	HHS	R01AG065209	KI		93.866	514,562.00	-	-
34	K822204003	HHS	R01MH118245	Yale University		93.242	149,234.53	-	-
35	K830724083	HHS	R01MH110427	University of North Carolina at Chapel Hill		93.242	27,622.97	-	-
36	C333740013	HHS	F32DE029662	KI		93.121	12,552.53	-	-
37	C62610133	HHS	R01TS000324	KI	Icahn School of Medicine at Mt Sinai	93.161	562,527.59	282,767.19	562,450.69
38	C225014933	HHS	R15A1154248	Florida Atlantic University		93.855	33,158.32	-	-
39	C233082533	HHS	1UM1MH130981	Allen Institute		93.242	214,848.24	-	-
40	C62610213/K95157015		1R01NS131433	Drexel University		93.853	102,974.00		
41	K822358073		5P30AG064198	Columbia University		93.866	10,978.87		
42	C45050163	HHS	2R01NS064964	KI		93.853	329,911.70	-	322,064.99
				TOTAL			5,986,733.31	638,950.04	2,856,287.30
				Total Value of Projects Sampled					3,232,921.15
				# Projects Sampled					9