**Additional Approvals Required Prior to Signature on Contractual Terms**

During negotiations, there are times when a sponsor is unwilling to negotiate terms which deviate from state law and/or University policy and procedures. When this occurs, additional review and approval is required by the below University stakeholders prior to an agreement being signed by a UVA authorized signatory.

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| **Contractual Component in Question** | **University Stakeholder** |
| F&A/IDC Waiver Requests | Please follow the steps in FIN-009 |
| Funded agreements when a PI has a disclosed Significant Financial Interest (“SFI”) | SOM – Danny Burdine  Non-SOM – Rob Merhige |
| Language related to animals (comparative medicine) | Raphael (Ralph) Malbrue |
| Publication Restriction Requests (issues related to academic freedom to publish) | Kelly Hochstetler |
| Publication – business related decisions regarding delayed publication timelines, consortium publication policies, etc. | SOM – Research Dean  Non-SOM – Research Dean (additional approval from PI, Department Chair and VPR also required for publication restriction waivers) |
| Safety Notification in Clinical Trials | SOM Research Dean |
| No Study Subject Injury or Indemnification (limited circumstances depending on type of sponsor, i.e. a non-profit entity) in Clinical Trials | SOM Research Dean |
| Informed Consent Form (“ICF”) Language (if it deviates from UVA standard option language) | Clinical Trials Unit and Office of University Counsel |
| HIPAA language if it deviates from UVA’s approved language | Office of University Counsel |
| Risk Assessment Issues (insurance coverage, liability caps) | UVA Risk Management |
| Equipment Terms (UVA liability for sponsor equipment) | UVA Risk Management |
| Legal and/or University Liability | Office of University Counsel |
| Business Associate Agreements (BAA) | Office of University Counsel |
| UVA required to comply with the law of another jurisdiction (within the US or a foreign jurisdiction) | Risk Assessment Form required to be signed by Department Chair, PI, Contract Negotiator, Research Dean and Executive Director of OSP. |
| Language that does not conform with directives from University Counsel’s Office | Executive Director of OSP |
| Intellectual Property language when a disclosure has been made to UVA Licensing and Ventures Group | UVA Licensing and Ventures Group |