



Toronto Academic Health Sciences Network

Joint Negotiation Process

Presentation to

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Objective of the Joint Negotiation Process (JNP)

- To improve the efficiency of the clinical trial agreement negotiation process at TAHSN institutions through collaboration.
- Improve harmonization among institutions and standardization of clinical trial agreement terms with industry.



What is the JNP?

- Process for joint negotiation of clinical trial agreements involving multiple TAHSN institutions.
- One institution assumes lead negotiation role with feedback from all participating institutions.
- Common framework and checklist of agreed upon terms guides the negotiation process.
- Unlike with REB Board of Record model, final approval of agreement rests with each institution.
- Initial focus on industry led multi-centre clinical trials.



Background to JNP

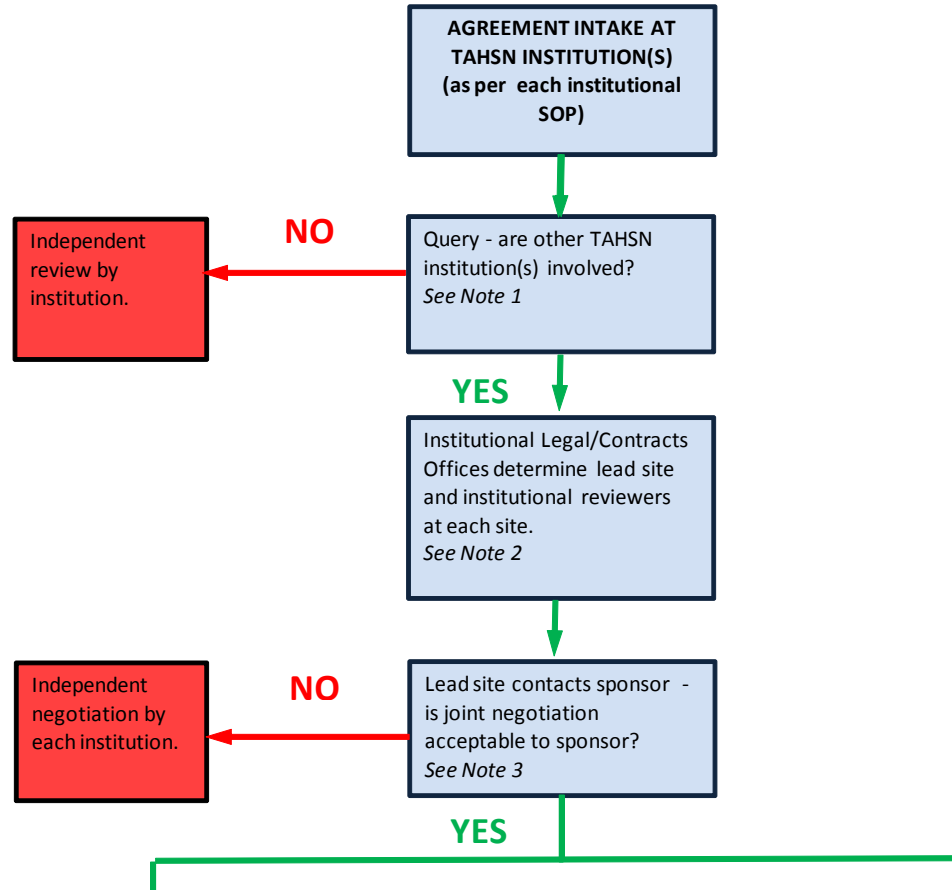
- TAHSN – network comprised of the University of Toronto and 13 affiliated academic healthcare institutions.
- TAHSN Vice Presidents Research initiative with the support of all TAHSN CEOs.
- Arose from recognition of common challenges in clinical trial negotiation and shared desire to increase efficiency and improve timelines.
- Working group developed draft process flowchart for review and feedback from all 13 TAHSN institutions and the University of Toronto.
- Discussion of challenges and potential solutions.



Final Product

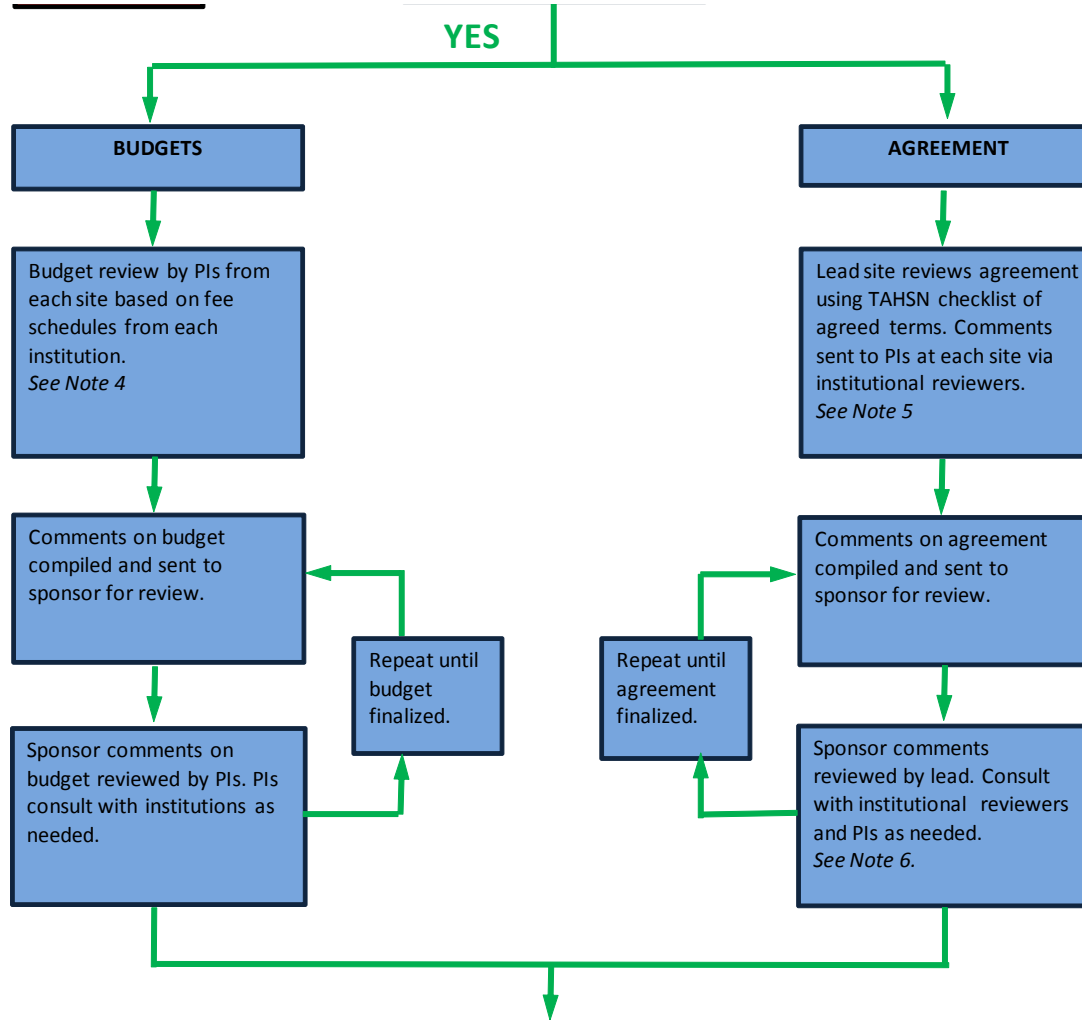
- Memorandum of Understanding signed by CEOs and VPRs of all 13 TAHSN institutions and the University of Toronto.
- Process flowchart.
- Checklist of agreed on clinical trial agreement terms to be used to guide the negotiation.

Flowchart



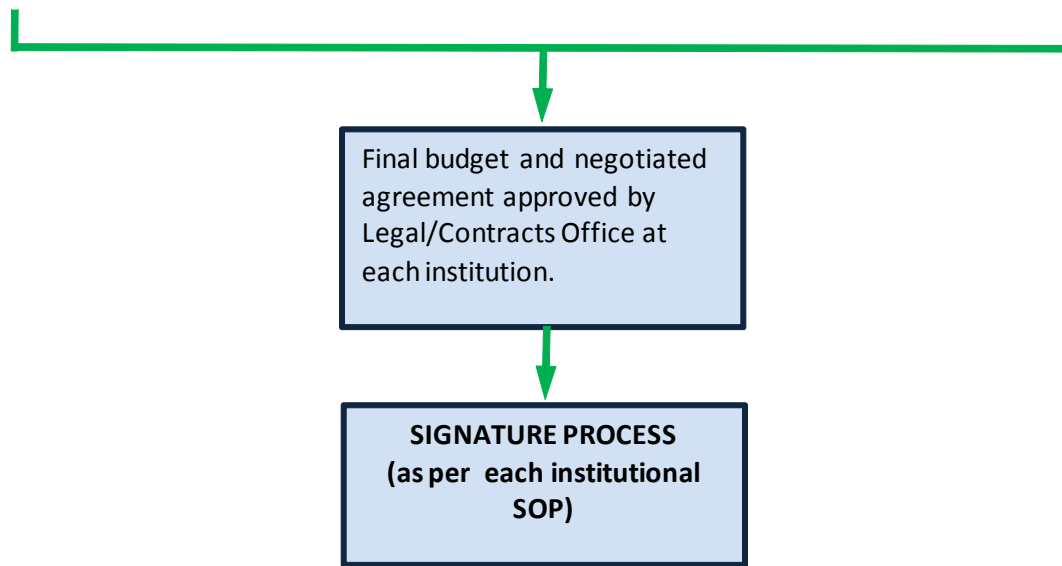


Flowchart





Flowchart





Challenges and Solutions

- Intake mechanism and identification of JNP studies
 - Intake questions posed by each institution.
 - Need for transparency from industry sponsors.
- Assumption of lead role
 - Willingness to decide on case by case basis which institution is best positioned to lead negotiation based on established criteria.
- Industry engagement
 - Willingness to engage in JNP and allow for transparency in negotiations.
- Budget negotiation
 - Budgets will continue to be negotiated by investigators in parallel.
 - Fair Market Value discussions may provide guidance.



Questions?

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