

The institutionalisation of principles of equitable partnerships by large international funders – naivety or lack of commitment?

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Introduction: Background to SU as case study

- Call for public feedback on NIH's Updated Policy for Subaward and Consortium Agreements¹- deadline 26 June 2023
- Abstract submitted before 26 June 2023 - reflected on potential implications.
- Feedback submitted to NIH on 23 June 2023 and some subsequent concessions made².
- Critically evaluate impact of funder's requirements on an LMIC university against the backdrop of WCRI Cape Town Statement³ and TRUST Code⁴.
- Significant increase in contract complexity due to increased sponsor compliance complexity, due diligence requirements & different legislative frameworks⁵⁻⁹.
- Limited capacity in LMICs to drive compliance (and compliance oversight over own activities) - acutely raises risk management concerns⁵⁻⁹.



Aims and Motivation

- 70% SU's research funding from international funding agencies. SU is 8th largest foreign recipient of NIH funding¹⁰.
- Varying compliance stringencies from funders globally - USA by far the strictest.
- Impact of unrealistic compliance requirements is a threat to SU's research activity (S889 & NIH's Updated Policy for Subaward and Consortium Agreements).
- Increased, complex and unbalanced compliance landscape - leads to unfair and inequitable practices and partnerships contrary to NIH values (ESSENCE of which NIH is a member)¹¹.



Context: Equitable partnerships

- *“ESSENCE is guided by the principle that good health is an essential foundation for social and economic development and that the attainment of self-reliance in research and development in low- and middle-income countries is key to sustainability. Low- and middle-income countries should not have to rely on the purchase or import of technologies and skills, rather scientific and development cooperation should aim to empower them to develop their own educational systems and institutional frameworks in order to become self-sufficient in efforts to reduce health inequalities”¹¹.*



Context: NIH requirements - highlights

- Section 15.2 Administrative and Other Requirements: *“For foreign subrecipients, a provision requiring the foreign subrecipient to **provide copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report. These supporting materials must be provided to prime recipient with each scientific update** (no less than once every six months, or more frequently based on risks) in line with the timelines outlined in the agreement¹.”*

Updated Policy Guidance

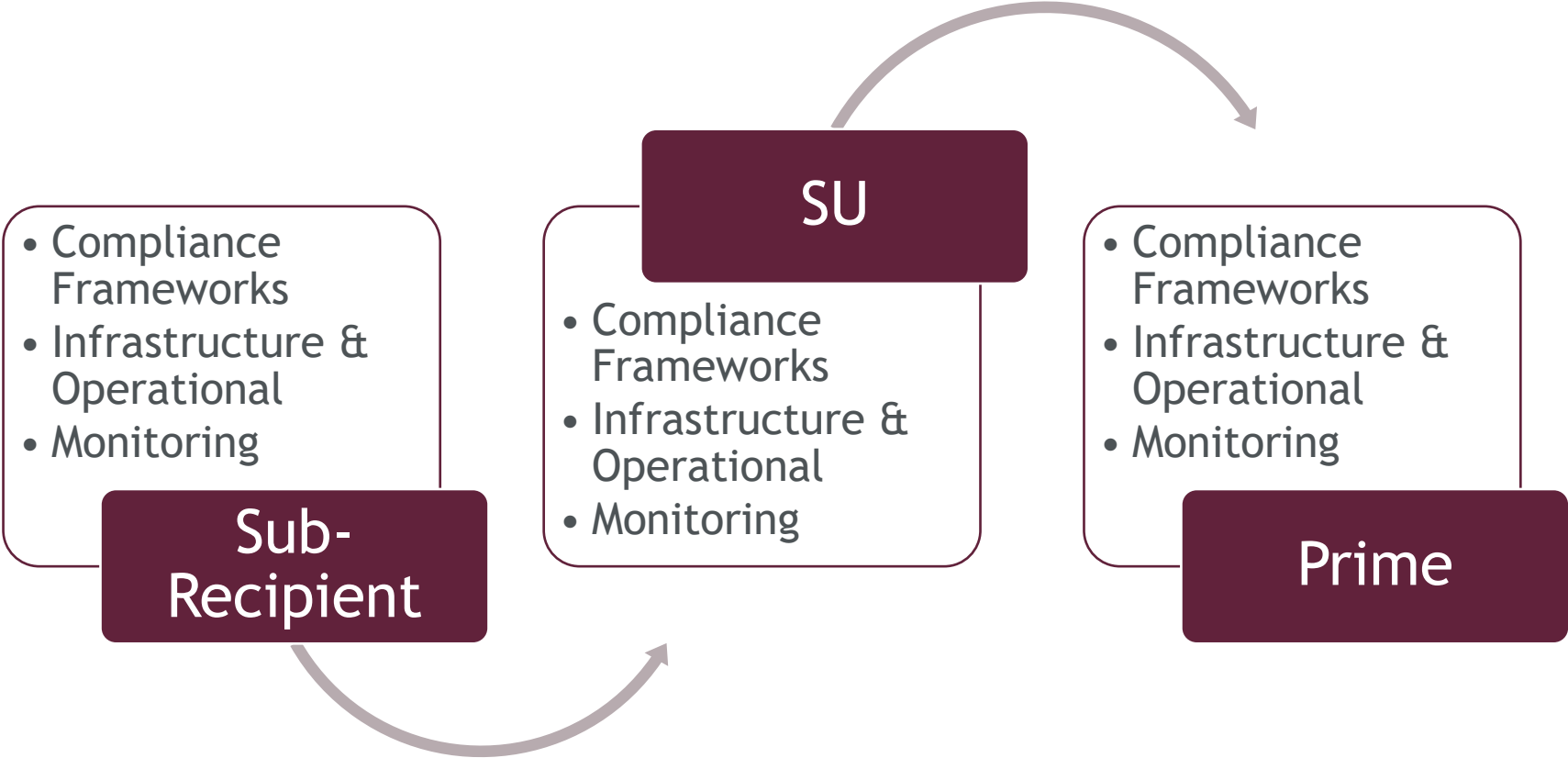
Therefore, effective January 1, 2024, section 15.2 will be updated to include the following clarifications (changes are **bold** and *italicized*):

15.2 ADMINISTRATIVE AND OTHER REQUIREMENTS

- Section 15.2.1 *“For foreign subrecipients, a provision requiring the foreign subrecipient to provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report, to the primary recipient with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic².”*



Method: Categories and roles



Interpretation and Analysis

Questions raised:

- Why is the monitoring of compliance required?
- What does the NIH (USA federal government) intend?
- Where is the balance between trust and monitoring?
- Excessive requirements - is this due to mistrust (real or misplaced) or non-compliance and misconduct by foreign (non-USA) partners?
- What is the point when excessive compliance requirements will lead to non-compliance?
- Do foreign institutions make a significant contribution to global public health?
- Did NIH consider the implications for non-foreign institutions and the impact on equitable partnerships?
- How will SU be able to comply?



Analysis of Impact: SU as Sub-Recipient

Compliance Frameworks

- Clash in legislation
- Unwillingness to agree to SA jurisdiction - POPIA¹² & Gazette Code of Conduct
- Data collection, transfer, use, security, management & 3rd party access /use
- Contracts
- Restricted use & access to Provincial Health Data Centre - no transfer of data permitted

Infrastructure & operational

- Resources: Infrastructure & Administrative
- Lab books - copying
Biosafety - prohibits copying of lab books
- SA context - 12 languages + dialects - additional translation burden
- Additional Financial burden on SU (not FEC)

Monitoring

- Too onerous
- Concern to share know-how without control over Prime's use of it
- POPIA - SU required to monitor storage, access, use and disposal of data by Prime
- Prior authorization from Regulator for sharing practices & limits on further processing - POPIA



Analysis: Most critical complications for SU as Sub-Recipient

- Reduced participation rates
- Increased compliance & monitoring requirements – SU may not opt out of its legislative requirements, which include monitoring & managing 3rd party risk
- Reduced ability to employ certain privacy-forward or security good practices (anonymisation and pseudonymisation) to manage compliance & information security risks / enable further processing of personal data
- No control over what the Prime recipients do with our know-how and raw data



Analysis: Push towards openness and transparency

COMMENT | 24 March 2023

The Cape Town Statement on fairness, equity and diversity in research

The benefits of scientific collaboration are too often skewed towards wealthier countries. Bioethicists and others present guidance on how stakeholders such as researchers can change this.

By [Lyn Horn](#) , [Sandra Alba](#), [Gowri Gopalakrishna](#), [Sabine Kleinert](#), [Francis Kombe](#), [James V. Lavery](#) & [Retha G. Visagie](#)

“Even the push towards openness and transparency in science publishing — which many have argued is a way to foster greater integrity in research — has created more barriers for investigators in low-resource environments.

Sharing data, for example, requires having enough institutional infrastructure and resources to first curate, manage, store and (in the case of data relating to people) encrypt the data — and to deal with requests to access them. Also, the pressure placed on researchers of LMICs by high-income-country funders to share their data as quickly as possible frequently relegates them to the role of data collectors for better-resourced teams. With enough time, all sorts of locally relevant questions that were not part of the original project could be investigated by local researchers. But, well-resourced investigators in high-income countries — who were not part of the original project — are often better placed to conduct secondary analyses¹³. ”



Analysis of Impact: SU as Prime and non-US as Sub-Recipient

Compliance Frameworks

- Escalated privacy regulations - many collaborators from other countries as Sub-Recipients
- Other countries' privacy legislations (i.e. GDPR¹⁴)
- Heightened security risk
- Contracts

Infrastructure & operational

- Escalated Infrastructure requirements - comply with SA and other countries' privacy laws where SU acts as Prime: Curate, manage, encrypt and store
- Storage size
- Additional Financial burden on SU (not FEC) - for monitoring of Subs and SU infrastructure and resources
- LMIC Sub-Recipients have similar challenges as SU as Sub

Monitoring

- Too onerous
- Prime Recipient responsibilities
- Monitoring Sub's compliance with NIH policies
- Controller vs Processor responsibilities & accountabilities
- Prior authorisation from regulators such as GDPR



Analysis: Most critical complications on SU as Prime-Recipient

- Possessing the required institutional infrastructure and resources to curate, manage, encrypt and store data with adherence to other countries' privacy laws (such as GDPR) - increased compliance & monitoring requirements and risk exposure of non-compliance
- Monitoring of compliance of Sub-Recipients regarding sharing of data and documentation – for what purpose does the NIH require the Prime to collect it? Level of inspection required by Primes – cost implications.



Recommendations

- Data, documentation and lab books made available by Subaward institutions for inspection/audits on-site at the Subaward institution, and not transferred to Prime Recipient - Cape Town Statements recommendations - openness & transparency.
- NIH make funding available to foreign Prime Recipient institutions to conduct these investigations/audits at the Subaward institutions, through the appointment of appropriate personnel.
- Balanced monitoring & compliance requirements on recipients- learn from EU & Wellcome who don't require this level of monitoring by an LMIC institute (treated as equals).
- Reconsider allowance of overheads / indirect cost for foreign institutions (8% NIH vs 20% Wellcome for LMICs¹⁵).



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Thank you

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Photo by Stefan Els

