Industry Contracting: Rationales Library and Streamlining Pilot

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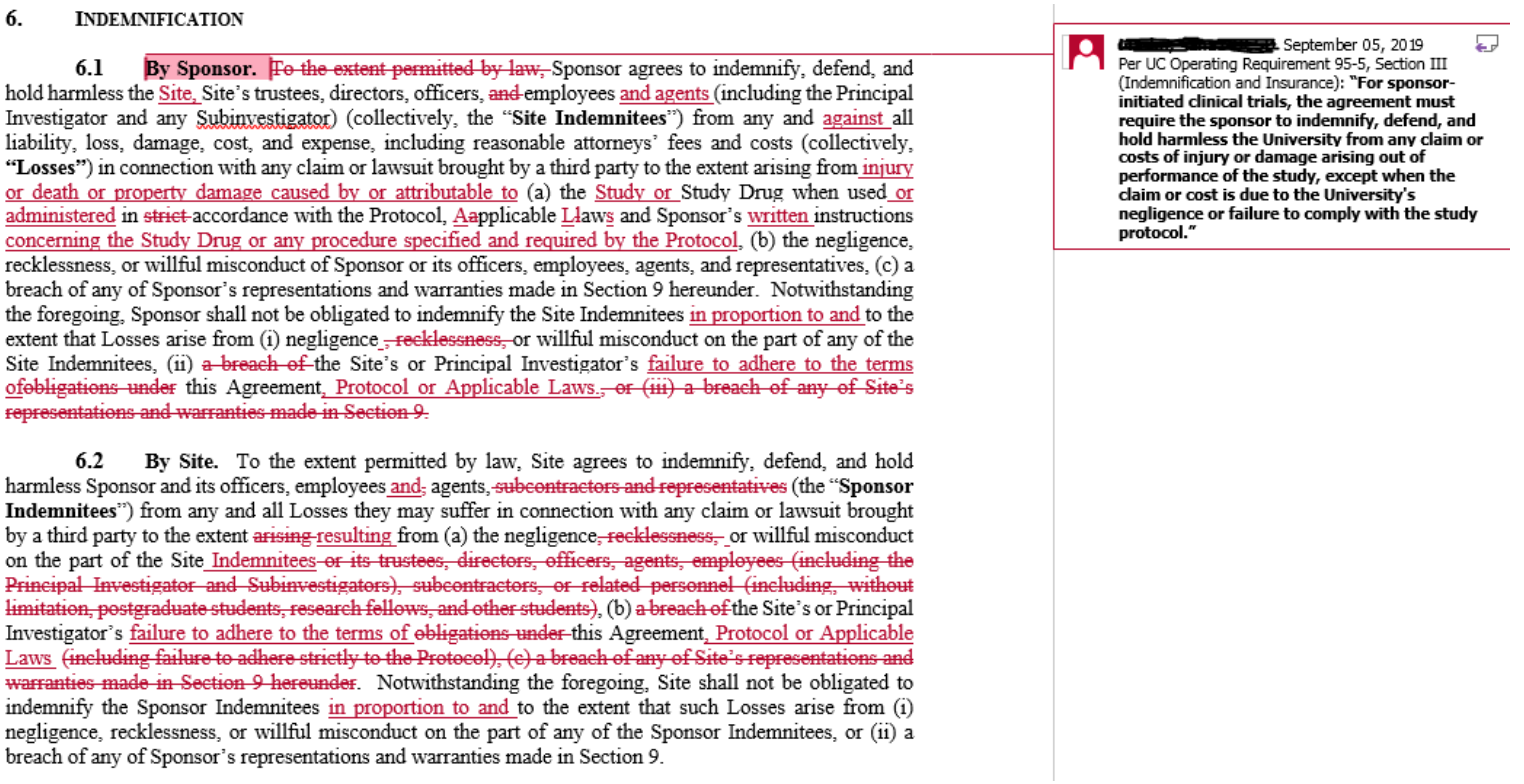
Contracting Rationales Library

- 5 AMCs and UCOP - creating a document that, **on a term by term basis**, provides **background, policies, legal requirements, resources and negotiation recommendations** to expedite clinical trial negotiations with industry
- The **goal** is to **reduce negotiation time for new and intermediate negotiators** and **improve consistency system-wide**
- **Metrics**: Under discussion. A survey will be sent to contracting officers to **gather feedback about efficiencies gained** and areas for improvement. Looking for ways to **track instances of use and effect on contract times**
- The Library is expected to be completed in Winter/Spring of 2019/2020

Sponsor Example

"The Site will use biological samples in accordance with the Protocol and in compliance with Applicable Laws. The Site shall not collect and/or reserve additional quantities of biological samples for use in research not described in the Protocol."



6. INDEMNIFICATION

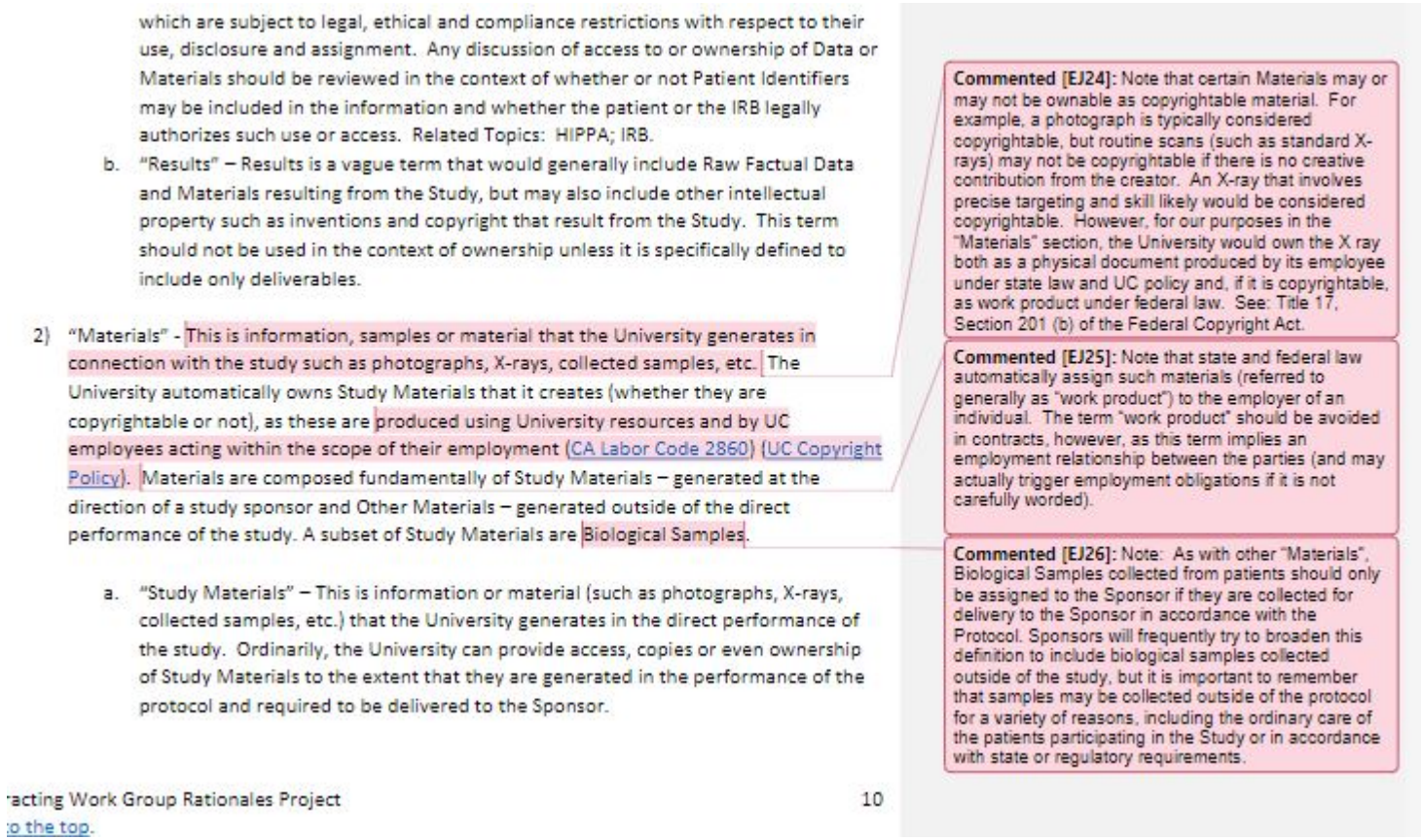
6.1 By Sponsor. ~~To the extent permitted by law,~~ Sponsor agrees to indemnify, defend, and hold harmless the Site, Site's trustees, directors, officers, ~~and~~ employees and agents (including the Principal Investigator and any Subinvestigator) (collectively, the "**Site Indemnitees**") from any and against all liability, loss, damage, cost, and expense, including reasonable attorneys' fees and costs (collectively, "**Losses**") in connection with any claim or lawsuit brought by a third party to the extent arising from injury or death or property damage caused by or attributable to (a) the Study or Study Drug when used or administered in ~~strict~~ accordance with the Protocol, Aapplicable Llaws and Sponsor's written instructions concerning the Study Drug or any procedure specified and required by the Protocol, (b) the negligence, recklessness, or willful misconduct of Sponsor or its officers, employees, agents, and representatives, (c) a breach of any of Sponsor's representations and warranties made in Section 9 hereunder. Notwithstanding the foregoing, Sponsor shall not be obligated to indemnify the Site Indemnitees in proportion to and to the extent that Losses arise from (i) negligence ~~, recklessness,~~ or willful misconduct on the part of any of the Site Indemnitees, (ii) ~~a breach of~~ the Site's or Principal Investigator's failure to adhere to the terms of~~obligations under~~ this Agreement, Protocol or Applicable Laws, ~~or (iii) a breach of any of Site's representations and warranties made in Section 9.~~

6.2 By Site. To the extent permitted by law, Site agrees to indemnify, defend, and hold harmless Sponsor and its officers, employees and~~,~~ agents, ~~subcontractors and representatives~~ (the "**Sponsor Indemnitees**") from any and all Losses they may suffer in connection with any claim or lawsuit brought by a third party to the extent ~~arising~~ resulting from (a) the negligence~~, recklessness,~~ or willful misconduct on the part of the Site Indemnitees ~~or its trustees, directors, officers, agents, employees (including the Principal Investigator and Subinvestigators), subcontractors, or related personnel (including, without limitation, postgraduate students, research fellows, and other students)~~, (b) ~~a breach of~~ the Site's or Principal Investigator's failure to adhere to the terms of ~~obligations under~~ this Agreement, Protocol or Applicable Laws ~~(including failure to adhere strictly to the Protocol), (c) a breach of any of Site's representations and warranties made in Section 9 hereunder~~. Notwithstanding the foregoing, Site shall not be obligated to indemnify the Sponsor Indemnitees in proportion to and to the extent that such Losses arise from (i) negligence, recklessness, or willful misconduct on the part of any of the Sponsor Indemnitees, or (ii) a breach of any of Sponsor's representations and warranties made in Section 9.

[redacted] September 05, 2019
Per UC Operating Requirement 95-5, Section III (Indemnification and Insurance): **"For sponsor-initiated clinical trials, the agreement must require the sponsor to indemnify, defend, and hold harmless the University from any claim or costs of injury or damage arising out of performance of the study, except when the claim or cost is due to the University's negligence or failure to comply with the study protocol."**

Rationales Response

"Biological samples that are required by the Study Protocol to be collected from Study subjects and delivered to the Sponsor under this Agreement are the property of Sponsor and will be used in accordance with the Protocol and in compliance with Applicable Laws and the IRB approved Informed Consent Form."



which are subject to legal, ethical and compliance restrictions with respect to their use, disclosure and assignment. Any discussion of access to or ownership of Data or Materials should be reviewed in the context of whether or not Patient Identifiers may be included in the information and whether the patient or the IRB legally authorizes such use or access. Related Topics: HIPPA; IRB.

b. "Results" – Results is a vague term that would generally include Raw Factual Data and Materials resulting from the Study, but may also include other intellectual property such as inventions and copyright that result from the Study. This term should not be used in the context of ownership unless it is specifically defined to include only deliverables.

2) "Materials" - This is information, samples or material that the University generates in connection with the study such as photographs, X-rays, collected samples, etc. The University automatically owns Study Materials that it creates (whether they are copyrightable or not), as these are produced using University resources and by UC employees acting within the scope of their employment (CA Labor Code 2860) (UC Copyright Policy). Materials are composed fundamentally of Study Materials – generated at the direction of a study sponsor and Other Materials – generated outside of the direct performance of the study. A subset of Study Materials are Biological Samples.

a. "Study Materials" – This is information or material (such as photographs, X-rays, collected samples, etc.) that the University generates in the direct performance of the study. Ordinarily, the University can provide access, copies or even ownership of Study Materials to the extent that they are generated in the performance of the protocol and required to be delivered to the Sponsor.

...acting Work Group Rationales Project 10

...o the top.

Commented [EJ24]: Note that certain Materials may or may not be ownable as copyrightable material. For example, a photograph is typically considered copyrightable, but routine scans (such as standard X-rays) may not be copyrightable if there is no creative contribution from the creator. An X-ray that involves precise targeting and skill likely would be considered copyrightable. However, for our purposes in the "Materials" section, the University would own the X ray both as a physical document produced by its employee under state law and UC policy and, if it is copyrightable, as work product under federal law. See: Title 17, Section 201 (b) of the Federal Copyright Act.

Commented [EJ25]: Note that state and federal law automatically assign such materials (referred to generally as "work product") to the employer of an individual. The term "work product" should be avoided in contracts, however, as this term implies an employment relationship between the parties (and may actually trigger employment obligations if it is not carefully worded).

Commented [EJ26]: Note: As with other "Materials", Biological Samples collected from patients should only be assigned to the Sponsor if they are collected for delivery to the Sponsor in accordance with the Protocol. Sponsors will frequently try to broaden this definition to include biological samples collected outside of the study, but it is important to remember that samples may be collected outside of the protocol for a variety of reasons, including the ordinary care of the patients participating in the Study or in accordance with state or regulatory requirements.

Life without the Rationale Library…

Contracting Streamlining Pilot: **Goals**

- Improve clinical trial contract negotiation time by leveraging resources at multiple campuses
- Share new trials to increase business opportunities
- Overall value to sponsors by reducing the time, costs, and efforts to open a clinical trial across multiple UC campuses

Contracting Streamlining Pilot: **Scope**

- Industry funded sponsor initiated clinical trials
- UC Davis and UC Irvine are participating in the pilot to leverage resources; Added in UC San Diego
- Therapeutic areas include Neurology (UCI/UC Davis); Dermatology (UC Davis/UC San Diego)
- Participating campuses/departments share new projects and coordinate the agreement negotiation through the primary campus

Contracting Streamlining Pilot: **Metrics**

- Pilot started November 2018; preliminary data to be analyzed at the one year mark
- 20 clinical trials successfully activated among the UC campuses
- Data include:
  - Contract terms finalized time; contract execution (study activation) time
  - Number of clinical trials as a new business at the secondary campus
  - Reasons for why clinical trial at secondary campus did not move forward (e.g. already selected by company, company not accepting new sites; investigators not interested; too many competing trials).

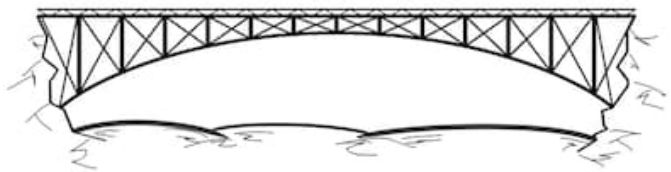
Based on data from the pilot, CWG will share observations/opportunities/considerations to achieve contracting pilot goals

Contracting Streamlining Pilot: **Next Steps**

- Next steps: Expand scope of pilot to include other therapeutic areas

San Diego

Neurology Pulmonary Dermatology



Davis

Neurology Surgery GI Pulmonary

Irvine

Partnerships - Thanks

- Erick Jenkins, UCD
- Valerie Ody, UCD
- Tam Tran, UCI (Work Group Lead)
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- *David Grady, UC BRAID*